Title 42: Public Health

CHAPTER I—PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUBCHAPTER A—GENERAL PROVISIONS

PART 8—CERTIFICATION OF OPIOID TREATMENT PROGRAMS

Subpart B—Certification and Treatment Standards

Contents

§8.11 Opioid treatment program certification.

(a) *General.* (1) An OTP must be the subject of a current, valid certification from SAMHSA to be considered qualified by the Secretary under section 303(g)(1) of the Controlled Substances Act (21 U.S.C. 823(g)(1)) to dispense opioid drugs in the treatment of opioid addiction. An OTP must be determined to be qualified under section 303(g)(1) of the Controlled Substances Act, and must be determined to be qualified by the Attorney General under section 303(g)(1), to be registered by the Attorney General to dispense opioid agonist treatment medications to individuals for treatment of opioid addiction.

(2) To obtain certification from SAMHSA, an OTP must meet the Federal opioid treatment standards in §8.12, must be the subject of a current, valid accreditation by an accreditation body or other entity designated by SAMHSA, and must comply with any other conditions for certification established by SAMHSA.

(3) Certification shall be granted for a term not to exceed 3 years, except that certification may be extended during the third year if an application for accreditation is pending.

(b) *Application for certification.* Three copies of an application for certification must be submitted by the OTP to the address identified in §8.3(b). SAMHSA will consider and accept the electronic submission of these materials when electronic submission systems are developed and available. The application for certification shall include:

(1) A description of the current accreditation status of the OTP;

(2) A description of the organizational structure of the OTP;

(3) The names of the persons responsible for the OTP;

(4) The addresses of the OTP and of each medication unit or other facility under the control of the OTP;

(5) The sources of funding for the OTP and the name and address of each governmental entity that provides such funding; and

(6) A statement that the OTP will comply with the conditions of certification set forth in paragraph (f) of this section.

(7) The application shall be signed by the program sponsor who shall certify that the information submitted in the application is truthful and accurate.

(c) *Action on application*. (1) Following SAMHSA's receipt of an application for certification of an OTP, and after consultation with the appropriate State authority regarding the qualifications of the applicant, SAMHSA may grant the application for certification, or renew an existing certification, if SAMHSA determines that the OTP has satisfied the requirements for certification or renewal of certification.

(2) SAMHSA may deny the application if SAMHSA determines that:

(i) The application for certification is deficient in any respect;

(ii) The OTP will not be operated in accordance with the Federal opioid treatment standards established under §8.12;

(iii) The OTP will not permit an inspection or a survey to proceed, or will not permit in a timely manner access to relevant records or information; or

(iv) The OTP has made misrepresentations in obtaining accreditation or in applying for certification.

(3) Within 5 days after it reaches a final determination that an OTP meets the requirements for certification, SAMHSA will notify the Drug Enforcement Administration (DEA) that the OTP has been determined to be qualified to provide opioid treatment under section 303(g)(1) of the Controlled Substances Act.

(d) *Transitional certification*. OTPs that before May 18, 2001 were the subject of a current, valid approval by FDA under 21 CFR, part 291 (contained in the 21 CFR parts 200 to 299 edition, revised as of July 1, 2000), are deemed to be the subject of a current valid certification for purposes of paragraph (a)(11) of this section. Such “transitional certification” will expire on August 17, 2001 unless the OTP submits the information required by paragraph (b) of this section to SAMHSA on or before August 17, 2001. In addition to this application, OTPs must certify with a written statement signed by the program sponsor, that they will apply for accreditation within 90 days of the date SAMHSA approves the second accreditation body. Transitional certification, in that case, will expire on May 19, 2003. SAMHSA may extend the transitional certification of an OTP for up to one additional year provided the OTP demonstrates that it has applied for accreditation, that an accreditation survey has taken place or is scheduled to take place, and that an accreditation decision is expected within a reasonable period of time (e.g., within 90 days from the date of survey). Transitional certification under this section may be suspended or revoked in accordance with §8.14.

(e) *Provisional certification*. (1) OTPs that have no current certification from SAMHSA, but have applied for accreditation with an accreditation body, are eligible to receive a provisional certification for up to 1 year. To receive a provisional certification, an OTP shall submit the information required by paragraph (b) of this section to SAMHSA along with a statement identifying the accreditation body to which the OTP has applied for accreditation, the date on which the OTP applied for accreditation, the dates of any accreditation surveys that have taken place or are expected to take place, and the expected schedule for completing the accreditation process. A provisional certification for up to 1 year will be granted, following receipt of the information described in this paragraph, unless SAMHSA determines that patient health would be adversely affected by the granting of provisional certification.

(2) An extension of provisional certification may be granted in extraordinary circumstances or otherwise to protect public health. To apply for a 90-day extension of provisional certification, an OTP shall submit to SAMHSA a statement explaining its efforts to obtain accreditation and a schedule for obtaining accreditation as expeditiously as possible.

(f) *Conditions for certification*. (1) OTPs shall comply with all pertinent State laws and regulations. Nothing in this part is intended to limit the authority of State and, as appropriate, local governmental entities to regulate the use of opioid drugs in the treatment of opioid addiction. The provisions of this section requiring compliance with requirements imposed by State law, or the submission of applications or reports required by the State authority, do not apply to OTPs operated directly by the Department of Veterans Affairs, the Indian Health Service, or any other department or agency of the United States. Federal agencies operating OTPs have agreed to cooperate voluntarily with State agencies by granting permission on an informal basis for designated State representatives to visit Federal OTPs and by furnishing a copy of Federal reports to the State authority, including the reports required under this section.

(2) OTPs shall allow, in accordance with Federal controlled substances laws and Federal confidentiality laws, inspections and surveys by duly authorized employees of SAMHSA, by accreditation bodies, by the DEA, and by authorized employees of any relevant State or Federal governmental authority.

(3) Disclosure of patient records maintained by an OTP is governed by the provisions of 42 CFR part 2, and every program must comply with that part. Records on the receipt, storage, and distribution of opioid agonist treatment medications are also subject to inspection under Federal controlled substances laws and under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.*). Federally-sponsored treatment programs are subject to applicable Federal confidentiality statutes.

(4) A treatment program or medication unit or any part thereof, including any facility or any individual, shall permit a duly authorized employee of SAMHSA to have access to and to copy all records on the use of opioid drugs in accordance with the provisions of 42 CFR part 2.

(5) OTPs shall notify SAMHSA within 3 weeks of any replacement or other change in the status of the program sponsor or medical director.

(6) OTPs shall comply with all regulations enforced by the DEA under 21 CFR chapter II, and must be registered by the DEA before administering or dispensing opioid agonist treatment medications.

(7) OTPs must operate in accordance with Federal opioid treatment standards and approved accreditation elements.

(g) *Conditions for interim maintenance treatment program approval*. (1) Before a public or nonprofit private OTP may provide interim maintenance treatment, the program must receive the approval of both SAMHSA and the chief public health officer of the State in which the OTP operates.

(2) Before SAMHSA may grant such approval, the OTP must provide SAMHSA with documentation from the chief public health officer of the State in which the OTP operates demonstrating that:

(i) Such officer does not object to the providing of interim maintenance treatment in the State;

(ii) The OTP seeking to provide such treatment is unable to place patients in a public or nonprofit private comprehensive treatment program within a reasonable geographic area within 14 days of the time patients seek admission to such programs;

(iii) The authorization of the OTP to provide interim maintenance treatment will not otherwise reduce the capacity of comprehensive maintenance treatment programs in the State to admit individuals (relative to the date on which such officer so certifies); and

(iv) The State certifies that each individual enrolled in interim maintenance treatment will be transferred to a comprehensive maintenance treatment program no later than 120 days from the date on which each individual first requested treatment, as provided in section 1923 of the Public Health Service Act (21 U.S.C. 300x-23).

(3) SAMHSA will provide notice to the OTP denying or approving the request to provide interim maintenance treatment. The OTP shall not provide such treatment until it has received such notice from SAMHSA.

(h) *Exemptions.* An OTP may, at the time of application for certification or any time thereafter, request from SAMHSA exemption from the regulatory requirements set forth under this section and §8.12. An example of a case in which an exemption might be granted would be for a private practitioner who wishes to treat a limited number of patients in a non-metropolitan area with few physicians and no rehabilitative services geographically accessible and requests exemption from some of the staffing and service standards. The OTP shall support the rationale for the exemption with thorough documentation, to be supplied in an appendix to the initial application for certification or in a separate submission. SAMHSA will approve or deny such exemptions at the time of application, or any time thereafter, if appropriate. SAMHSA shall consult with the appropriate State authority prior to taking action on an exemption request.

(i) *Medication units, long-term care facilities and hospitals.* (1) Certified OTPs may establish medication units that are authorized to dispense opioid agonist treatment medications for observed ingestion. Before establishing a medication unit, a certified OTP must notify SAMHSA by submitting form SMA-162. The OTP must also comply with the provisions of 21 CFR part 1300 before establishing a medication unit. Medication units shall comply with all pertinent state laws and regulations.

(2) Certification as an OTP under this part will not be required for the maintenance or detoxification treatment of a patient who is admitted to a hospital or long-term care facility for the treatment of medical conditions other than opiate addiction and who requires maintenance or detoxification treatment during the period of his or her stay in that hospital or long-term care facility. The terms “hospital” and “long-term care facility” as used in this section are to have the meaning that is assigned under the law of the State in which the treatment is being provided. Nothing in this section is intended to relieve hospitals and long-term care facilities from the obligation to obtain registration from the Attorney General, as appropriate, under section 303(g) of the Controlled Substances Act.

[66 FR 4090, Jan. 17, 2001, as amended at 66 FR 15347, Mar. 19, 2001]

§8.12 Federal opioid treatment standards.

(a) *General.* OTPs must provide treatment in accordance with the standards in this section and must comply with these standards as a condition of certification.

(b) *Administrative and organizational structure*. An OTP's organizational structure and facilities shall be adequate to ensure quality patient care and to meet the requirements of all pertinent Federal, State, and local laws and regulations. At a minimum, each OTP shall formally designate a program sponsor and medical director. The program sponsor shall agree on behalf of the OTP to adhere to all requirements set forth in this part and any regulations regarding the use of opioid agonist treatment medications in the treatment of opioid addiction which may be promulgated in the future. The medical director shall assume responsibility for administering all medical services performed by the OTP. In addition, the medical director shall be responsible for ensuring that the OTP is in compliance with all applicable Federal, State, and local laws and regulations.

(c) *Continuous quality improvement*. (1) An OTP must maintain current quality assurance and quality control plans that include, among other things, annual reviews of program policies and procedures and ongoing assessment of patient outcomes.

(2) An OTP must maintain a current “Diversion Control Plan” or “DCP” as part of its quality assurance program that contains specific measures to reduce the possibility of diversion of controlled substances from legitimate treatment use and that assigns specific responsibility to the medical and administrative staff of the OTP for carrying out the diversion control measures and functions described in the DCP.

(d) *Staff credentials*. Each person engaged in the treatment of opioid addiction must have sufficient education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. All physicians, nurses, and other licensed professional care providers, including addiction counselors, must comply with the credentialing requirements of their respective professions.

(e) *Patient admission criteria*—(1) *Maintenance treatment*. An OTP shall maintain current procedures designed to ensure that patients are admitted to maintenance treatment by qualified personnel who have determined, using accepted medical criteria such as those listed in the Diagnostic and Statistical Manual for Mental Disorders (DSM-IV), that the person is currently addicted to an opioid drug, and that the person became addicted at least 1 year before admission for treatment. In addition, a program physician shall ensure that each patient voluntarily chooses maintenance treatment and that all relevant facts concerning the use of the opioid drug are clearly and adequately explained to the patient, and that each patient provides informed written consent to treatment.

(2) *Maintenance treatment for persons under age 18*. A person under 18 years of age is required to have had two documented unsuccessful attempts at short-term detoxification or drug-free treatment within a 12-month period to be eligible for maintenance treatment. No person under 18 years of age may be admitted to maintenance treatment unless a parent, legal guardian, or responsible adult designated by the relevant State authority consents in writing to such treatment.

(3) *Maintenance treatment admission exceptions*. If clinically appropriate, the program physician may waive the requirement of a 1-year history of addiction under paragraph (e)(1) of this section, for patients released from penal institutions (within 6 months after release), for pregnant patients (program physician must certify pregnancy), and for previously treated patients (up to 2 years after discharge).

(4) *Detoxification treatment*. An OTP shall maintain current procedures that are designed to ensure that patients are admitted to short- or long-term detoxification treatment by qualified personnel, such as a program physician, who determines that such treatment is appropriate for the specific patient by applying established diagnostic criteria. Patients with two or more unsuccessful detoxification episodes within a 12-month period must be assessed by the OTP physician for other forms of treatment. A program shall not admit a patient for more than two detoxification treatment episodes in one year.

(f) *Required services*—(1) *General*. OTPs shall provide adequate medical, counseling, vocational, educational, and other assessment and treatment services. These services must be available at the

primary facility, except where the program sponsor has entered into a formal, documented agreement with a private or public agency, organization, practitioner, or institution to provide these services to patients enrolled in the OTP. The program sponsor, in any event, must be able to document that these services are fully and reasonably available to patients.

(2) *Initial medical examination services*. OTPs shall require each patient to undergo a complete, fully documented physical evaluation by a program physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician, before admission to the OTP. The full medical examination, including the results of serology and other tests, must be completed within 14 days following admission.

(3) *Special services for pregnant patients*. OTPs must maintain current policies and procedures that reflect the special needs of patients who are pregnant. Prenatal care and other gender specific services or pregnant patients must be provided either by the OTP or by referral to appropriate healthcare providers.

(4) *Initial and periodic assessment services*. Each patient accepted for treatment at an OTP shall be assessed initially and periodically by qualified personnel to determine the most appropriate combination of services and treatment. The initial assessment must include preparation of a treatment plan that includes the patient's short-term goals and the tasks the patient must perform to complete the short-term goals; the patient's requirements for education, vocational rehabilitation, and employment; and the medical, psychosocial, economic, legal, or other supportive services that a patient needs. The treatment plan also must identify the frequency with which these services are to be provided. The plan must be reviewed and updated to reflect that patient's personal history, his or her current needs for medical, social, and psychological services, and his or her current needs for education, vocational rehabilitation, and employment services.

(5) *Counseling services*. (i) OTPs must provide adequate substance abuse counseling to each patient as clinically necessary. This counseling shall be provided by a program counselor, qualified by education, training, or experience to assess the psychological and sociological background of patients, to contribute to the appropriate treatment plan for the patient and to monitor patient progress.

(ii) OTPs must provide counseling on preventing exposure to, and the transmission of, human immunodeficiency virus (HIV) disease for each patient admitted or readmitted to maintenance or detoxification treatment.

(iii) OTPs must provide directly, or through referral to adequate and reasonably accessible community resources, vocational rehabilitation, education, and employment services for patients who either request such services or who have been determined by the program staff to be in need of such services.

(6) *Drug abuse testing services*. OTPs must provide adequate testing or analysis for drugs of abuse, including at least eight random drug abuse tests per year, per patient in maintenance treatment, in accordance with generally accepted clinical practice. For patients in short-term detoxification treatment, the OTP shall perform at least one initial drug abuse test. For patients receiving long-term detoxification treatment, the program shall perform initial and monthly random tests on each patient.

(g) *Recordkeeping and patient confidentiality*. (1) OTPs shall establish and maintain a recordkeeping system that is adequate to document and monitor patient care. This system is required to comply with all Federal and State reporting requirements relevant to opioid drugs approved for use in treatment of opioid addiction. All records are required to be kept confidential in accordance with all applicable Federal and State requirements.

(2) OTPs shall include, as an essential part of the recordkeeping system, documentation in each patient's record that the OTP made a good faith effort to review whether or not the patient is enrolled any other OTP. A patient enrolled in an OTP shall not be permitted to obtain treatment in any other OTP except in exceptional circumstances. If the medical director or program physician of the OTP in which the patient is enrolled determines that such exceptional circumstances exist, the patient may be granted permission to seek treatment at another OTP, provided the justification for finding exceptional circumstances is noted in the patient's record both at the OTP in which the patient is enrolled and at the OTP that will provide the treatment.

(h) *Medication administration, dispensing, and use.* (1) OTPs must ensure that opioid agonist treatment medications are administered or dispensed only by a practitioner licensed under the appropriate State law and registered under the appropriate State and Federal laws to administer or dispense opioid drugs, or by an agent of such a practitioner, supervised by and under the order of the licensed practitioner. This agent is required to be a pharmacist, registered nurse, or licensed practical nurse, or any other healthcare professional authorized by Federal and State law to administer or dispense opioid drugs.

(2) OTPs shall use only those opioid agonist treatment medications that are approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for use in the treatment of opioid addiction. In addition, OTPs who are fully compliant with the protocol of an investigational use of a drug and other conditions set forth in the application may administer a drug that has been authorized by the Food and Drug Administration under an investigational new drug application under section 505(i) of the Federal Food, Drug, and Cosmetic Act for investigational use in the treatment of opioid addiction. Currently the following opioid agonist treatment medications will be considered to be approved by the Food and Drug Administration for use in the treatment of opioid addiction:

(i) Methadone;

(ii) Levomethadyl acetate (LAAM); and

(iii) Buprenorphine and buprenorphine combination products that have been approved for use in the treatment of opioid addiction.

(3) OTPs shall maintain current procedures that are adequate to ensure that the following dosage form and initial dosing requirements are met:

(i) Methadone shall be administered or dispensed only in oral form and shall be formulated in such a way as to reduce its potential for parenteral abuse.

(ii) For each new patient enrolled in a program, the initial dose of methadone shall not exceed 30 milligrams and the total dose for the first day shall not exceed 40 milligrams, unless the program physician documents in the patient's record that 40 milligrams did not suppress opiate abstinence symptoms.

(4) OTPs shall maintain current procedures adequate to ensure that each opioid agonist treatment medication used by the program is administered and dispensed in accordance with its approved product labeling. Dosing and administration decisions shall be made by a program physician familiar with the most up-to-date product labeling. These procedures must ensure that any significant deviations from the approved labeling, including deviations with regard to dose, frequency, or the conditions of use described in the approved labeling, are specifically documented in the patient's record.

(i) *Unsupervised or "take-home" use*. To limit the potential for diversion of opioid agonist treatment medications to the illicit market, opioid agonist treatment medications dispensed to patients for unsupervised use shall be subject to the following requirements.

(1) Any patient in comprehensive maintenance treatment may receive a single take-home dose for a day that the clinic is closed for business, including Sundays and State and Federal holidays.

(2) Treatment program decisions on dispensing opioid treatment medications to patients for unsupervised use beyond that set forth in paragraph (i)(1) of this section, shall be determined by the medical director. In determining which patients may be permitted unsupervised use, the medical director shall consider the following take-home criteria in determining whether a patient is responsible in handling opioid drugs for unsupervised use.

(i) Absence of recent abuse of drugs (opioid or nonnarcotic), including alcohol;

(ii) Regularity of clinic attendance;

(iii) Absence of serious behavioral problems at the clinic;

(iv) Absence of known recent criminal activity, e.g., drug dealing;

(v) Stability of the patient's home environment and social relationships;

(vi) Length of time in comprehensive maintenance treatment;

(vii) Assurance that take-home medication can be safely stored within the patient's home; and

(viii) Whether the rehabilitative benefit the patient derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion.

(3) Such determinations and the basis for such determinations consistent with the criteria outlined in paragraph (i)(2) of this section shall be documented in the patient's medical record. If it is determined that a patient is responsible in handling opioid drugs, the dispensing restrictions set forth in paragraphs (i)(3)(i) through (vi) of this section apply. The dispensing restrictions set forth in paragraphs (i)(3)(i) through (vi) of this section do not apply to buprenorphine and buprenorphine products listed under paragraph (h)(2)(iii) of this section.

(i) During the first 90 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) is limited to a single dose each week and the patient shall ingest all other doses under appropriate supervision as provided for under the regulations in this subpart.

(ii) In the second 90 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) are two doses per week.

(iii) In the third 90 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) are three doses per week.

(iv) In the remaining months of the first year, a patient may be given a maximum 6-day supply of take-home medication.

(v) After 1 year of continuous treatment, a patient may be given a maximum 2-week supply of take-home medication.

(vi) After 2 years of continuous treatment, a patient may be given a maximum one-month supply of take-home medication, but must make monthly visits.

(4) No medications shall be dispensed to patients in short-term detoxification treatment or interim maintenance treatment for unsupervised or take-home use.

(5) OTPs must maintain current procedures adequate to identify the theft or diversion of take-home medications, including labeling containers with the OTP's name, address, and telephone number. Programs also must ensure that take-home supplies are packaged in a manner that is designed to reduce the risk of accidental ingestion, including child-proof containers (see Poison Prevention Packaging Act, Public Law 91-601 (15 U.S.C. 1471 *et seq*.)).

(j) *Interim maintenance treatment*. (1) The program sponsor of a public or nonprofit private OTP may place an individual, who is eligible for admission to comprehensive maintenance treatment, in interim maintenance treatment if the individual cannot be placed in a public or nonprofit private comprehensive program within a reasonable geographic area and within 14 days of the individual's application for admission to comprehensive maintenance treatment. An initial and at least two other urine screens shall be taken from interim patients during the maximum of 120 days permitted for such treatment. A program shall establish and follow reasonable criteria for establishing priorities for transferring patients from interim maintenance to comprehensive maintenance treatment. These transfer criteria shall be in writing and shall include, at a minimum, a preference for pregnant women in admitting patients to interim maintenance and in transferring patients from interim maintenance to comprehensive maintenance treatment. Interim maintenance shall be provided in a manner consistent with all applicable Federal and State laws, including sections 1923, 1927(a), and 1976 of the Public Health Service Act (21 U.S.C. 300x-23, 300x-27(a), and 300y-11).

(2) The program shall notify the State health officer when a patient begins interim maintenance treatment, when a patient leaves interim maintenance treatment, and before the date of mandatory transfer to a comprehensive program, and shall document such notifications.

(3) SAMHSA may revoke the interim maintenance authorization for programs that fail to comply with the provisions of this paragraph (j). Likewise, SAMHSA will consider revoking the interim maintenance authorization of a program if the State in which the program operates is not in compliance with the provisions of §8.11(g).

(4) All requirements for comprehensive maintenance treatment apply to interim maintenance treatment with the following exceptions:

(i) The opioid agonist treatment medication is required to be administered daily under observation;

(ii) Unsupervised or “take-home” use is not allowed;

(iii) An initial treatment plan and periodic treatment plan evaluations are not required;

(iv) A primary counselor is not required to be assigned to the patient;

(v) Interim maintenance cannot be provided for longer than 120 days in any 12-month period; and

(vi) Rehabilitative, education, and other counseling services described in paragraphs (f)(4), (f)(5)(i), and (f)(5)(iii) of this section are not required to be provided to the patient.

[66 FR 4090, Jan. 17, 2001, as amended at 68 FR 27939, May 22, 2003; 77 FR 72761, Dec. 6, 2012; 80 FR 34838, June 18, 2015]

§8.13 Revocation of accreditation and accreditation body approval.

(a) *SAMHSA action following revocation of accreditation.* If an accreditation body revokes an OTP's accreditation, SAMHSA may conduct an investigation into the reasons for the revocation. Following such investigation, SAMHSA may determine that the OTP's certification should no longer be in effect, at which time SAMHSA will initiate procedures to revoke the facility's certification in accordance with §8.14. Alternatively, SAMHSA may determine that another action or combination of actions would better serve the public health, including the establishment and implementation of a corrective plan of action that will permit the certification to continue in effect while the OTP seeks reaccreditation.

(b) *Accreditation body approval.* (1) If SAMHSA withdraws the approval of an accreditation body under §8.6, the certifications of OTPs accredited by such body shall remain in effect for a period of 1 year after the date of withdrawal of approval of the accreditation body, unless SAMHSA determines that to protect public health or safety, or because the accreditation body fraudulently accredited treatment programs, the certifications of some or all of the programs should be revoked or suspended or that a shorter time period should be established for the certifications to remain in effect. SAMHSA may extend the time in which a certification remains in effect under this paragraph on a case-by-case basis.

(2) Within 1 year from the date of withdrawal of approval of an accreditation body, or within any shorter period of time established by SAMHSA, OTPs currently accredited by the accreditation body must obtain accreditation from another accreditation body. SAMHSA may extend the time period for obtaining reaccreditation on a case-by-case basis.

§8.14 Suspension or revocation of certification.

(a) *Revocation.* Except as provided in paragraph (b) of this section, SAMHSA may revoke the certification of an OTP if SAMHSA finds, after providing the program sponsor with notice and an opportunity for a hearing in accordance with subpart C of this part, that the program sponsor, or any employee of the OTP:

(1) Has been found guilty of misrepresentation in obtaining the certification;

(2) Has failed to comply with the Federal opioid treatment standards in any respect;

(3) Has failed to comply with reasonable requests from SAMHSA or from an accreditation body for records, information, reports, or materials that are necessary to determine the continued eligibility of the OTP for certification or continued compliance with the Federal opioid treatment standards; or

(4) Has refused a reasonable request of a duly designated SAMHSA inspector, Drug Enforcement Administration (DEA) Inspector, State Inspector, or accreditation body representative for permission to inspect the program or the program's operations or its records.

(b) *Suspension.* Whenever SAMHSA has reason to believe that revocation may be required and that immediate action is necessary to protect public health or safety, SAMHSA may immediately suspend the certification of an OTP before holding a hearing under subpart C of this part. SAMHSA may immediately suspend as well as propose revocation of the certification of an OTP before holding a hearing under subpart C of this part if SAMHSA makes a finding described in paragraph (a) of this section and also determines that:

(1) The failure to comply with the Federal opioid treatment standards presents an imminent danger to the public health or safety;

(2) The refusal to permit inspection makes immediate suspension necessary; or

(3) There is reason to believe that the failure to comply with the Federal opioid treatment standards was intentional or was associated with fraud.

(c) *Written notification.* In the event that SAMHSA suspends the certification of an OTP in accordance with paragraph (b) of this section or proposes to revoke the certification of an OTP in accordance with paragraph (a) of this section, SAMHSA shall promptly provide the sponsor of the OTP with written notice of the suspension or proposed revocation by facsimile transmission, personal service, commercial overnight delivery service, or certified mail, return receipt requested. Such notice shall state the reasons for the action and shall state that the OTP may seek review of the action in accordance with the procedures in subpart C of this part.

(d)(1) If SAMHSA suspends certification in accordance with paragraph (b) of this section:

(i) SAMHSA will immediately notify DEA that the OTP's registration should be suspended under 21 U.S.C. 824(d); and

(ii) SAMHSA will provide an opportunity for a hearing under subpart C of this part.

(2) Suspension of certification under paragraph (b) of this section shall remain in effect until the agency determines that:

(i) The basis for the suspension cannot be substantiated;

(ii) Violations of required standards have been corrected to the agency's satisfaction; or

(iii) The OTP's certification shall be revoked.

§8.15 Forms.

(a) SMA-162—Application for Certification to Use Opioid Agonist Treatment Medications for Opioid Treatment.

(b) SMA-163—Application for Becoming an Accreditation Body under §8.3.