

**Application for Approval as Accreditation Body  
Under 42 CFR § 8.3(b)**

DATE OF SUBMISSION

**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 the suspension or revocation of the accreditation body approval.

**1. NAME OF ACCREDITATION BODY**

**2. PURPOSE OF APPLICATION**

New **G** Renewal **G**

**3. ADDRESS OF ACCREDITATION BODY (Include Zip Code)**

**4. TELEPHONE NUMBER (Include Area Code)**

**5. FAX NUMBER (Include Area Code)**

**6. NAME AND ADDRESS OF RESPONSIBLE OFFICIAL (Include Zip Code)**

**7. TELEPHONE NUMBER (Include Area Code)**

**8. FAX NUMBER (Include Area Code)**

**9. Application**

Substance Abuse and Mental Health Services Administration  
Division of Pharmacologic Therapies  
Attention: OTP Certification Program  
Rockwall II Building, Suite 740  
5600 Fishers Lane  
Rockville, MD 20857

Dear Sir/Madam

As the official responsible for the accreditation body, I submit this application in triplicate 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, Accreditation Body Responsibilities. I have read, understand and will comply with these regulations 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 the creation of the record.

C. Attached is evidence of the accreditation body's nonprofit status (i.e., of fulfilling Internal Revenue Service requirements as a 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 42 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 qualifications; copies of an application for accreditation, guidelines, instructions, and other materials that the accreditation body will send to OTPs during the 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 accreditation 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, along 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 CFR §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 an accreditation body.

I, as the responsible official, certify that the information submitted in this application is truthful and accurate.

**RESPONSIBLE OFFICIAL (Signature)**

**DATE**

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

Substance Abuse and Mental Health Services Administration  
Attention: OTP Certification Program  
Center for Substance Abuse Treatment, Division of Pharmacologic Therapies  
Rockwall II Building, Suite 740  
5600 Fishers Lane  
Rockville, MD 20857

*If submitting this form electronically, please submit electronic copies of all attachments by e-mail to [otp@samhsa.gov](mailto:otp@samhsa.gov) or submit three copies of all attachments to the mailing address above.*

**FORM SMA-163 (revised 2002)** (FRONT) *(Submit in triplicate)*

**Paperwork Reduction Act Statement**

Public reporting burden for this collection of information is estimated to average 2 hours 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); Room 16-105, Parklawn Building; 5600 Fishers Lane, 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 2003)** (BACK)