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Online SMA-163 Form

*denotes a required field

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 § 8.3(b)

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

DATE OF SUBMISSION: 3/3/2010

Note: This form is required by 42 CFR 8.3(b) 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 opi treatment program registration.

* **1. NAME OF ACCREDITATION BODY:**

* **2. PURPOSE OF APPLICATION:** ◉ New ○ Renewal

3. ADDRESS OF ACCREDITATION BODY

* Address 1:

* Address 2:

* City:

* State:

* Zip:

4. ACCREDITATION BODY TELEPHONE NUMBER
(e.g., 999-999-9999)

5. ACCREDITATION BODY FAX NUMBER *(e.g., 999-999-9999)*

6. ACCREDITATION BODY E-MAIL ADDRESS

7. NAME AND ADDRESS OF RESPONSIBLE OFFICIAL

* Name:

☐ Same address as accreditation body location

* Address 1:

* Address 2:

* City:

* **8. RESPONSIBLE OFFICIAL TELEPHONE NUMBER**
(e.g., 999-999-9999)

9. RESPONSIBLE OFFICIAL FAX NUMBER *(e.g., 999-999-9999)*

* **10. RESPONSIBLE OFFICIAL E-MAIL ADDRESS**

A confirmation e-mail will be sent to this address. The responsible official will need to respond to that e-mail to sign this SMA-163 electronically and complete the submission process.

*State:

*Zip:

11. Application

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

Dear Sir/Madam:

As the official responsible for the accreditation body, I submit this application in for approval to serve as an accreditation body under 42 CFR Part 8.

A. I have a copy of, or access to 42 CFR Part 8, Certification of Opioid Treatment Programs, including 42 CFR §8.4, the Federal Opioid Treatment Standards. I have read, understand and will comply with these standards which address the accreditation of opioid treatment programs (OTPs) that treat narcotic addiction with approved opioid drugs.

B. 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 and agree to maintain records of accreditation activities for 5 years from creation of the record.

C. Attached is evidence of the accreditation body's nonprofit status (i.e., of fulfilling Internal Revenue Service requirements as nonprofit organization) if the accreditation body is not a State governmental entity or political subdivision.

D. Attached is a set of accreditation elements and a detailed discussion showing how the proposed accreditation elements will ensure that each OTP surveyed by the accreditation body is qualified to meet or is meeting each of the Federal opioid treatment standards set forth under 43 CFR § 8.12.

E. Attached is a detailed description of the accreditation body's decision making process, including: procedures for initiating and performing onsite accreditation surveys of OTPs, procedures for assessing OTP personnel qualification; copies of an application for accreditation, guidelines, instructions, and other materials that the accreditation body will send to OTPs during accreditation process; policies and procedures for notifying OTPs of deficiencies and for suspending or revoking an OTP's accreditation; policies and procedures for ensuring the timely processing of a accreditaton applications, and a description of the accreditation body's appeals process to allow OTPs to contest adverse accreditation decisions.

F. Attached are the policies and procedures established by the accreditation body to avoid conflicts of interest, or the appearance of conflicts of interest, by the accreditation body's board members, commissioners, professional personnel, consultants, administrative personnel, and other representatives.

G. Attached is a description of the education, experience, and training requirements for the accreditation body's professional staff, accreditation survey team membership, and the identification of at least one licensed physician on the accreditation body's staff, alon with a description of the accreditation body's training policies and survey fee schedules with supporting cost data.

H. Attached is an assurance that the accreditation body will comply with the accreditation body responsibilities set forth under 42 CFI §8.4, including a contingency plan for investigating complaints under 42 CFR §8.4(e).

I. Attached are the policies and procedures that the accreditation body has established to protect confidential information that the accreditation body will collect or receive in its role as accreditation body.

J. I, as the responsible official, 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 I 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 relative therto 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 th 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); 1 Choke Cherry Road, R 2-1075, 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.

FORM SMA-163 (revised 2007)

Note to users of screen readers and other assistive technologies: Please report your problems to us at otp-extranet@opioid.samhsa.gov.

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