DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION
CENTER FOR SUBSTANCE ABUSE TREATMENT

Application for Certification to Use Opioid Drugs in a Treatment Program Under 42 CFR § 8.11

Form Approved: OMB Number 0930-0206
Expiration Date: 01/31/2010
See OMB Statement on Reverse

Reset

DATE OF SUBMISSION

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. Opioid Treatment Program Number: (e.g., AL-10001-M)

c. DEA Registration Number

2. Address of Primary Dispensing Location: (Include Zip Code)

3. Telephone Number: (Include Area Code)

4. Fax Number: (Include Area Code)

5. E-Mail Address:

6. Name and Address of Program Sponsor: (Include Zip Code)

7. Telephone Number: (Include Area Code)

8. Fax Number: (Include Area Code)

9. E-Mail Address:

10. Name of Medical Director: (and Address—if different than Dispensing Location, above)

11 Telephone Number: (Include Area Code)

12. Fax Number: (Include Area Code)

13. E-Mail Address:

14. Purpose of Application

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

15. Number of Patients in Treatment on Date of Submission:

_____ Methadone _____ Levo-Alpha-Acetyl-Methadol (LAAM) _____ Subutex/Suboxone (Buprenorphine)

_____ Other (Specify)_____

16a. Program Status ☐ For-profit ☐ Nonprofit ☐ Public/Government ☐ Other (Specify) _____

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

☐ SAMHSA (Block Grant) ☐ Private Charities ☐ Department of Veterans Affairs

☐ Patient Payment ☐ State Government ☐ County Government

☐ Indian Health Service ☐ Private Health Insurance ☐ Other (Specify) _____

17. Application

Center for Substance Abuse Treatment
Division of Pharmacologic Therapies
Substance Abuse and Mental Health Services Administration
Attention: OTP Certification Program
1 Choke Cherry Road, Suite 2–1086
Rockville, MD 20857

Overnight:
1 Choke Cherry Road, Suite 2–1086
Rockville, MD 20850

Dear Sir/Madam:

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

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 of such an arrangement will be documented and submitted to SAMHSA. Within three weeks of any replacement of the medical director, I shall notify SAMHSA.

F. Attached is the address of each medication unit or other facility under control of the OTP. Any new dispensing site for this program, including medication units shall be approved by SAMHSA and the State authority prior to its 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 maintained to document and monitor patient care in this program. It shall be maintained so as to comply with the 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 to 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 to maintain the confidentiality of alcohol and drug abuse treatment patient records. I agree to protect the identity of 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 set forth under 42 CFR § 8.11(f). In addition, I shall allow, in accordance with Federal controlled substance laws and Federal confidentiality laws, inspections and surveys by duly authorized employees of SAMHSA, by accreditation bodies, the DEA, and by authorized employees of any relevant State or Federal governmental authority. I agree that OTPs must operate in accordance with Federal opioid treatment standards and accreditation elements.

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

L. I understand that failure to abide by the rules, directives, and procedures described above may cause a suspension or revocation of approval of my registration by the Drug Enforcement Administration.

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

Program Sponsor: (Signature)	**Date:**

Please send three copies of this form and all attachments to:

Center for Substance Abuse Treatment
Division of Pharmacologic Therapies
Substance Abuse and Mental Health Services Administration
Attention: OTP Certification Program
1 Choke Cherry Road, Suite 2–1086
Rockville, MD 20857

Overnight:
1 Choke Cherry Road, Suite 2–1086
Rockville, MD 20850

and two copies to the appropriate State authority.

If submitting this form electronically, please submit electronic copies of all attachments by e-mail to otp@samhsa.hhs.gov or submit three copies of all attachments to the mailing address above.

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 comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to SAMHSA Reports Clearance Officer; Paperwork Reduction Project (0930-0206); Suite 7-1043, 1 Choke Cherry Road, Rockville, MD 20857. An agency may not conduct or sponsor, and a person 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.