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Subpart A—General Provisions

§ 290.5 Drugs; statement of required warning.

The label of any drug listed as a ''controlled substance'' in schedule II, III, or IV of the Federal Controlled Substances Act shall, when dispensed to or for a patient, contain the following warning: ''Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.'' This statement is not required to appear on the label of a controlled substance dispensed for use in clinical investigations which are ''blind.''

§ 290.6 Spanish-language version of required warning.

By direction of section 305(c) of the Federal Controlled Substances Act, § 290.5, promulgated under section 503(b) of the Federal Food, Drug, and Cosmetic Act, requires the following warning on the label of certain drugs when dispensed to or for a patient: ''Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.'' The Spanish version of this is: ''Precaucion: La ley Federal prohibe el transferir de esta droga a otra persona que no sea el paciente para quien fue recetada.''

§ 290.10 Definition of emergency situation.

For the purposes of authorizing an oral prescription of a controlled substance listed in schedule II of the Federal Controlled Substances Act, the term *emergency situation* means those situations in which the prescribing practitioner determines:

(a) That immediate administration of the controlled substance is necessary, for proper treatment of the intended ultimate user; and

(b) That no appropriate alternative treatment is available, including administration of a drug which is not a controlled substance under schedule II of the Act, and

(c) That it is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the person dispensing the substance, prior to the dispensing.

Subpart B [Reserved]

Subpart C—Requirements for Specific Controlled Drugs [Reserved]

PART 291—DRUGS USED FOR TREATMENT OF NARCOTIC ADDICTS

Sec.

291.501 Narcotic drugs in the maintenance treatment of narcotic addicts.
291.505 Conditions for the use of narcotic drugs; appropriate methods of professional practice for medical treatment of the narcotic addiction of various classes of narcotic addicts under section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970.

AUTHORITY: 21 U.S.C. 355, 371, 823; 42 U.S.C. 241(d), 257a, 290ee–3, 300y–11.

§ 291.501 Narcotic drugs in the maintenance treatment of narcotic addicts.

(a) The Food and Drug Administration, the National Institute on Drug Abuse, and the Drug Enforcement Administration, Department of Justice, recognize that the use of narcotic drugs in the prolonged maintenance of narcotic dependence has been shown to be an effective part of a total treatment effort in the management and rehabilitation of selected narcotic addicts. It is also recognized that a number of dangers and possible abuses may arise from such efforts if professional services and controls are inadequately applied.

(b) Therefore, the Commissioner of Food and Drugs, the Director of the National Institute on Drug Abuse, and the Administrator of the Drug Enforcement Administration, Department of Justice, agree that interested professionals, municipalities, and organizations should be allowed to use narcotic drugs in the medical treatment of narcotic addiction within a framework of adequate controls designed to protect the individual patients and the community. Narcotic drugs that are to be used as part of the treatment of narcotic addiction must have an approved new drug application for such use. To facilitate this purpose, the Food and Drug Administration, the National Institute

on Drug Abuse, and the Drug Enforcement Administration, Department of Justice, have jointly agreed upon acceptable conditions for the use of narcotic drugs in a treatment program, which are set forth in § 291.505. In addition, such other provisions of the Federal narcotic laws and regulations as are applicable must also be observed.

[58 FR 38709, July 20, 1993]

§ 291.505 Conditions for the use of narcotic drugs; appropriate methods of professional practice for medical treatment of the narcotic addiction of various classes of narcotic addicts under section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970.

(a) *Definitions.* As used in this part:

(1) *Detoxification treatment* means the dispensing of a narcotic drug in decreasing doses to an individual to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period. There are two types of detoxification treatment: short-term detoxification treatment and long-term detoxification treatment.

(i) *Short-term detoxification treatment* is for a period not in excess of 30 days.

(ii) *Long-term detoxification treatment* is for a period more than 30 days but not in excess of 180 days.

(2) *Maintenance treatment* means the dispensing of a narcotic drug, at relatively stable dosage levels, in the treatment of an individual for dependence on heroin or other morphine-like drug. There are two types of maintenance treatment: comprehensive maintenance treatment and interim maintenance treatment.

(i) *Comprehensive maintenance treatment* is maintenance treatment provided in conjunction with a comprehensive range of appropriate medical and rehabilitative services.

(ii) *Interim maintenance treatment* is maintenance treatment provided in conjunction with appropriate medical services while a patient is awaiting transfer to comprehensive maintenance treatment.

(3) A *medical director* is a physician, licensed to practice medicine in the jurisdiction in which the program is located, who assumes responsibility for the administration of all medical services performed by the narcotic treatment program including ensuring that the program is in compliance with all Federal, State, and local laws and regulations regarding the medical treatment of narcotic addiction with a narcotic drug.

(4) A *medication unit* is a facility established as part of, but geographically dispersed, i.e., separate from a narcotic treatment program from which licensed private practitioners and community pharmacists—

(i) Are permitted to administer and dispense a narcotic drug, and

(ii) Are authorized to collect samples for drug testing or analysis for narcotic drugs.

(5) *Narcotic dependent* means an individual who physiologically needs heroin or a morphine-like drug to prevent the onset of signs of withdrawal.

(6) A *narcotic treatment program* is an organization (or a person, including a private physician) that administers or dispenses a narcotic drug to a narcotic addict for maintenance or detoxification treatment, provides, when appropriate or necessary, a comprehensive range of medical and rehabilitative services, is approved by the State authority and the Food and Drug Administration, and that is registered with the Drug Enforcement Administration to use a narcotic drug for the treatment of narcotic addiction.

(7) A *program sponsor* is a person (or representative of an organization) who is responsible for the operation of a narcotic treatment program and who assumes responsibility for all its employees including any practitioners, agents, or other persons providing services at the program (including its medication units).

(8) The term *services*, as used in this part, includes medical evaluations, counseling, rehabilitative and other social programs (e.g., vocational and educational guidance, employment placement), which will help the patient become a productive member of society.

(9) A *State authority* is the agency designated by the Governor or other

appropriate official to exercise the responsibility and authority within the State or Territory for governing the treatment of narcotic addiction with a narcotic drug.

(10) The term *HIV disease* means infection with the etiologic agent for acquired immunodeficiency syndrome.

(b) *Organizational structure and approval requirements*—(1) *Organizational structure.* (i) A narcotic treatment program may be an independent organization or part of a centralized organization. For example, if a centralized organizational structure consists of a primary facility and other outpatient facilities, all of which conduct initial evaluation of patients and administer or dispense medication, the primary facility and each outpatient facility are separate programs, even though some services (e.g., the same hospital or rehabilitative services) are shared.

(ii) The program sponsor shall submit to the Food and Drug Administration and the State authority a description of the organizational structure of the program, the name of the persons responsible for the program, the address of the program, and the responsibilities of each facility or medication unit. The sources of funding for each program shall be listed and the name and address of each governmental agency providing funding shall be stated.

(iii) Where two or more programs share a central administration (e.g., a city or State-wide organization), the person responsible for the organization (administrator or program sponsor) is required to be listed as the program sponsor for each separate participating program. An individual program shall indicate its participation in the central organization at the time of its application. The administrator or sponsor may fulfill all recordkeeping and reporting requirements for these programs, but each program must continue to receive separate approval.

(iv) One physician may assume primary medical responsibility for more than one program and be listed as medical director. If a physician assumes medical responsibility for more than one program, a statement documenting the feasibility of the arrangement is required to be attached to the application.

(v) *Interim maintenance treatment.* A public or nonprofit private narcotic treatment program may provide interim maintenance treatment only if the program also provides comprehensive maintenance treatment to which interim maintenance treatment patients may be transferred.

(2)(i) *Program approval.* Before a narcotic treatment program may be lawfully operated, the program, whether an outpatient facility or a private practitioner, shall submit the applications specified in this section simultaneously to the Food and Drug Administration and the State authority and must receive the approval of both, except as provided for in paragraph (h)(5) of this section. Before granting approval, the Food and Drug Administration will consult with the Drug Enforcement Administration, Department of Justice, to ascertain if the program is in compliance with Federal controlled substances laws. Each physical location within any program is required to be identified and listed in the approval application. At the time of application for approval, the program sponsor shall indicate whether medication will be administered or dispensed at the facility. Before medication may be administered or dispensed at a location not previously approved for this purpose, the program is required to obtain approval from FDA and the State agency. However, no approval is necessary, but notification is required when a facility in which medication is administered or dispensed is deleted by a program. In that event, the program shall notify the Food and Drug Administration and the State authority within three weeks of the deletion. Similarly, addition or deletion of facilities which provide services other than administering or dispensing medication is also permitted without approval, but notification must be made within 3 weeks to the Food and Drug Administration and the State authority about the addition and/or deletion.

(ii) *Exemption of Federal programs.* The provisions of this section requiring approval (or permitting disapproval or revocation of approval) by the State authority, 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.

(iii) *Services.* Each narcotic treatment program shall provide medical and rehabilitative services and programs. (See paragraph (d)(4) of this section.) These services should normally be made available at the primary facility, but the program sponsor may enter into a formal documented agreement with private or public agencies, organizations, or institutions for these services if they are available elsewhere. The program sponsor, in any event, must be able to document that medical and rehabilitative services are fully available to patients.

(iv) *Prohibition against unapproved use of narcotic drugs.* No prescribing, administering, or dispensing of a narcotic drug for the treatment of narcotic addiction may occur without prior approval by the Food and Drug Administration and the State authority, except as provided for in paragraph (h)(5) of this section, unless specifically exempted by this section.

(v) *Approved narcotic drugs for use in treatment programs.* The following narcotic drugs have been approved for use in the treatment of narcotic addiction: Methadone and Levo-*Alpha*-Acetyl-Methadol (LAAM).

(vi) *Interim maintenance treatment program approval.* Before a public or nonprofit private narcotic treatment program may provide interim maintenance treatment, the program must receive approval of both the Food and Drug Administration and the chief public health officer of the State. Before such approval is granted, the program must provide the Food and Drug Administration with certification from the chief public health officer of the State that:

(A) Such officer does not object to the authorization of programs providing interim maintenance treatment in the State and that programs seeking such authorization are 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;

(B) The authorization of programs providing interim maintenance treatment in the State will not reduce the capacity of comprehensive programs in the State to admit individuals to these programs (relative to the date on which such officer so certifies);

(C) The State guarantees that individuals enrolled in interim maintenance treatment will be transferred to comprehensive programs not later than 120 days, as provided by section 1923 of the Public Health Service Act (the PHS Act) and applicable regulations; and

(D) Requests for authorization should be submitted to the address specified in paragraph (l) of this section.

(3)(i) *Medication unit.* A program may establish a medication unit to facilitate the needs of patients who are stabilized on an optimal dosage level. To lawfully operate a medication unit, the program shall, for each separate unit, obtain approval from the Food and Drug Administration, the Drug Enforcement Administration, and the State authority, except as provided for in paragraph (h)(5) of this section. The Food and Drug Administration, in determining whether to approve a medication unit, will consider the distribution of units within a particular geographic area. Any new medication unit is required to receive approval before it may lawfully commence operation.

(ii) *Revocation of approval.* If the Food and Drug Administration revokes the primary program's approval, the approval for any medication unit associated with the program is deemed to be automatically revoked. The Food and Drug Administration's revocation of the approval of a particular medication unit, will not, in and of itself, affect the approval of the primary program.

(iii) *Narcotic drug supply.* A medication unit must receive its supply of the narcotic drug directly from the stocks

of the primary facility. Only persons permitted to administer or dispense the drug or security personnel licensed or otherwise authorized by State law to do so may deliver the drug to a medication unit.

(iv) *Referral.* (A) The patient shall be stabilized at his or her optimal dosage level before he or she may be referred to a medication unit.

(B) Since the medication unit does not provide a range of services, the program sponsor shall determine that the patient to be referred is not in need of frequent counseling, rehabilitative, and other services which are only available at the primary program facility.

(v) *Services.* A medication unit is limited to administering or dispensing a narcotic drug and collecting samples for drug testing or analysis for narcotic drugs in accordance with paragraph (d)(2) of this section. If a private practitioner wishes to provide other services besides administering or dispensing a narcotic drug and collecting samples for drug testing or analysis for narcotic drugs, he or she must submit an application for separate approval.

(vi) *Responsibility for patient.* After a patient is referred to a medication unit, the program sponsor retains continuing responsibility for the patient's care. The program sponsor shall ensure that the patient receives needed medical and rehabilitative services at the primary facility.

(c) *Conditions for approval of the use of a narcotic drug in a treatment program*—(1) *Applicants.* An individual listed as program sponsor for a treatment program using a narcotic drug need not personally be a licensed practitioner but shall employ a licensed physician for the position of medical director. Persons responsible for administering or dispensing the narcotic drug shall be practitioners as defined by section 102(21) of the Controlled Substances Act (21 U.S.C. 802(21)) and licensed to practice by the State in which the program is to be established.

(2)(i) *Assent to regulation.* A person who sponsors a narcotic treatment program, and any persons responsible for a particular program, shall agree to adhere to all the rules, directives, and procedures, set forth in this section, and any regulation regarding the use of narcotic drugs in the treatment of narcotic addiction which may be promulgated in the future. The program sponsor has responsibility for all personnel and individuals providing services, who work in the program at the primary facility or at other facilities or medication units. The program sponsors shall agree to inform all personnel and individuals providing services of the provisions of this section and to monitor their activities to assure compliance with the provisions.

(ii) The Food and Drug Administration and the State authority are required to be notified within 3 weeks of any replacement of the program sponsor or medical director. Activities in violation of this regulation may give rise to the sanctions set forth in paragraph (i) of this section.

(3) *Description of facilities.* Only program site(s) approved by Federal, State, and local authorities may treat narcotic addicts with a narcotic drug. To obtain program approval, the applicant shall demonstrate that he or she will have access to adequate physical facilities to provide all necessary services. A program must have ready access to a comprehensive range of medical and rehabilitative services so that the services may be provided when necessary. The name, address, and description of each hospital, institution, clinical laboratory, or other facility available to provide the necessary services are required to be included in the application submitted to the Food and Drug Administration and the State authority. The application is also required to include the name and address of each medication unit.

(4) *Submission of proper applications.* The following applications shall be filed simultaneously with both the Food and Drug Administration and the State authority:

(i) *Form FDA–2632 ''Application for Approval of Use of Narcotic Drugs in a Treatment Program.''* This form, required by paragraph (l) of this section, shall be completed and signed by the program sponsor and submitted in duplicate to the Food and Drug Administration and the State authority.

(ii) *Form FDA–2633 ''Medical Responsibility Statement for Use of Narcotic Drugs*

in a Treatment Program.'' This form, required by paragraph (l) of this section, shall be completed and signed by each licensed physician authorized to administer or dispense narcotic drugs and submitted in duplicate to the Food and Drug Administration and the State authority. The names of any other persons licensed by law to administer or dispense narcotic drugs working in the program shall be listed even if they are not responsible for administering or dispensing the drug at the time the application is submitted.

(5) *State and Federal approval, denial, and revocation of approval of narcotic treatment programs.* (i) The Food and Drug Administration may grant approval to a program only after FDA has received notification from both the State authority and the Drug Enforcement Administration that the program conforms to all pertinent State and Federal requirements.

(ii) The Food and Drug Administration will revoke the approval of a narcotic treatment program if so requested by the State authority or the Drug Enforcement Administration. If approval of a program is denied or revoked, the program shall have a right to appeal to the Commissioner, as provided for in paragraph (h)(5) of this section.

(iii) No shipment of a narcotic drug may lawfully be made to any program which does not have current approval from the Food and Drug Administration. Within 60 days after receipt of the application from the program sponsor for approval, the Food and Drug Administration will notify the sponsor whether the application is approved or denied.

(d)(1) *Minimum standards for admission*—(i) *History of addiction and current physiologic dependence.* (A) A person may be admitted as a patient for a comprehensive maintenance program only if a program physician determines that the person is currently physiologically dependent upon a narcotic drug and became physiologically dependent at least 1 year before admission for comprehensive maintenance treatment. A 1-year history of addiction means that an applicant for admission to a comprehensive maintenance program was physiologically addicted to a narcotic at a time at least 1 year before admission to a program and was addicted, continuously or episodically, for most of the year immediately before admission to a program. In the case of a person for whom the exact date on which physiological addiction began cannot be ascertained, the admitting program physician may, in his or her reasonable clinical judgment, admit the person to comprehensive maintenance treatment, if from the evidence presented, observed, and recorded in the patient's record, it is reasonable to conclude that there was physiologic dependence at a time approximately 1 year before admission.

(B) Although daily use of a narcotic for an entire year could satisfy the regulatory definition of a 1-year history of addiction, operationally one might be physiologically dependent without daily use during the entire 1-year period and still satisfy the definition. The following, although not exhaustive, are examples of applicants who would meet the minimum standard of a 1-year history of addiction and who, if currently physiologically dependent on the date of application for admission, would be eligible for admission to a comprehensive maintenance program:

(*1*) Physiologic addiction began in August 1987 and continued to the date of application for admission in August 1988.

(*2*) Physiologic addiction began in January 1988 and continued until April 1988. Physiologic addiction began again in July 1988 and continued until the application for admission in January 1989.

(*3*) Physiologic addiction began in January 1987 and continued until October 1987. The date of application for admission was January 1988, at which time the patient had been readdicted for 1 month preceding his or her admission.

(*4*) Physiologic addiction consisted of four episodes in the last year, each episode lasting 2½ months.

(C) The program physician or an appropriately trained staff member designated and supervised by the physician shall record in the patient's record the criteria used to determine the patient's current physiologic dependence and history of addiction. In the latter

circumstance, the program physician shall review, date, and countersign the supervised staff member's evaluation to demonstrate his or her agreement with the evaluation. The program physician shall make the final determination concerning a patient's physiologic dependence and history of addiction. The program physician shall sign, date, and record a statement that he or she has reviewed all the documented evidence to support a 1-year history of addiction and the current physiologic dependence and that in his or her reasonable clinical judgment the patient fulfills the requirements for admission to comprehensive maintenance treatment. The program physician shall complete and record the statement before the program administers any narcotic drug to the patient.

(ii) *Voluntary participation, informed consent.* The person responsible for the program shall ensure that: A patient voluntarily chooses to participate in a program; all relevant facts concerning the use of the narcotic drug used by the program are clearly and adequately explained to the patient; all patients, with full knowledge and understanding of its contents, sign the ''Consent to Treatment with an Approved Narcotic Drug'' Form FDA–2635 (see paragraph (l) of this section); a parent, legal guardian, or responsible adult designated by the State authority (e.g., ''emancipated minor'' laws) sign for patients under the age of 18 the second part of Form FDA–2635 ''Consent to Treatment with an Approved Narcotic Drug.''

(iii) *Exceptions to minimum admission criteria*—(A) *Penal or chronic care.* A person who has resided in a penal or chronic care institution for 1 month or longer may be admitted to comprehensive maintenance treatment within 14 days before release or discharge, or within 6 months after release from such an institution without documented evidence to support findings of physiological dependence, provided the person would have been eligible for admission before he or she was incarcerated or institutionalized and, in the reasonable clinical judgment of a program physician, treatment is medically justified. Documented evidence of the prior residence in a penal or chronic care institution and evidence of all other findings and the criteria used to determine the findings are required to be recorded in the patient's record by the admitting program physician, or by program personnel supervised by the admitting program physician. The admitting program physician shall date and sign these recordings or review the health-care professional's recordings before the initial dose is administered to the patient. In the latter case, the admitting program physician shall date and sign the recordings in the patient's record made by the health-care professional within 72 hours of administration of the initial dose to the patient.

(B) *Pregnant patients.* (*1*) Pregnant patients, regardless of age, who have had a documented narcotic dependency in the past and who may return to narcotic dependency, with all its attendant dangers during pregnancy, may be placed on a comprehensive maintenance regimen, except as provided in paragraph (d)(1)(iii)(B)(*6*) of this section. For such patients, evidence of current physiological dependence on narcotic drugs is not needed if a program physician certifies the pregnancy and, in his or her reasonable clinical judgment, finds treatment to be medically justified. Evidence of all findings and the criteria used to determine the findings are required to be recorded in the patient's record by the admitting program physician, or by program personnel supervised by the admitting program physician. The admitting program physician shall date and sign these recordings or review the health-care professional's recordings before the initial dose is administered to the patient. In the latter case, the admitting program physician shall date and sign the recordings in the patient's record made by the health-care professional within 72 hours of administration of the initial dose to the patient. Pregnant patients are required to be given the opportunity for prenatal care either by the program or by referral to appropriate health-care providers.

(*2*) If a program cannot provide direct prenatal care for pregnant patients in treatment, the program shall establish a system for informing the patients of

the publicly or privately funded prenatal care opportunities available. If there are no publicly funded prenatal referral opportunities and the program cannot provide such services or the patient cannot afford them or refuses them, then the treatment program shall, at a minimum, offer her basic prenatal instruction on maternal, physical, and dietary care as part of its counseling service.

(*3*) Counseling records and/or other appropriate patient records are required to reflect the nature of prenatal support provided by the program. If the patient is referred for prenatal services, the physician to whom she is referred is required to be notified that she is in comprehensive maintenance treatment, provided that notification is in accordance with the Department of Health and Human Services' confidentiality regulations (42 CFR part 2). If a pregnant patient refuses direct treatment or appropriate referral for treatment, the treating program physician should consider using informed consent procedures; e.g., to have the patient acknowledge in writing that she had the opportunity for this treatment but refuses it. The program physician, consistent with the confidentiality regulations, shall request the physician or the hospital to which a patient is referred to provide, following birth, a summary of the delivery and treatment outcome for the patient and offspring. If the program physician does not receive a response to the request, he or she shall document in the record that such a request was made.

(*4*) Within 3 months after termination of pregnancy, the program physician shall enter an evaluation of the patient's treatment state into her record and state whether she should remain in the comprehensive maintenance program or be detoxified.

(*5*) Caution should be taken in the comprehensive maintenance treatment of pregnant patients. Dosage levels should be maintained at the lowest effective dose if treatment is deemed necessary. The program sponsor shall ensure that each female patient is fully informed of the possible risks to her or to her unborn child from continued use of illicit drugs and from the use of, or withdrawal from, a narcotic drug administered or dispensed by the program in comprehensive maintenance or detoxification treatment.

(*6*) Patients who are or become pregnant shall not be started or continued on LAAM, except by the written order of a physician who determines this to be the best choice of therapy for that patient. Clinics providing treatment with LAAM must advise all patients of childbearing potential of the risks of LAAM and make a medical evaluation available to all patients who become pregnant while taking the drug. An initial pregnancy test shall be performed for each prospective female patient of childbearing potential before admission to LAAM comprehensive maintenance treatment and monthly pregnancy tests performed thereafter on such female patients in LAAM comprehensive maintenance treatment. Analysis of such tests shall be performed in a laboratory approved under the Clinical Laboratory Improvement Amendments of 1988 or in a laboratory certified by a State or private accrediting body approved by the Health Care Financing Administration.

(C) *Previously treated patients.* Under certain circumstances a patient who has been treated and later voluntarily detoxified from comprehensive maintenance treatment may be readmitted to maintenance treatment, without evidence to support findings of current physiologic dependence, up to 2 years after discharge, if the program attended is able to document prior narcotic drug comprehensive maintenance treatment of 6 months or more, and the admitting program physician, in his or her reasonable clinical judgment, finds readmission to comprehensive maintenance treatment to be medically justified. For patients meeting these criteria, the quantity of take-home medication, if take-home medication is permitted for the narcotic drug, will be determined in the reasonable clinical judgment of the program physician, but in no case may the quantity of take-home medication be greater than would have been allowed at the time the patient voluntarily terminated previous treatment. The admitting program physician or a program employee

under supervision of the admitting program physician must enter in the patient's record documented evidence of the patient's prior treatment and evidence of all decisions and criteria used relating to the admission of the patient and the quantity of take-home medication permitted. The admitting program physician shall date and sign these entries in the patient's record or review the health-care professional's entries therein before the program administers any medication to the patient. In the latter case, the admitting program physician shall date and sign the entries in the patient's record made by the health-care professional within 72 hours of administration of the initial dose to the patient.

(iv) *Special limitation; treatment of patients under 18 years of age.* (A) 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, except as provided in paragraph (d)(1)(iv)(B) of this section. A 1-week waiting period is required after such a detoxification attempt, however, before an attempt is repeated. The program physician shall document in the patient's record that the patient continues to be or is again physiologically dependent on narcotic drugs. No person under 18 years of age may be admitted to a maintenance treatment program unless a parent, legal guardian, or responsible adult designated by the State authority (e.g., ''emancipated minor'' laws) completes and signs consent form, Form FDA–2635 ''Consent to Treatment with an Approved Narcotic Drug.''

(B) A person under 18 years of age shall not be admitted to LAAM maintenance treatment.

(v) *Denial of admission.* If in the reasonable clinical judgment of the medical director a particular patient would not benefit from treatment with a narcotic drug, the patient may be refused such treatment even if the patient meets the admission standards.

(2) *Minimum testing or analysis for drugs: Uses and frequency.* (i) The person(s) responsible for a program shall ensure that: An initial drug-screening test or analysis is completed for each prospective patient; at least eight additional random tests or analyses are performed on each patient during the first year in comprehensive maintenance treatment; and at least quarterly random tests or analyses are performed on each patient in comprehensive maintenance treatment for each subsequent year, except that a random test or analysis is performed monthly on each patient who receives a 6-day supply of take-home medication. When a sample is collected from each patient for such test or analysis, it must be done in a manner that minimizes opportunity for falsification. Each test or analysis must be analyzed for opiates, methadone, amphetamines, cocaine, and barbiturates. In addition, if any other drug or drugs have been determined by a program to be abused in that program's locality, or as otherwise indicated, each test or analysis must be analyzed for any of those drugs as well. Any laboratory that performs the testing required under this regulation shall be in compliance with all applicable Federal proficiency testing and licensing standards and all applicable State standards. If a program proposes to change a laboratory used for such testing or analysis, the program shall have the change approved by the Food and Drug Administration.

(ii) The person responsible for a program shall ensure that test results are not used as the sole criterion to force a patient out of treatment but are used as a guide to change treatment approaches. The person responsible for a program shall also ensure that when test results are used, presumptive laboratory results are distinguished from results that are definitive.

(3) *Patient evaluation; minimum admission and periodic requirements*—(i) *Minimum contents of medical evaluation.* Each patient is required to have a medical evaluation by a program physician or an authorized health-care professional under the supervision of a program physician on admission to a program. At a minimum, this evaluation is required to consist of a medical history which includes the required history of narcotic dependence, evidence of current physiologic dependence unless excepted by the regulations, and a physical examination, and includes the

following laboratory examinations: serological test for syphilis, a tuberculin skin test, and a test or analysis for drug determination. A pregnancy test is required for any woman of childbearing potential before she may be administered LAAM as directed in paragraph (d)(1)(iii)(B)(*1*) of this section. If in the reasonable clinical judgment of the program physician, a patient's subcutaneous veins are severely damaged to the extent that a blood specimen cannot be obtained, the serological test for syphilis may be omitted. The physical examination is required to consist of an investigation of the organ systems for possibilities of infectious disease, pulmonary, liver, and cardiac abnormalities, and dermatologic sequelae of addiction. In addition, the physical examination is required to include a determination of the patient's vital signs (temperature, pulse, and blood pressure and respiratory rate); an examination of the patient's general appearance, head, ears, eyes, nose, throat (thyroid), chest (including heart, lungs, and breasts), abdomen, extremities, skin, and neurological assessment; and the program physician's overall impression of the patient.

(ii) *Recordings of findings.* The admitting program physician or an appropriately trained health care professional supervised by the admitting program physician shall record in the patient's record all findings from the admission medical evaluation. In each case the admitting program physician shall date and sign these entries, or date, review, and countersign these recordings in the patient's record to signify his or her review of and concurrence with the history and physical findings.

(iii) *Admission evaluation.* (A) Each patient seeking admission or readmission for treatment services is required to be interviewed by a well-trained program counselor, qualified by virtue of education, training, or experience to assess the psychological and sociological background of drug abusers, to determine the appropriate treatment plan for the patient. To determine the most appropriate treatment plan for a patient, the interviewer shall obtain and document in the patient's record the patient's history.

(B) A patient's history includes information relating to his or her educational and vocational achievements. If a patient has no such history; i.e., he or she has no formal education or has never had an occupation, this requirement is met by writing this information in the patient's history.

(iv) *Initial treatment plan.* (A)(*1*) The initial treatment plan is required to contain a statement that outlines realistic short-term treatment goals which are mutually acceptable to the patient and the program. The initial treatment plan is also required to spell out the behavioral tasks a patient must perform to complete each short-term goal; 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 plan is also required to identify the frequency with which these services are likely to be provided. Prior to developing a treatment plan, the patient's needs for medical, social, and psychological services; education; vocational rehabilitation; and employment must be assessed, and the needs reflected, when clinically appropriate, in the treatment plan.

(*2*) A primary counselor is one who is assigned by the program to develop, implement, and evaluate the patient's initial and periodic treatment plan and to monitor a patient's progress in treatment. The primary counselor shall enter in the patient's record the counselor's name, the contents of a patient's initial assessment, and the initial treatment plan. The primary counselor shall make these entries immediately after the patient is stabilized on a dose or within 4 weeks after admission, whichever is sooner.

(B) It is recognized that patients need varying degrees of treatment and rehabilitative services which are often dependent on or limited by a number of variables; e.g., patient resources, available program, and community services. It is not the intent of this regulation to prescribe a particular treatment and rehabilitative service or the frequency at which a service should be offered.

(C) The program supervisory counselor or other appropriate program personnel so designated by the program

physician shall review and countersign all the information and findings required to be recorded in each patient's record under paragraph (d)(3)(iv) of this section.

(v) *Periodic treatment plan evaluation.* (A) The program physician or the primary counselor shall review, reevaluate, and alter where necessary each patient's treatment plan at least once each 90 days during the first year of treatment, and then at least twice a year after the first year of continuous treatment.

(B) The program physician shall ensure that the periodic treatment plan becomes part of each patient's record and that it is signed and dated in the patient's record by the primary counselor and is countersigned and dated by the supervisory counselor.

(C) At least once a year, the program physician shall date, review, and countersign the treatment plan recorded in each patient's record and ensure that each patient's progress or lack of progress in achieving the treatment goals is entered in the patient's record by the primary counselor. When appropriate, the treatment plan and progress notes should deal with the patient's mental and physical problems, apart from drug abuse. The treatment plan is required to include the name of and the reasons for prescribing any medication for emotional or physical problems.

(D) The requirement for annual physician review and signature by the program physician in paragraph (d)(3)(v)(C) of this section is discretionary, however, as it applies to a patient who has satisfactorily adhered to program rules for at least 3 consecutive years from his or her entrance into the comprehensive maintenance treatment program and who has made substantial progress in rehabilitation.

(4) *Minimum program services*—(i)(A) *Access to a range of services.* A treatment program shall provide a comprehensive range of medical and rehabilitative services to its patients especially during the first 3 years of treatment.

(B) *Pregnant patients.* (*1*) For pregnant patients in a treatment program who were not admitted under paragraph (d)(1)(iii)(B) of this section, a treatment program shall give them the opportunity for prenatal care either by the narcotic treatment program or by referral to appropriate health care providers. If a program cannot provide direct prenatal care for pregnant patients in treatment, it shall establish a system of referring them for prenatal care which may be either publicly or privately funded. If there is no publicly funded prenatal care available to which a patient may be referred, and the program cannot provide such services, or the patient cannot afford or refuses prenatal care services, then the treatment program shall, at a minimum, offer her basic prenatal instruction on maternal, physical, and dietary care as a part of its counseling service.

(*2*) Counseling records and other appropriate patient records are required to reflect the nature of prenatal support provided by the program. If the program refers a patient for prenatal services, it shall inform the physician to whom she is referred that the patient is in comprehensive maintenance treatment, provided such notification is in accordance with the Department of Health and Human Services' confidentiality regulations (42 CFR part 2). If a pregnant patient refuses direct prenatal services or appropriate referral for prenatal services, the treating program physician should consider using informed consent procedures; i.e., to have the patient acknowledge in writing that she has the opportunity for this treatment but refuses it. The program physician shall request the physician or the hospital to which a patient is referred to provide, following birth, a summary of the delivery and treatment outcome for the patient and offspring. The information should be obtained in accordance with the Department of Health and Human Services' confidentiality regulations (42 CFR part 2). If no response is received, the program physician shall document in the record that such a request was made and no response was received.

(*3*) Caution should be taken in the maintenance treatment of pregnant patients. Dosage levels should be maintained at the lowest effective dose if continued treatment is deemed necessary. It is the responsibility of the program sponsor to ensure that each female patient is fully informed of the

possible risks to a pregnant woman and her unborn child from continued use of illicit drugs and from the use of, or withdrawal from, a narcotic drug administered or dispensed by the program in maintenance or detoxification treatment.

(C) *Counseling on HIV disease.* A narcotic treatment program shall provide counseling on preventing exposure to, and the transmission of, HIV disease for each patient admitted or readmitted to maintenance or detoxification treatment. Although HIV testing is not required, an interim program shall inform patients of the availability of HIV testing. The program sponsor shall also ensure that HIV testing is accessible to patients who request such testing either on site or by the programs entering into agreements with HIV testing facilities to make HIV testing accessible to those patients who request it.

(D) *Off-site services.* Any service not furnished at the primary facility is required to be listed in any application for approval submitted to the Food and Drug Administration or to the State authority. The addition, modification, or deletion of any program service is required to be reported immediately to the Food and Drug Administration.

(ii) *Minimum medical services; designation of medical director and responsibilities.* Each program shall have a designated medical director who assumes responsibility for administering all medical services performed by the program. The medical director and other authorized program physicians are required to be licensed to practice medicine in the jurisdiction in which the program is located. The medical director is responsible for ensuring that the program is in compliance with all Federal, State, and local laws and regulations regarding medical treatment of narcotic addiction. In addition, the medical director or other authorized physicians shall:

(A) Ensure that evidence of current physiologic dependence, length of history of addiction, or exceptions to criteria for admission are documented in the patient's record before the patient receives the initial dose.

(B) Ensure that a medical evaluation including a medical history has been taken, and physical examination has been done before the patient receives the initial dose (except that in an emergency situation, the initial dose may be given before the physical examination).

(C) Ensure that appropriate laboratory studies have been performed and reviewed.

(D) Sign or countersign all medical orders as required by Federal or State law. (Such medical orders include but are not limited to the initial medication orders and all subsequent medication order changes, all changes in the frequency of take-home medication, and prescribing additional take-home medication for an emergency situation.)

(E) Review and countersign treatment plans at least annually as qualified by paragraph (d)(3)(v)(D) of this section.

(F) Ensure that justification is recorded in the patient's record for reducing the frequency of clinic visits for observed drug ingesting, providing additional take-home medication under exceptional circumstances or when there is physicial disability, or prescribing any medication for physical or emotional problems.

(iii) *Use of health-care professionals.* Although the final decision to accept a patient for treatment may be made only by the medical director or other designated program physician, it is recognized that physicians can train program personnel to detect and document narcotic abstinence symptons and that some jurisdictions allow State-licensed or certified health-care professionals; e.g., physician's assistants, nurse practitioners, to perform certain functions—record medical histories, perform physicial examinations, and prescribe, administer, or dispense certain medications—that are ordinarily performed by a licensed physician. These regulations do not prohibit licensed or certified health-care professionals from performing those functions in narcotic treatment programs if it is authorized by Federal, State, and local laws and regulations, and if those functions are delegated to them by the medical director, and records are properly countersigned by the medical director or a licensed physician.

(iv) *Vocational rehabilitation, education, and employment.* Each program shall provide opportunities directly, or through referral to community resources, for patients who either desire or have been deemed by the program staff to be ready to participate in educational job training programs or to obtain gainful employment as soon as possible.

(v) *Authorized dispensers of narcotic drugs; responsibility.* A narcotic drug may be administered or dispensed only by a practitioner licensed under the appropriate State law and registered under the appropriate State and Federal laws to order narcotic drugs for patients, or by an agent of such a practitioner, supervised by and under the order of the practitioner. This agent is required to be a pharmacist, registered nurse, or licensed practical nurse, or any other health care professional authorized by Federal and State law to administer or dispense narcotic drugs. The licensed practitioner assumes responsibility for the amounts of narcotic drugs administered or dispensed and shall record and countersign all changes in dosage schedule.

(5) *Staffing patterns*—(i) *Program personnel.* The person(s) responsible for a program shall determine program personnel requirements after considering the number of patients who are vocationally and educationally impaired; the number of patients with significant psychopathology; the number of patients who are also nonnarcotic drug or alcohol abusers; the number of patients with behavioral problems in the program; and the number of patients with serious medical problems.

(ii) *Supportive services.* The person(s) responsible for the program shall take notice, when considering the staffing pattern, that comprehensive maintenance treatment programs need to establish supportive services in accordance with the varying characteristics and needs of their patient populations. The person(s) responsible for a program shall also take notice of the availability of existing community resources which may complement or enhance the program's delivery of supportive services and then establish a staffing pattern based on a combination of patient needs and available, accessible community resources.

(6) *Use of methadone in a treatment program; frequency of attendance; quantity of take–home medication; dosage of methadone; initial and stabilization*—(i) *Dosage and responsibility.* (A) The person(s) responsible for the program shall ensure that the initial dose of methadone does not exceed 30 milligrams and that the total dose for the first day does not exceed 40 milligrams, unless the program medical director documents in the patient's record that 40 milligrams did not suppress opiate abstinence symptoms.

(B) A licensed physician shall assume responsibility for the amount of the narcotic drug administered or dispensed and shall record, date, and sign in each patient's record each change in the dosage schedule.

(C) The administering licensed physician shall ensure that a daily dose greater than 100 milligrams is justified in the patient's record.

(ii) [Reserved]

(iii) *Form.* Methadone may be administered or dispensed in oral form only when used in a treatment program. Hospitalized patients under care for a medical or surgical condition are permitted to receive methadone in parenteral form when the attending physician judges it advisable. Although tablet, syrup concentrate, or other formulations may be distributed to the program, all oral medication is required to be administered or dispensed in a liquid formulation. The oral dosage form is required to be formulated in such a way as to reduce its potential for parenteral abuse. Take-home medication is required to be labeled with the treatment center's name, address, and telephone number and must be packaged in special packaging as required by 16 CFR 1700.14 in accordance with the Poison Prevention Packaging Act (Pub. L. 91–601, 15 U.S.C. 1471 *et seq.*) to reduce the chances of accidental ingestion. Exceptions may be granted when these provisions conflict with State law with regard to the administering or dispensing of drugs.

(iv) *Take-home medication.* (A) Take-home medication may be given only to

a patient who, in the reasonable clinical judgment of the program physician, is responsible in handling narcotic drugs. Before the program physician reduces the frequency of a patient's clinical visits, she or he or a designated staff member shall record the rationale for the decision in the patient's clinical record. If this is done by a designated staff member, a program physician shall review, countersign, and date the patient's record where this information is recorded.

(B) The program physician shall consider the following in determining whether, in his or her reasonable clinical judgment, a patient is responsible in handling narcotic drugs:

(*1*) Absence of recent abuse of drugs (narcotic or nonnarcotic), including alcohol;

(*2*) Regularity of clinic attendance;

(*3*) Absence of serious behavioral problems at the clinic;

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

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

(*6*) Length of time in comprehensive maintenance treatment;

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

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

(v) *Take-home requirements.* The requirement of time in treatment is a minimum reference point after which a patient may be eligible for take-home privileges. The time reference is not intended to mean that a patient in treatment for a particular time has a specific right to take-home medication. Thus, regardless of time in treatment, a program physician may, in his or her reasonable judgment, deny or rescind the take-home medication privileges of a patient.

(A)(*1*) In comprehensive maintenance treatment it is required that a patient come to the clinic for observation daily or at least 6 days a week. If, in the reasonable clinical judgment of the program physician, a patient demonstrates that he or she has satisfactorily adhered to program rules for at least 3 months, has made substantial progress in rehabilitation and responsibility in handling narcotic drugs (see paragraphs (d)(6)(iv)(B) (*1*) through (*8*) of this section, and would improve his or her rehabilitative progress by decreasing the frequency of attendance at the clinic for observation, the patient may be permitted to reduce his or her attendance at the clinic for observation to three times weekly. The patient may receive no more than a 2-day take-home supply of medication.

(*2*) If, in the reasonable clinical judgment of the program physician, a patient demonstrates that he or she has satisfactorily ahered to program rules for at least 2 years from his or her entrance into the program, has made substantial progress in rehabilitation and responsibility in handling narcotic drugs (see paragraphs (d)(6)(iv)(B) (*1*) through (*8*) of this section), and would improve his or her rehabilitative progress by decreasing the frequency of attendance at the clinic for observation, the patient may be permitted to reduce his or her clinic attendance at the clinic for observation to twice weekly. Such a patient may receive no more than a 3-day take-home supply of medication.

(*3*) If, in the reasonable clinical judgment of the program physician, a patient demonstrates that he or she has satisfactorily adhered to program rules for at least 3 consecutive years from his or her entrance into the comprehensive maintenance treatment program, has made substantial progress in rehabilitation, has no major behavioral problems, is responsible in handling narcotic drugs (see paragraphs (d)(6)(iv)(B) (*1*) through (*8*) of this section), and would improve his or her rehabilitative progress by decreasing the frequency of his or her clinic attendance for observation, the patient may be permitted to reduce clinic attendance for observation to once weekly, provided that the following additional criteria are met: The program physician has written into the patient's record an evaluation that the patient is responsible in handling narcotic drugs (paragraphs (d)(6)(iv)(B) (*1*) through (*8*) of this section); the patient is employed (or actively seeking employment), attends school, is a homemaker, or is considered unemployable

for mental or physical reasons by a program physician; the patient is not known to have abused drugs including alcohol in the last year; and the patient is not known to have engaged in criminal activity; e.g., drug dealing, in the last year. A patient permitted to reduce clinic attendance for observation to once weekly may receive no more than a 6-day take-home supply of medication.

(B)(*1*) If a patient, after receiving a supply of take-home medication, is inexcusably absent from or misses a scheduled appointment with a treatment program without authorization from the program staff, the program physician shall increase the frequency of the patient's clinic attendance for drug ingestion under observation. For such a patient, the program physician shall not reduce the frequency of the patient's clinic attendance for drug ingestion under observation until she or he has had at least three consecutive monthly tests or analyses that are neither positive for morphine-like drugs (except from the narcotic drug administered or dispensed by the program) or other drugs of abuse, nor negative for the narcotic drug administered or dispensed by the program, and until she or he is again determined by a program physician to be responsible in handling narcotic drugs (see paragraphs (d)(6)(iv)(B) (*1*) through (*8*) of this section) and to meet criteria in paragraph (d)(6)(v)(A) of this section.

(*2*) If a patient, after receiving a 6-day supply of take-home medication, has a test or analysis which is confirmed to be positive for morphine-like drugs (except for the narcotic drug administered or dispensed by the program) or other drugs of abuse, or negative for the narcotic drug administered or dispensed by the program, the program physician shall place the patient on probation for 3 months. If, during this probation, the patient has a test or analysis either positive for morphine-like drugs (except for the narcotic drug administered or dispensed by the program) or other drugs of abuse, or negative for the narcotic drug administered or dispensed by the program, the program physician shall increase the frequency of the patient's clinic attendance for observation to at least twice weekly. Such a patient may receive no more than a 3-day take-home supply of medication until she or he has had at least three consecutive monthly tests or analyses which are neither positive for morphine-like drugs (except for the narcotic drug administered or dispensed by the program) or other drugs of abuse, nor negative for the narcotic drug administered or dispensed by the program, and the program physician again determines that the patient is responsible in handling narcotic drugs (see paragraphs (d)(6)(iv)(B) (*1*) through (*8*) of this section) and meets the criteria contained in paragraph (d)(6)(v)(A) of this section.

(C) In calculating the number of years of comprehensive maintenance treatment, the period is considered to begin on the first day the medication is administered, or on readmission if a patient has had a continuous absence of 90 days or more. Cumulative time spent by the patient in more than one program is counted toward the number of years of treatment, provided there has not been a continuous absence of 90 days or more.

(D) Each patient whose daily dose is above 100 milligrams is required to be under observation while ingesting the drug at least 6 days per week irrespective of the length of time in treatment, unless the program has received prior approval from the Food and Drug Administration with the concurrence of the State authority.

(vi) *Exceptions to take-home requirements.* If, in the reasonable clinical judgment of the program physician:

(A) A patient is found to have a physical disability which interferes with his or her ability to conform to the applicable mandatory schedule, she or he may be permitted a temporarily or permanently reduced schedule, provided she or he is also found to be responsible in handling narcotic drugs.

(B) A patient, because of exceptional circumstances such as illness, personal or family crises, travel, or other hardship, is unable to conform to the applicable mandatory schedule, she or he may be permitted a temporarily reduced schedule, provided she or he is also found to be responsible in handling narcotic drugs. The rationale for an exception to a mandatory schedule is to

be based on the reasonable clinical judgment of the program physician and shall be recorded in the patient's record by the program physician or by program personnel supervised by the program physician. In the latter situation, the physician shall review, countersign, and date the patient's record where this rationale is recorded. In any event, a patient may not be given more than a 2-week supply of narcotic drugs at one time.

(vii) *Official State holidays.* If a treatment center program is not in operation due to the observance of an official State holiday, patients may be permitted one extra take-home dose per visit and one fewer clinic visit per week to allow patients not to have to attend the clinic on an official State holiday. An official State holiday is a holiday on which most State offices are usually closed and routine State government business is not conducted.

(7) *Minimum standards for interim maintenance treatment.* The person(s) responsible for a program 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. 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 available for inspection 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 (mandatory transfer) and 1927(a) (pregnant patients) of the PHS Act. The program shall notify the State health officer when a patient begins interim treatment, when a patient leaves interim treatment, and before the date of mandatory transfer to a comprehensive program, and shall document such notifications. Programs in States not in compliance with provisions of this regulation risk loss of authorization for interim maintenance. All requirements for comprehensive maintenance treatment apply to interim maintenance treatment with the following exceptions:

(i) The narcotic drug is required to be administered daily under observation;

(ii) Take-home medication is not allowed;

(iii) The initial treatment plan and periodic treatment plan evaluation are not required;

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

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

(vi) The requirements and exceptions in paragraphs (b)(2)(iii) (as apply to rehabilitative services), in paragraphs (b)(3)(iv)(B) and (d)(4)(i)(A) (as apply to rehabilitative services), and in paragraphs (d)(4)(ii)(E), (d)(4)(ii)(F), (d)(4)(iv), (d)(6)(iv), (d)(6)(v), (d)(6)(vi), and (d)(6)(vii) of this section do not apply.

(8) *Minimum standards for short-term detoxification treatment.* (i) For short-term detoxification from narcotic drugs, the narcotic drug is required to be administered by the program physician or by an authorized agent of the physician, supervised by and under the order of the physician. The narcotic drug is required to be administered daily, under close observation, in reducing dosages over a period not to exceed 30 days. All requirements for comprehensive maintenance treatment apply to short-term detoxification treatment with the following exceptions:

(A) Take-home medication is not allowed during short-term detoxification.

(B) A history of 1 year physiologic dependence is not required for admission to short-term detoxification.

(C) Patients who have been determined by the program physician to be currently physiologically narcotic dependent may be placed in short-term

detoxification treatment, regardless of age.

(D) No test or analysis is required except for the initial drug screening test or analysis.

(E) The initial treatment plan and periodic treatment plan evaluation required for comprehensive maintenance patients are not necessary for short-term detoxification patients. However, a primary counselor must be assigned by the program to monitor a patient's progress toward the goal of short-term detoxification and possible drug-free treatment referral.

(F) The requirements of paragraph (d)(4) of this section, except paragraphs (d)(4)(i)(C), (d)(4)(ii)(A) through (d)(4)(ii)(D), and (d)(4)(iii) of this section, do not apply to short-term detoxification treatment.

(ii) A patient is required to wait at least 7 days between concluding a short-term detoxification treatment episode and beginning another. Before a short-term detoxification attempt is repeated, the program physician shall document in the patient's record that the patient continues to be, or is again, physiologically dependent on narcotic drugs. The provisions of these requirements, except as noted in paragraph (d)(8)(i) of this section, apply to both inpatient and ambulatory short-term detoxification treatment.

(iii) Short-term detoxification treatment is not recommended for a pregnant patient.

(9) *Minimum standards for long-term detoxification treatment.* (i) For long-term detoxification from narcotic drugs, the narcotic drug is required to be administered by the program physician or by an authorized agent of the physician, supervised by and under the order of the physician. The narcotic drug is required to be administered on a regimen designed to reach a drug-free state and to make progress in rehabilitation in 180 days or less. All requirements for comprehensive maintenance treatment apply to long-term detoxification treatment with the following exceptions.

(A) In long-term detoxification treatment it is required that the patient be under observation while ingesting the drug daily or at least 6 days a week, for the duration of the long-term detoxification treatment.

(B) A history of 1 year physiologic dependence is not required for admission to long-term detoxification.

(C) The program physician shall document in the patient's record that short-term detoxification is not a sufficiently long enough treatment course to provide the patient with the additional program services he or she deems necessary for the patient's rehabilitation. The program physician shall document this information in the patient's record before long-term detoxification may begin.

(D) Patients who have been determined by the program physician to be currently physiologically dependent on narcotics may be placed in long-term detoxification treatment, regardless of age.

(E) An initial drug screening test or analysis is required for each patient. And at least one additional random test or analysis must be performed monthly on each patient during long-term detoxification.

(F) The initial treatment plan and periodic treatment plan evaluation required for comprehensive maintenance patients are also required for long-term detoxification patients, except that the required periodic treatment plan evaluation is required to occur monthly.

(ii) A patient is required to wait at least 7 days between concluding a long-term treatment episode and beginning another. Before a long-term detoxification attempt is repeated, the program physician shall document in the patient's record that the patient continues to be or is again physicologically dependent on narcotic drugs. The provisions of these requirements apply to both inpatient and ambulatory long-term detoxification treatment.

(iii) Long-term detoxification is not recommended for a pregnant patient.

(10) *Inspections of programs; patient confidentiality.* A program shall allow

inspections by duly authorized employees of the State authority, and in accordance with Federal controlled substances laws and Federal confidentiality laws, by duly authorized employees of the Food and Drug Administration, the Drug Enforcement Administration of the Department of Justice, and the National Institute on Drug Abuse.

(11) *Exemptions from specific program standards.* (i) A program is permitted, at the time of application or any time thereafter, to request exemption from specific program standards. The rationale for an exemption shall be thoroughly documented in an appendix to be submitted with the application or at some later time. The Food and Drug Administration will approve such exemptions of program standards at the time of application, or any time thereafter, with the concurrence of the State authority. An example of a case in which an exemption might be granted would be for a private practitioner who wishes to treat a limited number of patients in a nonmetropolitan area with few physicians and no rehabilitative services geographically accessible and requests exemption from some of the staffing and service standards.

(ii) The Food and Drug Administration has the right to withhold the granting of an exemption requested at the time of application until a program is in actual operation in order to assess if the exemption is necessary. If periodic inspections of the progam reveal that discrepancies or adverse conditions exist, the Food and Drug Administration shall reserve the right to revoke any or all exemptions previously granted.

(12) *Research.* When a program conducts research on human subjects or provides subjects for research, there must be written policies and written review to assure the rights of the patients involved. Appropriate informed consent forms are required to be signed by the patient and to be retained in his or her patient record at the program. All research, development, and related activities which involve human subjects and which are funded by grants from or contracts with the Department of Health and Human Services are required to comply with the Department of Health and Human Services' regulations on the protection of human subjects, 45 CFR part 46, and confidentiality of information, 42 CFR part 2. All investigational research involving human subjects conducted for submission to the Food and Drug Administration must be conducted in compliance with part 312 of this chapter.

(13) *Patient record system*—(i) *Patient care.* The person(s) responsible for a program shall establish a record system to document and monitor patient care. This system is required to comply with all Federal and State reporting requirements relevant to narcotic drugs approved for use in treatment of narcotic addiction. All records are required to be kept confidential and in accordance with all applicable Federal and State regulations regarding confidentiality.

(ii) *Drug dispensing.* The person(s) responsible for a program shall ensure that accurate records traceable to specific patients are maintained showing dates, quantity, and batch or code marks of the drug dispensed. These records must be retained for a period of 3 years from the date of dispensing.

(iii) *Patient's record.* An adequate record must be maintained for each patient. The record is required to contain a copy of the signed consent form(s), the date of each visit, the amount of drug administered or dispensed, the results of each test or analysis for drugs, any significant physical or psychological disability, the type of rehabilitative and counseling efforts employed, an account of the patient's progress, and other relevant aspects of the treatment program. For recordkeeping purposes, if a patient misses appointments for 2 weeks or more without notifying the program, the episode of care is considered terminated and is to be so noted in the patient's record. This does not mean that the patient cannot return for care. If the patient does return for care and is accepted into the program, this is considered a readmission and is to be so noted in the patient's record. This method of recordkeeping helps assure the easy detection of sporadic attendance and decreases the possibility of administering inappropriate doses of narcotic drugs (e.g., the patient who has received no medication

for several days or more and upon return receives the usual stabilization dose). An annual evaluation of the patient's progress must be entered in the patient's record.

(14) *Security of drug stocks.* adequate security is required to be maintained over drug stocks, over the manner in which it is administered or dispensed, over the manner in which it is distributed to medication units, and over the manner in which it is stored to guard against theft and diversion of the drug. The program is required to meet the security standards for the distribution and storage of controlled substances as required by the Drug Enforcement Administration, Department of Justice (21 CFR 1301.72–1301.76).

(e) *Multiple enrollments*—(1) *Administering or dispensing to patients enrolled in other programs.* There is a danger of drug dependent persons attempting to enroll in more than one narcotic treatment program to obtain quantities of drugs for the purpose of self-administration or illicit marketing. Therefore, except in an emergency situation, drugs shall not be provided to a patient who is known to be currently receiving drugs from another treatment program

(2) *Patient attendance requirements.* The patient shall always report to the same treatment facility unless prior approval is obtained from the program sponsor for treatment at another program. Permission to report for treatment at the facility of another program shall be granted only in exceptional circumstances and shall be noted on the patient's clinical record.

(f) *Conditions for use of narcotic drugs in hospitals for detoxification treatment*—(1) *Form.* The drug may be administered or dispensed in either oral or parenteral form. (See paragraph (d)(6)(iii) of this section.)

(2) *Use of narcotic drugs in hospitals*—(i) *Approved uses.* For hospitalized patients, the use of a narcotic drug for narcotic addict treatment may be administered or dispensed only for detoxification treatment. If a narcotic drug is administered for treatment of narcotic dependence for more than 180 days, the procedure is no longer considered detoxification but is, rather, considered maintenance treatment. Only approved narcotic treatment programs may undertake maintenance treatment. This does not preclude the maintenance treatment of a patient who is hospitalized for treatment of medical conditions other than addiction and who requires temporary maintenance treatment during the critical period of his or her stay or whose enrollment in a program which has approval for maintenance treatment using narcotic drugs has been verified. (See 21 CFR 1306.07(c).) Any hospital which already has received approval under this paragraph (f) may serve as a temporary narcotic treatment program when an approved treatment program has been terminated and there is no other facility immediately available in the area to provide narcotic drug treatment for the patients. The Food and Drug Administration may give this approval upon the request of the State authority or the hospital, When no State authority has been established.

(ii) *Individuals responsible for supplies.* Hospitals shall submit to the Food and Drug Administration and the State authority the name of the individual (e.g., pharmacist) responsible for receiving and securing supplies of narcotic drugs for the treatment of narcotic addicts. The individual responsible for supplies shall ensure that the only persons who receive supplies of narcotic drugs are those who are authorized to do so by Federal or State law.

(iii) *General description.* The hospital shall submit to the Food and Drug Administration and the State authority a general description of the hospital including the number of beds, specialized treatment facilities for drug dependence, and nature of patient care undertaken.

(iv) *Anticipated quantity of drug needed.* The hospital shall submit to the Food and Drug Administration and the State authority the anticipated quantity of narcotic drugs for narcotic addict treatment needed per year.

(v) *Records.* The hospital shall maintain accurate records showing dates, quantity, and batch or code marks of the drug used for inpatient treatment. The hospital shall retain the records for at least a period of 3 years.

(vi) *Inspection.* The hospital shall permit the Food and Drug Administration

and the State authority to inspect supplies of the drug at the hospital and evaluate the uses to which the drug is being put. The Food and Drug Administration and the State authority will keep the identity of the patients confidential in accordance with confidentiality requirements of 42 CFR part 2. Records on the receipt, storage, and distribution of narcotic medication are subject to inspection under Federal controlled substances laws; but use or disclosure of records identifying patients will, in any case, be limited to actions involving the program or its personnel.

(vii) *Approval of hospital pharmacy.* Application for a hospital pharmacy to provide narcotic drugs for detoxification treatment must be submitted to the Food and Drug Administration and the State authority and approval from both is required, except as provided for in paragraph (h)(5) of this section. Within 60 days after the Food and Drug Administration receives the application, it will notify the applicant of approval or denial or will request additional information, when necessary.

(viii) *Approval of shipments to hospital pharmacies.* Before a hospital pharmacy may lawfully receive shipments of narcotic drugs for detoxification treatment, a responsible official shall complete, sign, and file in duplicate with the Food and Drug Administration and the State authority Form FDA–2636 ''Hospital Request for Methadone Detoxification Treatment'' (see paragraph (l) of this section) and must have received from the Food and Drug Administration a notice that the request has been approved.

(ix) *Sanctions.* Failure to abide by the requirements described in this section may result in revocation of approval to receive shipments of narcotic drugs for narcotic addict treatment, seizure of the drug supply on hand, injunction, and criminal prosecution.

(g) *Confidentiality of patient records.* (1) Except as provided in paragraph (g)(2) of this section, disclosure of patient records maintained by any program 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 narcotic medication are also subject to inspection under Federal controlled substances laws: But use or disclosure of records identifying patients will, in any case, be limited to actions involving the program or its personnel.

(2) A treatment program or medication unit or any part thereof, including any facility or any individual, shall permit a duly authorized employee of the Food and Drug Administration to have access to and to copy all records on the use of narcotic drugs in accordance with the provisions of 42 CFR part 2. A treatment program may reveal such records only when necessary in a related administrative or court proceeding.

(h) *Denial or revocation of approval.* (1) Complete or partial denial or revocation of approval of an application to receive shipments of narcotic drugs (Forms FDA–2632 ''Application for Approval of Use of Narcotic Drugs in a Treatment Program'' and FDA–2636 ''Hospital Request for Methadone Detoxification Treatment'') may be proposed to the Commissioner of Food and Drugs by the Director of the Food and Drug Administration's Center for Drug Evaluation and Research, on his or her own initiative or at the request of representatives of the Drug Enforcement Administration, Department of Justice, National Institute of Drug Abuse, the State authority, or any other interested person.

(2) Before presenting such a proposal to the Commissioner, the Director of the Center for Drug Evaluation and Research, or his or her representative, will notify the applicant in writing of the proposed action and the reasons therefor and will offer the applicant an opportunity to explain the matters in question in an informal conference and/or in writing within 10 days after receipt of such notification. The applicant shall have the right to hear and to question the information on which the proposal to deny or revoke approval is based, and may present any oral or written information and views.

(3) If the explanation offered by the applicant is not accepted by the Center for Drug Evaluation and Research as sufficient to justify approval of the application, and denial or revocation of approval is therefore proposed, the

Commissioner will evaluate information obtained in the informal conference and/or in writing before the Director of the Center for Drug Evaluation and Research. If the Commissioner finds that the applicant has failed to submit adequate assurance justifying approval of the application, the Commissioner shall issue a notice of opportunity for hearing with respect to the matter pursuant to § 314.200 of this chapter and the matter shall thereafter be handled in accordance with established procedures for denial or revocation of approval of a new drug application. If the Secretary determines that there is an imminent hazard to health, revocation of approval will become effective immediately and any administrative procedure will be expedited. Upon revocation of approval of an application, the Commissioner will notify the applicant, the State authority, the Drug Enforcement Administration, Department of Justice, and all other appropriate persons that the applicant may no longer receive shipments of narcotic drugs, and will require the recall of all of the drugs from the applicant. Revocation of approval may also result in criminal prosecution.

(4) Denial or revocation of approval may be reversed when the Commissioner determines that the applicant has justified approval of the application.

(5) A treatment program or medication unit or any part thereof, including any facility or any individual, may appeal to the Food and Drug Administration a complete or partial denial or revocation of approval by the State authority unless the denial or revocation is based upon a State law or regulation. The appeal shall first be made to the Director of the Center for Drug Evaluation and Research, who shall hold an informal conference on the matter in accordance with paragraph (h)(2) of this section. The State authority may participate in the conference. The appellant or the State authority may appeal the Director's decision to the Commissioner, who shall decide the matter in accordance with paragraph (h)(3) of this section. If the Commissioner denies or revokes approval, such action shall be handled in accordance with paragraph (h)(3) of this section. The Commissioner may not grant or retain Food and Drug Administration approval if the Commissioner finds that the appellant is not in compliance with all applicable State laws and regulations and with this section.

(i) *Sanctions*—(1) *Program sponsor or individual responsible for a particular program.* If the program sponsor or the person responsible for a particular program fails to abide by all the requirements set forth in this regulation, or fails to adequately monitor the activities of those employed in the program, he or she may have the approval of his or her application revoked, his or her narcotic drug supply seized, an injunction granted precluding operation of his or her program, and criminal prosecution instituted against him or her.

(2) *Persons responsible for administering or dispensing narcotic drugs.* If a person responsible for administering or dispensing narcotic drugs for narcotic addict treatment fails to abide by all the requirements set forth in this regulation, criminal prosecution may be instituted against him or her, his or her drug supply may be seized, the approval of the program may be revoked, and an injunction may be granted precluding operation of the program.

(j) *Requirements for distribution by manufacturers of narcotic drugs for narcotic addict treatment*—(1) *Distribution requirements.* Shipments of narcotic drugs for narcotic addict treatment are restricted to direct shipments by manufacturers of the drugs to approved treatment programs using the narcotic drugs and to approved hospital pharmacies. If requested by a manufacturer or State authority, wholesale pharmacy outlets in some regions or States may be authorized to stock narcotic drugs for narcotic addict treatment for that area and then transship the drug to approved narcotic treatment programs and approved hospital pharmacies. Alternative methods of distribution will be permitted if they are approved by the Food and Drug Administration and the State authority. Prior to any approval of an alternative method of distribution there will be consultation with the Drug Enforcement Administration, Department of Justice, to assure compliance with its

regulations regarding controlled substance distribution.

(2) *Information regarding approved programs and hospitals.* The Food and Drug Administration will provide manufacturers and the public with names and locations of programs and hospitals that have been approved to receive shipments of narcotic drugs for narcotic addiction treatment. All information contained in the forms required by paragraph (k) of this section is available for public disclosure, except the names or other identifying information with respect to patients.

(3) *Acceptance of delivery.* Delivery shall only be made to a licensed practitioner or a licensed pharmacist employed at the facility. At the time of delivery the licensed practitioner or licensed pharmacist shall sign for the drugs and place his or her specific title and identification number on any invoice. Copies of these signed invoices shall be kept by the manufacturer.

(k) *Use of narcotics other than methadone in a treatment program.* Narcotic drug products other than methadone that have been approved for treatment of narcotic addiction are listed in paragraph (b)(2)(v) of this section. Detailed information on the conditions for use of narcotic drug products other than methadone, with the exception of take-home and dosage form requirements, can be found in the respective approved product labeling. Treatment programs shall review the most recent approved product labeling for up-to-date information on important treatment parameters for each drug. Deviation from doses, frequencies, and conditions of usage described in the approved labeling shall be justified in the patient's record. Treatment programs that dispense narcotics other than methadone shall conform with the requirements set forth under paragraphs (a), (b), (c), (d)(1) through (d)(5), (d)(8) through (d)(14), and (e) through (l) of this section. Specifics regarding take-home and dosage form requirements along with any additional requirements are set forth in this paragraph.

(1) *LAAM*—(i) *Dosage and responsibility for administration.* After a patient's tolerance to LAAM is established, LAAM shall be administered no more frequently than every other day. Dosage of LAAM shall be individualized at doses, frequencies, and under conditions of usage described in approved labeling and as follows:

(A) *New patients.* The persons responsible for the program shall ensure that the initial dose of LAAM to a patient whose tolerance for the drug is unknown does not exceed 40 milligrams.

(B) *Stabilized methadone maintenance patient.* The persons responsible for the program shall ensure that the initial dose of LAAM for a previously stabilized methadone maintenance patient is less than or equal to 1.3 times the patient's daily methadone dose, not to exceed 120 milligrams.

(C) A licensed physician shall assume responsibility for the amount of the narcotic drug administered or dispensed and shall record, date, and sign or countersign in each patient's record each change in dosage schedule.

(D) The administering licensed physician shall ensure that a single dose of LAAM greater than 140 milligrams is justified in the patient's record.

(ii) *Dosage form.* LAAM may be administered in oral form when used in a maintenance treatment program. Hospitalized patients under care for a medical or surgical condition are permitted to receive LAAM in oral form when the attending physician judges it advisable. Although syrup concentrate or other formulations may be distributed to the program, all oral medication is required to be administered in a liquid formulation. Clinics that administer both LAAM and methadone shall take appropriate measures, including contrasting color and taste, to ensure that dosage forms of LAAM and methadone are easily distinguished.

(iii) *Take-home medication.* Take-home doses of LAAM are not permitted. A patient who is eligible for one or more take-home doses of methadone under paragraph (d)(6) of this section and who is unable to conform to the applicable mandatory LAAM dosing schedule because of exceptional circumstances such as illness, personal or family crises, travel, or other hardship, or official State holidays, may be temporarily transferred to methadone. Take-home doses of methadone for a patient eligible for a planned temporary discontinuation of treatment

with LAAM shall be individualized at doses, frequencies, and under conditions of usage described in the approved labeling and the applicable provisions for take-home methadone medication under paragraph (d)(6) of this section. The maximum number of take-home doses of methadone shall be determined in accordance with the provisions of 21 CFR 291.505 (d)(6)(v) and (d)(6)(vi).

(2) [Reserved]

(l) *Program forms.* The program sponsor must ensure that the following forms are completed by the proper program staff and submitted to the appropriate State authority and the Division of Scientific Investigations, Regulatory Management Branch (HFD–342), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855. The sponsor will indicate on the appropriate form which treatment drug is being utilized. Forms are available upon request from the Regulatory Management Branch (HFD–342) at the same address.

FORMS

FDA–2632 Application for Approval of Use of Narcotic Drugs in a Treatment Program.

FDA–2633 Medical Responsibility Statement for Use of Narcotic Drugs in a Treatment Program.

FDA–2635 Consent to Treatment with an Approved Narcotic Drug.

FDA–2636 Hospital Request for Methadone Detoxification Treatment.

(Approved by the Office of Management and Budget under number 0910–0140)

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PART 299—DRUGS; OFFICIAL NAMES AND ESTABLISHED NAMES

Subpart A—General Provisions

Sec.
299.3 Definitions and interpretations.
299.4 Established names for drugs.
299.5 Drugs; compendial name.

AUTHORITY: 21 U.S.C. 331, 351, 352, 355, 358, 360b, 371.

SOURCE: 40 FR 14041, Mar. 27, 1975, unless otherwise noted.

Subpart A—General Provisions

§ 299.3 Definitions and interpretations.

(a) As used in this part 299, *act* means the Federal Food, Drug, and Cosmetic Act, sections 201–902, 52 Stat. 1040 (21 U.S.C. 321–392), with all amendments thereto.

(b) The definitions and interpretations contained in section 201 of the act shall be applicable to such terms when used in this part 299.

(c) The term *official name* means, with respect to a drug or ingredient thereof, the name designated in this part 299 under section 508 of the act as the official name.

§ 299.4 Established names for drugs.

(a) Section 508 of the Federal Food, Drug, and Cosmetic Act (added by the Kefauver-Harris Drug Amendments of 1962; Pub. L. 87–781) authorizes the Commissioner of Food and Drugs to designate an official name for any drug if he determines that such action is necessary or desirable in the interest of usefulness and simplicity. Section 502(e) of the act (as amended by said Drug Amendments) prescribes that the labeling of a drug must bear its established name, if there is one, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula) and, if the drug is fabricated from two or more ingredients, the established name of each active ingredient.

(b) The term *established name* is defined in section 502(e)(3) of the act as (1) an official name designated pursuant to section 508 of the act; (2) if no such official name has been designated for the drug and the drug is an article recognized in an official compendium, then the official title thereof in such compendium; and (3) if neither paragraphs (b) (1) or (2) of this section applies, then the common or usual name of the drug.

(c) The Food and Drug Administration recognizes the skill and experience of the U.S. Adopted Names Council (USAN) in deriving names for drugs. The U.S. Adopted Names Council is a private organization sponsored by the American Medical Association, the United States Pharmacopeia, and the