

SAMHSA within 48 hours of receipt of a complaint and keep SAMHSA informed of all aspects of the response to the complaint.

(f) *Modifications of accreditation elements.* Accreditation bodies shall obtain SAMHSA's authorization prior to making any substantive (i.e., noneditorial) change in accreditation elements.

(g) *Conflicts of interest.* The accreditation body shall maintain and apply policies and procedures that SAMHSA has approved in accordance with § 8.3 to reduce the possibility of actual conflict of interest, or the appearance of a conflict of interest, on the part of individuals who act on behalf of the accreditation body. Individuals who participate in accreditation surveys or otherwise participate in the accreditation decision or an appeal of the accreditation decision, as well as their spouses and minor children, shall not have a financial interest in the OTP that is the subject of the accreditation survey or decision. _____

(h) *Accreditation teams.* (1) An accreditation body survey team shall consist of healthcare professionals with expertise in drug abuse treatment and, in particular, opioid treatment. The accreditation body shall consider factors such as the size of the OTP, the anticipated number of problems, and the OTP's accreditation history, in determining the composition of the team. At a minimum, survey teams shall consist of at least 2 healthcare professionals whose combined expertise includes:

(i) The dispensing and administration of drugs subject to control under the Controlled Substances Act (21 U.S.C. 801 *et seq.*);

(ii) Medical issues relating to the dosing and administration of opioid agonist treatment medications for the treatment of opioid addiction;

(iii) Psychosocial counseling of individuals undergoing opioid treatment; and

(iv) Organizational and administrative issues associated with opioid treatment programs.

(2) Members of the accreditation team must be able to recuse themselves at any time from any survey in which either they or the OTP believes there is an actual conflict of interest or the appearance of a conflict of interest.

(i) *Accreditation fees.* Fees charged to OTP's for accreditation shall be reasonable. SAMHSA generally will find fees to be reasonable if the fees are limited to recovering costs to the accreditation body, including overhead incurred. Accreditation body activities that are not related to accreditation functions are not recoverable through fees established for accreditation.

(1) The accreditation body shall make public its fee structure, including those factors, if any, contributing to variations in fees for different OTP's.

(2) At SAMHSA's request, accreditation bodies shall provide to SAMHSA financial records or other materials, in a manner specified by SAMHSA, to assist in assessing the reasonableness of accreditation body fees.

§ 8.5 Periodic evaluation of accreditation bodies.

SAMHSA will evaluate periodically the performance of accreditation bodies primarily by inspecting a selected sample of the OTP's accredited by the accrediting body and by evaluating the accreditation body's reports of surveys conducted, to determine whether the OTP's surveyed and accredited by the accreditation body are in compliance with the Federal opioid treatment standards. The evaluation will include a determination of whether there are major deficiencies in the accreditation body's performance that, if not corrected, would warrant withdrawal of the approval of the accreditation body under § 8.6.

§ 8.6 Withdrawal of approval of accreditation bodies.

If SAMHSA determines that an accreditation body is not in substantial compliance with this subpart, SAMHSA shall take appropriate action as follows:

(a) *Major deficiencies.* If SAMHSA determines that the accreditation body has a major deficiency, such as commission of fraud, material false statement, failure to perform a major accreditation function satisfactorily, or significant noncompliance with the requirements of this subpart, SAMHSA shall withdraw approval of that accreditation body.

(1) In the event of a major deficiency, SAMHSA shall notify the accreditation body of the agency's action and the grounds on which the approval was withdrawn.

(2) An accreditation body that has lost its approval shall notify each OTP that has been accredited or is seeking accreditation that the accreditation body's approval has been withdrawn. Such notification shall be made within a time period and in a manner approved by SAMHSA.

(b) *Minor deficiencies.* If SAMHSA determines that the accreditation body has minor deficiencies in the performance of an accreditation function, that are less serious or more limited than the types of deficiencies described in paragraph (a) of this section, SAMHSA will notify the body that it has 90 days to submit to SAMHSA a plan of corrective action. The plan must include a summary of corrective actions and a schedule for their implementation. SAMHSA may place the body on probationary status for a period of time determined by SAMHSA, or may withdraw approval of the body if corrective action is not taken.

(1) If SAMHSA places an accreditation body on probationary status, the body shall notify all OTP's that have been accredited, or that are seeking accreditation, of the accreditation body's probationary status within a time period and in a manner approved by SAMHSA.

(2) Probationary status will remain in effect until such time as the body can demonstrate to the satisfaction of SAMHSA that it has successfully implemented or is implementing the corrective action plan within the established schedule, and the corrective actions taken have substantially eliminated all identified problems.

(3) If SAMHSA determines that an accreditation body that has been placed on probationary status is not implementing corrective actions satisfactorily or within the established schedule, SAMHSA may withdraw approval of the accreditation body. The accreditation body shall notify all OTP's that have been accredited, or are seeking accreditation, of the accreditation body's loss of SAMHSA approval within a time period and in a manner approved by SAMHSA.

(c) *Reapplication.* (1) An accreditation body that has had its approval withdrawn may submit a new application for approval if the body can provide information to SAMHSA to establish that the problems that were grounds for withdrawal of approval have been resolved.

(2) If SAMHSA determines that the new application demonstrates that the body satisfactorily has addressed the causes of its previous unacceptable performance, SAMHSA may reinstate approval of the accreditation body.

(3) SAMHSA may request additional information or establish additional conditions that must be met before SAMHSA approves the reapplication.

(4) SAMHSA may refuse to accept an application from a former accreditation body whose approval was withdrawn because of fraud, material false statement, or willful disregard of public health.

(d) *Hearings.* An opportunity to challenge an adverse action taken regarding withdrawal of approval of an accreditation body shall be addressed through the relevant procedures set forth in subpart C of this part, except that the procedures in § 8.28 for expedited review of an immediate suspension would not apply to an accreditation body that has been notified under paragraph (a) or (b) of this section of the withdrawal of its approval.

Subpart B—Certification and Treatment Standards

§ 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) and (g)(3) of the Controlled Substances Act (21 U.S.C. 823(g)(1) and (g)(3)) to dispense opioid drugs in the treatment of opioid addiction. An OTP must be determined to be qualified under section 303(g)(1) and (g)(3) of the Controlled Substances Act, and must be determined to be qualified by the Attorney General under section 303(g)(2), 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). 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 address 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) and (g)(3) of the Controlled Substances Act.

(d) *Transitional certification.* OTP's that on (date 60 days after date of publication of final rule in the **Federal Register**) were the subject of a current, valid approval by FDA under 21 CFR part 291, are deemed to be the subject of a current valid certification for purposes of paragraph (a)(11) of this section. Such "transitional" certification shall expire on (date 150 days after date of publication of final rule in the **Federal Register**), except that such transitional certification of an OTP that submits the information required by paragraph (b) of this section to SAMHSA on or before (date 150 days after date of publication of the final rule in the **Federal Register**), along with a statement certifying that the OTP will apply for accreditation from a SAMHSA approved accreditation body within 90 days from the date SAMHSA announces the approval of the first accreditation body under § 8.3, shall expire on (date 2 years and 60 days after date of publication of final rule in the **Federal Register**). SAMHSA may extend the transitional certification of an OTP for up to 1 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.

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(e) *Provisional certification.* (1) OTP's 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 the program's efforts to obtain accreditation and a schedule for obtaining accreditation as expeditiously as possible.

(f) *Conditions for certification.* (1) OTP's shall comply with all pertinent State laws and regulations. Nothing in this part is intended to limit the authority of State and 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 programs operated directly by the Veterans' Administration or any other department or agency of the United States. Federal agencies operating narcotic treatment programs have agreed to cooperate voluntarily with State agencies by granting permission on an informal basis for designated State representatives to visit Federal narcotic treatment programs and by furnishing a copy of Federal reports to the State authority, including the reports required under this section.]

(2) OTP's 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) OTP's shall notify SAMHSA within 3 weeks of any replacement or other change in the status of the program sponsor or medical director.

(6) OTP's 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) OTP's 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 §§ 8.11 and 8.12. 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 may 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 OTP's 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 SMA-162. The OTP must also comply with the provisions of 21 CFR part 1300 before establishing a medication unit.

(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 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.

§8.12 Federal opioid treatment standards.

(a) *General.* OTP’s must provide treatment in accordance with these standards and must comply with these standards as a condition of certification.

(b) *Administrative and organizational structure.* An OTP’s organizational structure 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 program shall formally designate a program sponsor and medical director. The program sponsor shall agree on behalf of the program 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 program. In addition, the medical director shall be responsible for ensuring that the program 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 attempts at short-term detoxification or drug-free treatment to be eligible for maintenance treatment. A waiting period of no less than 7 days is required between the first and the second short-term detoxification 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. At a minimum, a program physician shall determine that each patient admitted is physically dependent on opioid drugs. In addition, a patient is required to wait no less than 7 days between concluding a short-term detoxification or long-term detoxification treatment episode and beginning another.

(f) *Required services*—(1) *General.* OTP's shall provide adequate medical, counseling, vocational, educational, and assessment 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.* OTP's shall require each patient to undergo a complete, fully documented medical evaluation by a program physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician, within the first 30 days following admission to the OTP.

(3) *Special services for [pregnant] patients.* OTP's must maintain current policies and procedures that reflect the special needs of patients [who are pregnant]. Prenatal care and other [gender] specific services for [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 patients'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) OTP's 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 drug abusers, to contribute to the appropriate treatment plan for the patient and to monitor patient progress.

(ii) OTP's 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) OTP's 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.* OTP's must provide adequate testing or analysis for drugs of abuse, including at least eight random drug abuse tests per year, per patient, 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) OTP's 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) OTP's shall include, as an essential part of the recordkeeping system, documentation in each patient's record showing that the OTP made the determination, upon the admission of each patient, that the patient is not enrolled in 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) OTP's 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) OTP's 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, OTP's 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, provided the investigational use of the drug by the OTP is fully consistent with the protocol and other conditions set forth in that

application. Only 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; and

(ii) Levo-Alpha-Acetyl-Methadol (LAAM).

(3) OTP's 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.

(iii) The administering physician shall ensure that any time a daily dose greater than 100 milligrams is provided to a patient, the justification for such a daily dose is stated in the patient's record.

(4) OTP's 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 deviations from the approved labeling, including deviations with regard to dose, frequency, or the conditions of use described in the approved labeling, are justified 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 (h)(4)(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 (h)(4)(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 following restrictions apply:

(i) During the first month of treatment, the maximum take-home supply is limited to a single dose each week and the patient shall ingest all other doses under appropriate supervision as provided for under these regulations.

(ii) In the second month of treatment, the maximum take-home supply is two doses after each supervised ingestion.

(iii) In the third month of treatment, the patient shall have observed ingestion at least twice a week, with take-home permitted for other doses.

(iv) In the remaining months of the first year, the maximum take-home supply of opioid medication is three doses after each supervised ingestion.

(v) After 1 year, a patient may be given a maximum of 31 days 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) OTP's 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 (see Poison Prevention Packaging Act, Pub. L. 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 § 8.12(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.

§ 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 OTP's 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, OTP's 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 42 CFR 8.3.

Subpart C—Procedures for Review of Suspension or Proposed Revocation of OTP Certification

§ 8.21 Applicability.

These procedures apply when:

(a) SAMHSA has notified an OTP in writing that its certification under these regulations has been suspended or that SAMHSA proposes to revoke such certification; and

(b) The OTP has, within 30 days of the date of such notification or within 3 days of the date of such notification when seeking an expedited review of a suspension, requested in writing an opportunity for a review of the suspension or proposed revocation.

§ 8.22 Definitions.

(a) *Appellant* means the treatment program which has been notified of its suspension or proposed revocation of its certification under these regulations and has requested a review thereof.

(b) *Respondent* means the person or persons designated by the Secretary in implementing these regulations.

(c) *Reviewing official* means the person or persons designated by the Secretary who will review the suspension or proposed revocation. The reviewing official may be assisted by one or more of his or her employees or consultants in assessing and weighing the scientific and technical

evidence and other information submitted by the appellant and respondent on the reasons for the suspension and proposed revocation.

§ 8.23 Limitation on issues subject to review.

The scope of review shall be limited to the facts relevant to any suspension or proposed revocation, the necessary interpretations of those facts, these regulations, and other relevant law.

§ 8.24 Specifying who represents the parties.

The appellant's request for review shall specify the name, address, and phone number of the appellant's representative. In its first written submission to the reviewing official, the respondent shall specify the name, address, and phone number of the respondent's representative.

§ 8.25 Informal review and the reviewing official's response.

(a) Within 30 days of the date of the notice of the suspension or proposed revocation, the appellant must submit a written request to the reviewing official seeking review, unless some other time period is agreed to by the parties. A copy must also be sent to the respondent. The request for review must include a copy of the notice of suspension or proposed revocation, a brief statement of why the decision to suspend or propose revocation is incorrect, and the appellant's request for an oral presentation, if desired.

(b) Within 5 days after receiving the request for review, the reviewing official will send an acknowledgment and advise the appellant of the next steps. The reviewing official will also send a copy of the acknowledgment to the respondent.

§ 8.26 Preparation of the review file and written argument.

The appellant and the respondent each participate in developing the file for the reviewing official and in submitting written arguments. The procedures for development of the review file and submission of written argument are:

(a) *Appellant's documents and brief.* Within 15 days after receiving the acknowledgment of the request for review, the appellant shall submit to the reviewing official the following (with a copy to the respondent):

(1) A review file containing the documents supporting appellant's argument, tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not to exceed 20 double-spaced pages, explaining why respondent's decision to suspend or propose revocation of appellant's certification is incorrect (appellant's brief).

(b) *Respondent's documents and brief.* Within 15 days after receiving a copy of the acknowledgment of the request for review, the respondent shall submit to the reviewing official the following (with a copy to the appellant):

(1) A review file containing documents supporting respondent's decision to suspend or revoke appellant's certification, tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not exceeding 20 double-spaced pages in length, explaining the basis for suspension or proposed revocation (respondent's brief).

(c) *Reply briefs.* Within 5 days after receiving the opposing party's submission, or 20 days after receiving acknowledgment of the request for review, whichever is later, each party may submit a short reply not to exceed 10 double-spaced pages.

(d) *Cooperative efforts.* Whenever feasible, the parties should attempt to develop a joint review file.

(e) *Excessive documentation.* The reviewing official may take any appropriate step to reduce excessive documentation, including the return of or refusal to consider documentation found to be irrelevant, redundant, or unnecessary.

§ 8.27 Opportunity for oral presentation.

(a) *Electing oral presentation.* If an opportunity for an oral presentation is desired, the appellant shall request it at the time it submits its written request for review to the reviewing official. The reviewing official will grant the request if the official determines that the decisionmaking process will be substantially aided by oral presentations and arguments. The reviewing official may also provide for an oral presentation at the official's own initiative or at the request of the respondent.

(b) *Presiding official.* The reviewing official or designee will be the presiding official responsible for conducting the oral presentation.

(c) *Preliminary conference.* The presiding official may hold a prehearing conference (usually a telephone conference call) to consider any of the following: simplifying and clarifying issues; stipulations and admissions; limitations on evidence and witnesses that will be presented at the hearing; time allotted for each witness and the hearing altogether; scheduling the hearing; and any other matter that will assist in the review process. Normally, this conference will be conducted informally and off the record; however, the presiding official may, at his or her discretion, produce a written document summarizing the conference or transcribe the conference, either of which will be made a part of the record.

(d) *Time and place of oral presentation.* The presiding official will attempt to schedule the oral presentation within 30 days of the date appellant's request for review is received or within 10 days of submission of the last reply brief, whichever is later. The oral presentation will be held at a time and place determined by the presiding official following consultation with the parties.

(e) *Conduct of the oral presentation—(1) General.* The presiding official is responsible for conducting the oral presentation. The presiding official may be assisted by one or more of his or her employees or consultants in conducting the oral presentation and reviewing the evidence. While the oral presentation will be kept as informal as possible, the presiding official may take all necessary steps to ensure an orderly proceeding.

(2) *Burden of proof/standard of proof.* In all cases, the respondent bears the burden of proving by a preponderance of the evidence that its decision to suspend or propose revocation is appropriate. The appellant, however, has a responsibility to respond to the respondent's allegations with evidence and argument to show that the respondent is incorrect.

(3) *Admission of evidence.* The rules of evidence do not apply and the presiding official will generally admit all testimonial evidence unless it is clearly irrelevant, immaterial, or unduly repetitious. Each party may make an opening and closing statement, may present witnesses as agreed upon in the prehearing conference or otherwise, and may question the opposing party's witnesses. Since the parties have ample opportunity to prepare the review file, a party may introduce additional documentation during the oral presentation only with the permission of the presiding official. The presiding official may question witnesses directly and take such other steps necessary to ensure an effective and efficient consideration of the evidence, including setting time limitations on direct and cross-examinations.

(4) *Motions.* The presiding official may rule on motions including, for example, motions to exclude or strike redundant or immaterial evidence, motions to dismiss the case for insufficient evidence, or motions for summary judgment. Except for those made during the hearing, all motions and opposition to motions, including argument, must be in writing and be no more than 10 double-spaced pages in length. The presiding official will set a reasonable time for the party opposing the motion to reply.

(5) *Transcripts.* The presiding official shall have the oral presentation transcribed and the transcript shall be made a part of the record. Either party may request a copy of the transcript and the requesting party shall be responsible for paying for its copy of the transcript.

(f) *Obstruction of justice or making of false statements.* Obstruction of justice or the making of false statements by a witness or any other person may be the basis for a criminal prosecution under 18 U.S.C. 1505 or 1001.

(g) *Post-hearing procedures.* At his or her discretion, the presiding official may require or permit the parties to submit post-hearing briefs or proposed findings and conclusions. Each party may submit comments on any major prejudicial errors in the transcript.

§ 8.28 Expedited procedures for review of immediate suspension.

(a) *Applicability.* When the Secretary notifies a treatment program in writing that its certification has been immediately suspended, the appellant may request an expedited review of the suspension and any proposed revocation. The appellant must submit this request in writing to the reviewing official within 5 days of the date the OTP received notice of the suspension. The request for review must include a copy of the suspension and any proposed revocation, a brief statement of why the decision to suspend and propose revocation is incorrect, and the appellant's request for an oral presentation, if desired. A copy of the request for review must also be sent to the respondent.

(b) *Reviewing official's response.* As soon as practicable after the request for review is received, the reviewing official will send an acknowledgment with a copy to the respondent.

(c) *Review file and briefs.* Within 10 days of the date the request for review is received, but no later than 2 days before an oral presentation, each party shall submit to the reviewing official the following:

(1) A review file containing essential documents relevant to the review, tabbed, indexed, and organized chronologically; and

(2) A written statement, not to exceed 20 double-spaced pages, explaining the party's position concerning the suspension and any proposed revocation. No reply brief is permitted.

(d) *Oral presentation.* If an oral presentation is requested by the appellant or otherwise granted by the reviewing official in accordance with § 8.27(a), the presiding official will attempt to schedule the oral presentation within 10 to 14 days of the date of appellant's request for review at a time and place determined by the presiding official following consultation with the parties. The presiding

official may hold a pre-hearing conference in accordance with § 8.27(c) and will conduct the oral presentation in accordance with the procedures of § 8.27(e), (f), and (g).

(e) *Written decision.* The reviewing official shall issue a written decision upholding or denying the suspension or proposed revocation and will attempt to issue the decision within 7 to 10 days of the date of the oral presentation or within 3 days of the date on which the transcript is received or the date of the last submission by either party, whichever is later. All other provisions set forth in § 8.33 will apply.

(f) *Transmission of written communications.* Because of the importance of timeliness for these expedited procedures, all written communications between the parties and between either party and the reviewing official shall be by facsimile transmission, personal service, commercial overnight delivery service, or certified mail, return receipt requested.

§ 8.29 Ex parte communications.

Except for routine administrative and procedural matters, a party shall not communicate with the reviewing or presiding official without notice to the other party.

§ 8.30 Transmission of written communications by reviewing official and calculation of deadlines.

(a) Because of the importance of a timely review, the reviewing official should normally transmit written communications to either party by facsimile transmission, personal service, commercial overnight delivery service, or certified mail, return receipt requested, in which case the date of transmission or day following mailing will be considered the date of receipt. In the case of communications sent by regular mail, the date of receipt will be considered 3 days after the date of mailing.

(b) In counting days, include Saturdays, Sundays, and holidays. However, if a due date falls on a Saturday, Sunday, or Federal holiday, then the due date is the next Federal working day.

§ 8.31 Authority and responsibilities of reviewing official.

In addition to any other authority specified in these procedures, the reviewing official and the presiding official, with respect to those authorities involving the oral presentation, shall have the authority to issue orders; examine witnesses; take all steps necessary for the conduct of an orderly hearing; rule on requests and motions; grant extensions of time for good reasons; dismiss for failure to meet deadlines or other requirements; order the parties to submit relevant information or witnesses; remand a case for further action by the respondent; waive or modify these procedures in a specific case, usually with notice to the parties; reconsider a decision of the reviewing official where a party promptly alleges a clear error of fact or law; and to take any other action necessary to resolve disputes in accordance with the objectives of these procedures.

§ 8.32 Administrative record.

The administrative record of review consists of the review file; other submissions by the parties; transcripts or other records of any meetings, conference calls, or oral presentation; evidence submitted at the oral presentation; and orders and other documents issued by the reviewing and presiding officials.

§ 8.33 Written decision.

(a) *Issuance of decision.* The reviewing official shall issue a written decision upholding or denying the suspension or proposed revocation. The decision will set forth the reasons for the decision and describe the basis therefor in the record. Furthermore, the reviewing official may remand the matter to the respondent for such further action as the reviewing official deems appropriate.

(b) *Date of decision.* The reviewing official will attempt to issue his or her decision within 15 days of the date of the oral presentation, the date on which the transcript is received, or the date of the last submission by either party, whichever is later. If there is no oral presentation,

the decision will normally be issued within 15 days of the date of receipt of the last reply brief. Once issued, the reviewing official will immediately communicate the decision to each party.

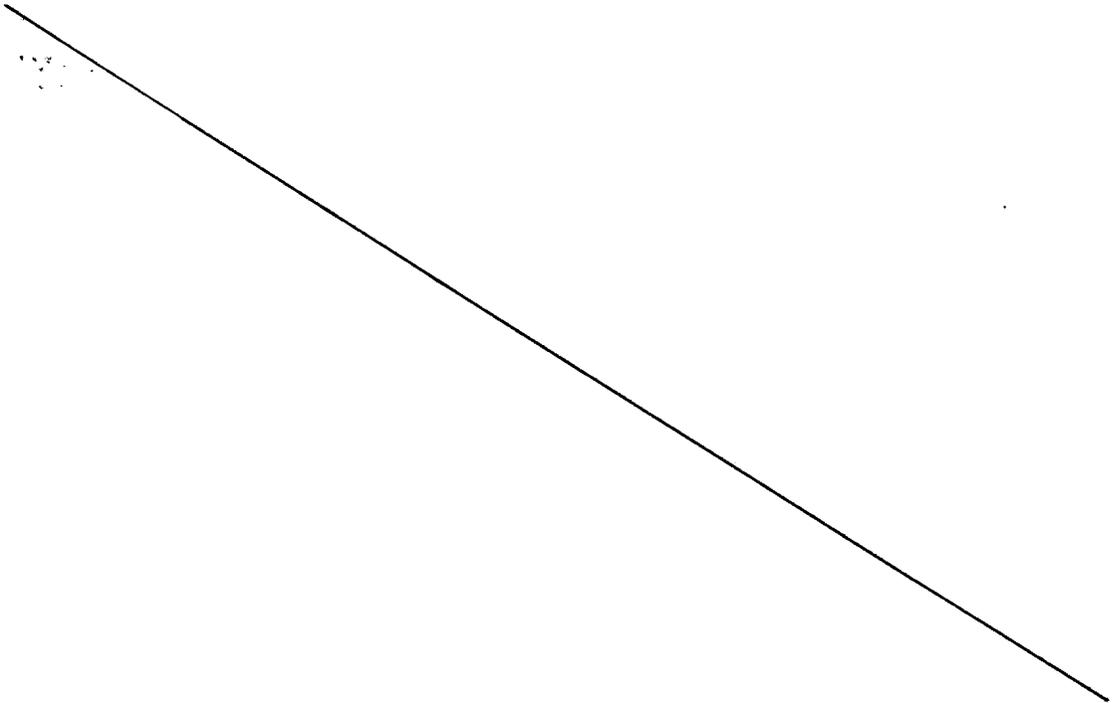
(c) *Public notice and communications to the Drug Enforcement Administration (DEA).*

(1) If the suspension and proposed revocation are upheld, the revocation of certification will become effective immediately and the public will be notified by publication of a notice in the **Federal Register**. SAMHSA will notify DEA within 5 days that the OTP's registration should be revoked.

(2) If the suspension and proposed revocation are denied, the revocation will not take effect and the suspension will be lifted immediately. Public notice will be given by publication in the **Federal Register**. SAMHSA will notify DEA within 5 days that the OTP's registration should be restored, if applicable.

§ 8.34 Court review of final administrative action; exhaustion of administrative remedies.

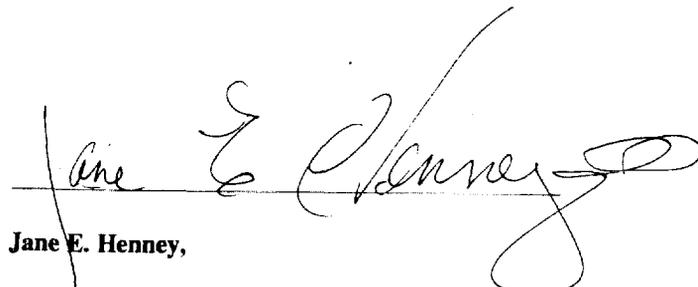
Before any legal action is filed in court challenging the suspension or proposed revocation, respondent shall exhaust administrative remedies provided under this subpart, unless otherwise



provided by Federal law. The reviewing official's decision, under § 8.28(e) or § 8.33(a), constitutes final agency action as of the date of the decision.

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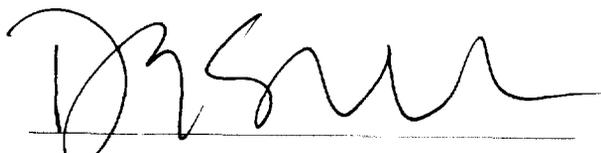
Dated: _____



Jane E. Henney,
Commissioner of Food and Drugs.



Nelba Chavez,
Administrator, Substance Abuse and Mental Health Services Administration.



Donna E. Shalala,

Secretary of Health and Human Services.

[Insert Appendix 1 Here]

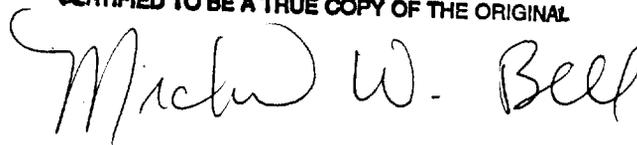
[FR Doc. 98-???? Filed ??-??-98; 8:45 am]

The following appendix will not appear in the Code of Federal Regulations.

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Appendix 1

OMB

**OFFICE OF NATIONAL DRUG CONTROL POLICY
POLICY PAPER
OPIOID AGONIST TREATMENT**



March 1999

**OFFICE OF NATIONAL DRUG CONTROL POLICY (ONDCP)
POLICY PAPER -- OPIOID AGONIST TREATMENT**

INTRODUCTION

This paper is circulated by the Director, ONDCP, under his statutory authority [Section 704 (b) (3) of Public Law 105-2 77, the Office of National Drug Control Policy Reauthorization Act of 1998] to coordinate and oversee the implementation by the National Drug Control Program agencies of the policies, goals, objectives, and priorities established for the national drug control programs and the fulfillment of the responsibilities of such agencies under the National Drug Control Strategy.

In response to recent increases in heroin use, ONDCP has joined with the Departments of Health and Human Services (DHHS) and Justice (DOJ), to address the problems and potential of opioid agonist treatment, primarily methadone treatment. In addition to a shortfall in treatment capacity, problems have long existed at two levels: first, methadone treatment programs have not functioned with uniform high quality; and, second, Federal oversight, grounded in process-focused regulations, has not served to improve or maintain the quality of methadone treatment programs. To reduce the use of illicit drugs, both of these problems must be addressed.

1. **PURPOSE:** The purpose of this document is to discuss national policy and direction regarding the role of methadone, levo-alpha-acetylmethadol hydrochloride (LAAM), and other opioid agonist treatments in reducing opiate addiction.
2. **OBJECTIVE:** A major priority of the Office of National Drug Control Policy (ONDCP) is to allow those addicted to heroin to receive quality drug treatment, including opioid agonist treatment when it is the indicated modality, in the context of expanding overall treatment capacity for all drugs of abuse.
3. **DISCUSSION:**

A. The Scope of the Heroin Problem: Although a relatively small percentage of America's illegal drug users use heroin, the debilitating effects of the drug make it, along with cocaine, a major source of drug-related health, crime, and social costs. And the heroin using population has grown in recent years. Data from the National Household Survey on Drug Abuse indicate that current (i.e., past month) use of heroin in the household population, age 12 years and older, has risen dramatically, from 71,000 in 1991 to 325,000 in 1997. ONDCP estimates a population of 810,000 chronic heroin users in the United States in 1995.

(1) Trends -- High Purity: While the number of new heroin initiates is still relatively low, it is apparent that the availability of high-purity heroin has led to an increase in use, probably related to changes in the route of administration. High purity heroin can be snorted, smoked, or otherwise inhaled, and need not be injected. Heroin users

who have snorted or smoked heroin increased from 55 percent of heroin users in 1994 to 82 percent in 1996. This trend is disturbing in two aspects: first, because it expands the use of heroin to those who might be reluctant to inject drugs; and, second, because heroin can now be ingested using the same "pathway" as abused substances such as tobacco, crack, methamphetamine, and marijuana. The ability to snort or smoke heroin is likely to foster experimentation, adding to the number of users and leading to injection for many of them over time. The *Drug Abuse Warning Network (DAWN)* reports that the proportion of drug-related episodes that involve heroin/morphine increased steadily from 4 percent in 1978 to 13.8 percent in 1995, before leveling off in 1996 and the first six months of 1997. The number of heroin/morphine "mentions" increased each year from 1991 through 1996 (35,898 in 1991, 48,003 in 1992, 63,232 in 1993, 64,013 in 1994, 70,838 in 1995, and 73,846 in 1996). Most of these patients sought detoxification or medical treatment to deal with overdose or the chronic health effects of heroin use.

(2) Trends -- Heroin Addicts and Other Chronic, Hardcore Drug Users are Undercounted: Because of the nature of heroin abuse, many chronic users may not be captured by traditional surveys such as the *National Household Survey on Drug Abuse* (which only surveys those living in households) and *Monitoring the Future* (which only surveys youth enrolled in school and present on the day of the survey). To provide a more accurate estimate, ONDCP sponsored a pilot research study in Cook County, Illinois, to test a new methodology for estimating addicted drug users. In addition to validating the new methodology, the study found that there were three times as many hardcore addicts in Cook County than the number estimated by the Household Survey. These results suggest that the actual number of chronic heroin users in the United States may be even larger than ONDCP's estimate of 810,000.

(3) Trends -- The Population of Addicts is Aging, Even as Younger Initiates Increase: Many heroin addicts encounter serious health problems after years of use. Heroin addicts who began use in the last great heroin epidemic of the late 1960s and early 1970s now require significantly increased and costly medical care for the cumulative debilitating effects of their drug use. Since 1978 the number of emergency room mentions for heroin among those aged 35 and older has tripled. The DAWN report of drug mentions in hospital emergency departments shows that heroin/morphine mentions more than doubled from 1990 through 1996 (from 33,900 to 73,800), as did the rate per 100,000 population (from 15.3 in 1990 to 31.4 in 1996). And, although their numbers remain relatively small, increases in heroin mentions are also seen among youth ages 12 to 17 and 18 to 25. This DAWN data is consistent with the finding of the National Household Survey on Drug Abuse that the mean age of initiation for heroin dropped from 26.2 years in 1988 to 18.1 in 1996.

B. The Implications of the Problem: As with cocaine and methamphetamine users, heroin users are at risk for a plethora of negative social and health consequences.

(1) Heroin is a Toxic Substance: The danger of a fatal overdose is more immediate and likely for a heroin user today than for users of other common drugs of abuse because of the route of administration and common miscalculations regarding drug purity. Misjudging heroin purity can have fatal implications. Heroin use is involved in about 15 percent of all drug-related emergency room visits -- a number that far exceeds the proportion of heroin users in the general drug-using population.

(2) Heroin Use is Associated with Crime: Because of the addictive and tolerance properties of heroin, users find that they need heroin frequently in increasing amounts. Because the withdrawal effects of heroin are both severe and frequent, addicts typically use heroin several times a day. The need to purchase large amounts of a costly drug inevitably leads to crime. For decades some cities have estimated that over half of all property crime is attributable to heroin use. Twenty percent of all people arrested in Manhattan in 1997 tested positive for opiates. In the same year, 22 percent of all arrestees in Chicago tested positive for opiates.

(3) Heroin Use Affects Public Health: There is a strong nexus between heroin use and many life-threatening diseases, including infections such as hepatitis B and C, HIV/AIDS, and endocarditis; as well as tuberculosis and sexually transmitted diseases. The heroin subculture -- with its sharing of needles and "cooking equipment" and associated high-risk sexual behaviors, including prostitution and trading sex for drugs -- is a major factor in the transmission of disease. The Centers for Disease Control (CDC) estimates injecting drug users (most of whom are heroin users) account for between 15 and 36 percent of the nation's new HIV infections each year. According to CDC's HIV/AIDS Surveillance Report, of 13,111 new HIV cases reported between July 1996 and June 1997, injecting drug use was an "exposure category" for over 2,200. Heroin not only undermines the health of users, but -- in the case of pregnant women -- can seriously affect the health of their children.

(4) Heroin Addiction is Difficult to Overcome: The National Institute of Drug Abuse has declared that heroin is a powerfully addicting substance producing tolerance, physical dependence, and the clinical state of addiction (defined as compulsive, often truly uncontrollable drug craving, seeking, and use). The psychopharmacological effects of heroin are extremely strong. Satisfaction of the self-destructive need becomes nearly a full-time occupation. Heroin addicts spend a large amount of their time searching for drugs. An ONDCP study of cocaine, crack, and heroin abuse in six cities found that the percentage of heroin users who used heroin for 30 or more consecutive days over a 90 day period was four times greater than the percentage for crack and powder cocaine users. This finding indicates that there is a high proportion of heroin addicts among the users of heroin. Cessation of heroin use is difficult: the same study found that heroin users reporting 30 or more consecutive days of abstinence in a 90 day period tended to be lower than for crack or powder cocaine users. The relatively stable number of heroin addicts over the years,

particularly in older age groups, indicates the relative shortfall in effective treatment capacity and aggressive outreach programs to get the addicts into treatment. In some cities, an entire heroin culture that spans generations has evolved, as addicts cycle through the criminal justice system and back into street addiction without any prospect of entering an effective treatment regimen.

C. Methadone -- Part of the Solution: Methadone has been used for the treatment of heroin addiction since the 1960s. It is an orally effective, long-acting, synthetic opioid agonist. In other words, methadone operates by "occupying" the brain receptor sites that are affected by heroin and blocks the craving attendant to addiction. Eventually it produces tolerance to its own analgesic effects, as well as its psychoactive effects, and also produces a physiological cross-tolerance to other opiates. Initially, methadone was used in the context of abstinence-based drug treatment to alleviate withdrawal pains for heroin addicts. Because of methadone's long duration of action before withdrawal begins (24 hours at adequate doses), it is relatively easy to maintain an addict on methadone without abrupt side effects. A more recently approved agent, levo-alpha-acetylmethadol hydrochloride (LAAM), will last even longer, up to three days.

Although much is known about the action and effectiveness of methadone, less is known about the addict population. Among the questions remaining to be answered by research and experience is how to determine with confidence which addicts should most properly be referred to therapeutic community-like residential treatment, which to methadone detoxification, which to limited term methadone-to-abstinence treatment, and which to long-term maintenance.

(1) The Rise of Methadone Treatment: Heroin addiction became a major public concern during the epidemic of the 1960s and early 1970s. The growth in heroin addiction occurred during a major shift in public health approaches, away from an (often coercive) in-patient treatment regimen to out-patient, community-based treatment. Confronted with a rising number of heroin addicts and faced with a choice between methadone treatment and other treatment regimes, which promised uncertain results at the time, many governmental agencies opted to pursue methadone treatment. The American Bar Association noted in a 1972 report that New York City had 18,072 people in methadone programs, with a waiting list of 15,000 more, and that 65 percent of all participants in New York City treatment programs were in methadone treatment. National estimates of the number of patients in methadone treatment have indicated growth, with an estimate of 81,852 in methadone treatment in 1987, nearly 95,300 in 1991, and 117,000 in 1993. A recent survey of the states by the American Methadone Treatment Association (AMTA) indicates that over 170,000 patients are engaged in some form of methadone treatment at this time.

(2) Methadone Treatment Today: Methadone treatment is the most widely used treatment for heroin addiction today. It has been studied more than any other drug treatment modality, with uniformly positive results. Thousands of Americans are able to

lead stable lives as a result of methadone treatment. Most of the over 900 methadone treatment programs in America provide an invaluable service. Typically, methadone patients go to a treatment program each day, to receive, and be observed ingesting, an oral dose of methadone in liquid form. Many stable, compliant patients are eventually allowed to take a number of doses home, reducing the number of trips they must make to the program. Better treatment programs make provision for systematic drug testing, monitoring for compliance, counseling, provision of other needed services, and periodic assessment of the continuing appropriateness of methadone. Unfortunately, many programs do not provide such comprehensive services.

Given the less than uniform state of methadone treatment, the outcomes achieved are remarkable. The National Institute on Drug Abuse (NIDA) has conducted literally dozens of studies that show the effectiveness of methadone treatment. *The Drug Abuse Treatment Outcome Study (DATOS)*, the most recent study by NIDA, found that among participants in outpatient methadone treatment, weekly heroin use decreased 69 percent, cocaine use by 48 percent (many heroin users are polydrug users), illegal activity decreased 52 percent, and full time work increased by 24 percent. Methadone treatment, at an average cost of \$13 or less per day, is clearly a cost effective alternative to incarceration for many drug-dependent offenders. Yet, in spite of this proven track record, methadone treatment capacity has not experienced marked growth. Treatment capacity is insufficient to provide most of the 810,000 chronic heroin addicts with methadone treatment or any other effective form of drug abuse treatment. Methadone treatment is still not available in eight states: Idaho, Mississippi, Montana, New Hampshire, North Dakota, South Dakota, Vermont, and West Virginia.

(3) Criticisms of Methadone Treatment: The full benefits of any intervention, including methadone treatment, are only obtained within a comprehensive treatment environment, which screens and evaluates patients and assigns them to appropriate treatment regimes, based upon the nature of each patient's addiction as well as other problems (e.g., psychological, family, vocational). By itself, methadone is simply a medication, a drug. As noted by the November 1997 National Institutes of Health Consensus Development Statement, non-pharmacologic supportive services are pivotal to successful treatment. Ongoing substance abuse counseling and other psychosocial therapies, vocational rehabilitation, and needed medical and social services are essential for program retention and positive outcome. For example, a study by McLellan in 1993 showed that patients who received comprehensive services including methadone, when compared to those who received methadone only, had a strikingly higher level of improvement. Comprehensive programs evaluate continued use of methadone and assess methadone's utility for each patient at regular intervals, as well as evaluating the need for treatment of problems that often interfere with adequate rehabilitation.

Unfortunately, such discipline has not universally been the case among programs. A 1990 GAO report based on observations of 24 methadone treatment organizations found that policies, goals and practices varied greatly and that not one of the programs studied

evaluated the effectiveness of their treatment. Although many improvements have been made, the failures of the unsuccessful programs tarnished the entire idea of methadone treatment, rather than spurring significant efforts to improve the quality of services and acknowledging the effectiveness of comprehensive programs.

(4) The Future of Methadone Treatment:

a. A standardized accreditation system for opioid agonist treatment programs with transfer of regulatory oversight from the Food and Drug Administration (FDA) to the Substance Abuse and Mental Health Services Administration (SAMHSA): The current, process-oriented regulatory approach will be replaced with a system that is more akin to a clinically-based accreditation model. Providers will know with certainty what is required of them --clinically, administratively, and programmatically -- to initiate or continue an opioid agonist treatment program. Regulatory and enforcement agencies will have a clear understanding of the nature and limits of their authority.

To start this process, CSAT/SAMHSA will lead the interagency effort, in 1999, to assess the impact of the accreditation process and proposed accreditation standards on methadone program quality, capacity, and oversight. Based on the results of the evaluation, feedback from treatment experts and public officials, and public comments on the Notice of Proposed Rule Making, a final rule will be promulgated to introduce reformed treatment standards and an accreditation process. Integrating regulatory oversight for methadone into CSAT/SAMHSA responsibilities for overseeing treatment services will facilitate the much-needed expansion of methadone treatment capacity while enhancing the application of clinical standards. In the interim, programs will remain subject to FDA oversight and monitoring.

Responsibility for preventing the diversion of methadone to illicit use will remain with the Drug Enforcement Administration (DEA). For the process of reform to progress with clear expectations, DEA's role will be spelled out in detail and distinguished from that of the Substance Abuse and Mental Health Services Administration's Center for Substance Abuse Treatment (SAMHSA/CSAT). Specifically, DEA's anti-diversion authority will be clearly distinguished from SAMHSA/CSAT's clinical practice authority.

b. Provision for individual physician administration of methadone treatment to stabilized, methadone-maintained patients: Methadone is a tool of proven effectiveness in treating heroin addicts. But no tool is effective in isolation. The recovering heroin addict must be integrated back into employment and into society. It is estimated that, at a minimum, seven percent of those presently receiving methadone are sufficiently stable to be transferred to a private

physician for continued maintenance. When this transfer can be accomplished, additional program capacity will be made available for those awaiting treatment.

This will not happen overnight. Most physicians are ill-equipped to practice addiction medicine. However, as physician training and certification in the administration of opioid agonist treatment is accomplished, regulations will be reformed to allow trained physicians to use all the counter-addiction modalities in the physician's preferred clinical setting supported by ancillary services.

4. THE CHALLENGE: Currently only a fraction of those addicts who can benefit from methadone treatment do so. Expansion of methadone and other heroin treatment modalities, such as residential treatment, is essential to reach the untreated majority of the opiate addicted.

A. Policy Barriers: The laws governing methadone treatment -- the Controlled Substances Act (C.S.A.) and Narcotic Addict Treatment Act (NAIA) -- date from the 1970s, and reflect the political and social climate of the day, rather than rigorous study. These laws pre-date research breakthroughs on the nature of addiction and the success of drug treatment, and they arbitrarily limit the administration of treatment programs and the expansion of treatment capacity. Furthermore, they are implemented with process-focused regulations, which do not address treatment quality.

(1) Uneven Application of Standards for Admission to Methadone Treatment:

As the 1990 GAO study noted, there is a wide variance of policies among methadone treatment programs. FDA admission standards are not uniformly applied by programs in evaluating potential patients and referring them to appropriate treatment. This lack of uniformity in practice continues under state managed care systems. Not everyone will benefit from methadone treatment and the failure to apply uniform assessment standards makes it probable that some addicts will be assigned to methadone or other treatment regimes inappropriately.

(2) Variance in Oversight and Limits on Program Administration: There is considerable overlap in governmental oversight and enforcement, with Federal, state, and local agencies involved in some states with different priorities and concerns. And an attempt to accomplish, with regulations, matters that depend on medical discretion. For example, Federal regulations address limits on dosage and on take-home medication privileges, with take-home privileges based on time spent in the program, rather than on clinical criteria. Both practices should be based on sound clinical criteria for decision-making, as the former practice can lead to under-treatment and the latter to both diversion to illicit use and interference with rehabilitation.

Given the critical role of the states in the reform of methadone regulations, lead Federal agencies must maintain continuing communication with relevant state authorities, to identified state-specific issues and plan for their resolution.

(3) Lack of Enforceable Clinical Guidelines: Paradoxically, in an environment in which methadone is over-regulated, there is a dearth of enforceable clinical guidelines. In lieu of outcome-oriented measures, the Federal Government has developed over time a regime of regulatory oversight that has controlled diversion to illegal use, but does little to enhance treatment quality, and at times actually interferes with treatment. There is a substantial body of knowledge and a rare scientific consensus on both the utility of methadone treatment and its appropriateness for many addicts. This body of clinical knowledge -- rather than the current regulatory maze -- should form the basis for clinical oversight and broader employment of methadone treatment.

Bringing existing treatment programs into conformance with established science will, at a minimum, require comprehensive technical assistance. And funding assistance might well be needed for programs to be able to meet the costs of the accreditation process and meet accreditation standards.

(4) Stigmatization of Addiction and Methadone Treatment: Some critics have called methadone treatment simply a way to keep people addicted, simply the substitution of one addiction for another. But methadone treatment is not simply a substitute for heroin. As noted by scholars such as Avram Goldstein, methadone's totally different pharmacokinetics make it a very different drug. While both heroin and methadone can occupy the mu opioid receptors in the brain, the steady, stable occupancy by methadone contrasts sharply with the repeated, excessive "highs" followed by excessive "lows" with heroin. This continuous receptor occupancy is the stabilizing factor that permits addicts on methadone to normalize their behavior and to discontinue heroin use. It diminishes the craving for heroin and, by producing opioid tolerance, blocks the heroin "high." Methadone makes possible the substitution of a stable existence for one of compulsive drug seeking and taking, criminal behavior, chronic unemployment, and high risk sexual and drug use behaviors.

"Drug-free" treatment (i.e., treatment with no pharmacologic agents) is considered by many to be preferable to methadone. (And it should be noted that evaluations of residential programs, although fewer in number, yield essentially similar results.) Some who prefer drug-free treatment reject the use of methadone entirely and others would set specific time limits on its use (e.g., six months). The problem with these strident approaches is that they fail to recognize the changes in brain structure that accompany, and might in certain cases precede, addiction. Medical technology has enabled scientists to observe the changes in the addicted brain, specifically the damage to the reward pathway that spurs compulsive use and the sick feeling that

accompanies withdrawal. And while it is clear that addiction is a disease of the brain, more research is needed to distinguish those addicts who may have had a damaged brain reward pathway from birth, thus being predisposed to addiction, from those who have damaged their brain reward pathway through drug use. Furthermore, research will be required to distinguish brain changes that can be reversed from those that appear permanent. The decision to administer methadone and the duration of its use are clinical matters that should be informed by a science-based assessment of each patient's requirements.

B. Understanding the Role of Drug Treatment: The contributions of drug treatment in general and methadone treatment in particular are not universally understood or accepted. Drug treatment is sometimes characterized as another form of welfare, as "something for nothing," when it is actually very demanding for participants and the single most cost effective policy option for reducing the consumption of drugs and the commission of drug-related crimes. Indeed, from a public policy perspective, drug treatment is not solely, or even primarily, a service for the benefit of the drug-dependent. Although addicts clearly benefit with the acceptance of personal accountability, it is public safety, public health, and the public purse that are the primary beneficiaries of drug treatment. And they suffer when treatment is withheld or poorly delivered.

The Institute of Medicine of the National Academy of Sciences found in 1995 that a reduction in existing regulations could be accomplished without negative impact on health or safety standards. A 1997 consensus development conference, convened by the National Institutes of Health (NIH), strongly recommended broader availability of methadone treatment programs for people who are addicted to heroin or other opiate drugs and assessed as likely to benefit from agonist treatment. The NIH conference called for the elimination of Federal and State regulations and other barriers that improperly impede access. And a 1998 GAO review of the science identified methadone as the most effective treatment (to date) for heroin addiction. The conclusions of these prestigious bodies join the overwhelming scientific evidence supporting the expansion of methadone treatment within the overall context of an expansion of drug abuse treatment.

5. OUTCOMES: Methadone treatment is a lynchpin of modern opiate addiction treatment. It must be more widely available to those who need it and it must be conducted in a way that ensures quality and inspires public confidence.

Effective methadone treatment is an essential contributor to the attainment of the Performance Measures of Effectiveness established for the *National Drug Control Strategy*. This is most directly the case regarding Impact Targets for Goal 3, Reduce health and social costs to the public of illegal drug use:

- Reduce the health and social costs associated with illegal drugs by 10 percent by 2002, and by 25 percent by 2007, and

- Reduce the number of chronic drug users by 20 percent by 2002, and by 50 percent by 2007.

A. DESIRED END STATE:

(1) A comprehensive system of treatment oversight and delivery, guided by continuous assessment to ensure appropriate initial placement, appropriate retention, and movement to other modalities as necessary.

(2) A national cadre of well-trained health professionals, skilled in treating and managing addiction.

(3) Adequate treatment capacity for all who need and are willing to accept drug treatment.

(4) Adequate methadone treatment capacity for all of America's opiate drug addicts for whom it is indicated by appropriate assessment.

(5) Well-run programs with sufficient capacity, and ancillary services, to accommodate:

- state-of-the-art detoxification services;
- those who need long-term maintenance;
- those who can benefit from short-term methadone treatment, while receiving appropriate rehabilitation services to increase the likelihood they can remain abstinent after detoxification.

(6) A comprehensive evaluation and accreditation system to continue to ensure the effectiveness of methadone treatment.

- programs should be held accountable for, and required to monitor, participant cessation of alcohol and other drug use, engagement in productive employment, and cessation of criminal activity.

B. INTERMEDIATE BENCHMARKS:

(1) Increased public and, especially, medical community understanding of the efficacy of methadone treatment for those for whom it is indicated by appropriate assessment.

(2) Development of rational rules governing access to methadone treatment, allowing such treatment, where clinically warranted, in the offices of trained and accredited physicians.

- Both certification by a nationally recognized professional organization, and successful completion of a specific training program on issues pertinent to opioid maintenance therapies, should be required for primary care physicians to provide office-based narcotic addiction treatment.
- Physicians in private practice who prescribe methadone for stabilized addicts should make provision for simultaneous treatment of substance abuse disorders and physical and psychiatric comorbidity, and for other community services and self-help.
- Methadone treatment programs should function as hub referral sites.

(3) Development and utilization of a field-tested and proven system for accrediting methadone treatment programs with transfer of regulatory oversight from FDA to SAMHSA.

C. IMMEDIATE ACTIONS:

- (1) Testing and evaluation of newly developed accreditation standards.
 - Accreditation standards should be adopted only after a demonstration of their successful application.
- (2) SAMHSA and FDA provision of technical assistance to programs, and continuing communication with Federal, state, and local government authorities, to facilitate a thorough demonstration and evaluation.
- (3) Active ONDCP oversight of the demonstration and evaluation process, and subsequent action plan, to be accomplished through the Interagency Narcotic Treatment Policy Review Board
- (4) Discussion of the role of both short- and long-term methadone treatment and of alternative strategies for expanding treatment capacity for opiate drug addicts in the drug treatment and medical communities.
- (5) A clear delineation and distinction of the roles and authorities of SAMHSA/CSAT and DEA.
- (6) Active ONDCP oversight of the development of educational standards in addictions for health professionals, to be accomplished through the Interagency Narcotic Treatment Policy Review Board.

6. CONCLUSION: Methadone treatment, in its present state, has been demonstrated to be effective. However, it is not as effective as it can and should be. With increased funding must come increased quality and accountability. Appropriate treatment needs to be based on an assessment of

each individual and development of a regimen best suited to that individual's condition
Comprehensive patient assessment should precede any decision to provide opioid-based therapy
Anti-addiction medication should be prescribed in conjunction with comprehensive treatment
services, such as counseling and needed medical services to diagnose and treat infectious diseases.
And periodic assessment should determine the appropriateness of continuing opioid-based therapy.
To improve quality and access, continuing work is necessary regarding government oversight of
programs, quality assurance in both public and private programs, and the role of private medical
practitioners.