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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Alcohol, Drug Abuse, and Mental Health Administration

Food and Drug Administration

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NARCOTIC TREATMENT PROGRAM STANDARDS AND METHADONE IN MAINTENANCE AND DETOXIFICATION

Notice of Intent and Proposed Rule

[4110-03]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 291]

[Docket No. 77N-0253]

NARCOTIC TREATMENT PROGRAM STANDARDS

Use of Narcotic Drugs Other Than Methadone by Narcotic Treatment Programs; Joint Notice of Intent To Propose Regulations and Request for Data, Information, and Views

AGENCY: Food and Drug Administration and the National Institute on Drug abuse.

ACTION: Notice of intent.

SUMMARY: The Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), Alcohol, Drug Abuse, and Mental Health Administration, request data, information, and views on several specific issues concerning the use of narcotic drugs other than methadone in the maintenance or detoxification treatment of narcotic addicts. Information obtained will be used to develop proposed regulations concerning narcotic treatment standards specified in the Narcotic Addict Treatment Act of 1974.

DATES: Submissions by December 27, 1977.

ADDRESS: Written submissions (preferably in quadruplicate and identified with the Hearing Clerk docket number found in brackets in the heading of this document) should be addressed to: Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

Food and Drug Administration: Buddy F. Stonecipher, Bureau of Drugs (HFD-340), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-3414.

National Institute on Drug Abuse: James R. Cooper, M.D., National Institute on Drug Abuse, Alcohol, Drug Abuse and Mental Health Administration, Department of Health, Education, and Welfare, 11400 Rockville Pike, Rockville, Md. 20952, 301-443-4877.

SUPPLEMENTARY INFORMATION: Under the Controlled Substances Act (21 U.S.C. 801), practitioners are required to be registered with the Department of Justice, Drug Enforcement Administration (DEA), to prescribe or dispense controlled drugs listed in schedule II, III, IV, or V of that act. In 1974, the Controlled Substances Act was amended by the Narcotic Addict Treatment Act providing among other things, that practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment must obtain annually a separate registration from DEA to conduct such treatment. This registration is separate and distinct from the general registration required to dispense controlled drugs.

Under the Narcotic Addict Treatment Act, practitioners who wish to engage in a narcotic treatment program must register with DEA. These practitioners must comply with the security and recordkeeping requirements established by DEA and must be found to be qualified under treatment standards established by the Secretary of Health, Education, and Welfare (HEW) to be registered by DEA. Authority to establish the treatment standards has been delegated by the Secretary jointly to FDA and NIDA. These treatment standards, which will be incorporated into FDA's methadone regulation (21 CFR 291.505 (formerly § 310.505)), are now being revised by FDA and NIDA.

Currently, the methadone regulations issued by FDA prescribing conditions for use of methadone (21 CFR 291.505 (formerly § 310.505)) contain the only standards for the use of a narcotic drug in the treatment of narcotic addiction. No standards exist that prescribe the use of other narcotic drugs in the treatment of narcotic addiction because no other narcotic drug has been approved by FDA as safe and effective in the maintenance treatment of narcotic addiction. Therefore, methadone should normally be used where chemotherapeutic treatment is the most appropriate modality of treatment.

The FDA and NIDA recognize, however, that for some persons who have become addicted to narcotic drugs other than methadone, it may be medically inappropriate to transfer such persons to methadone. In addition, there may be some narcotic dependent individuals who do not respond to methadone, or in whom methadone is contraindicated for some reason. Therefore, the two agencies plan to develop criteria within the narcotic treatment standards to be applied in determining when a practitioner may use a narcotic drug other than methadone in a narcotic treatment program. It is expected that a practitioner who meets such criteria may then make the medical judgment on the appropriate drug to be used in a given situation. In light of the experience wherein methadone is easily substituted for other narcotic drugs pharmacologically in the vast preponderance of patients, together with the potential for diversion and abuse of other legitimate narcotics, the circumstances in which alternatives to methadone should be permitted should be narrowly drawn.

The medical community was previously acquainted with the need for the development of such criteria through an article by NIDA entitled "Treatment of Narcotics Addiction With Narcotic Drugs" in the "Journal of the American Medical Association," April 12, 1976, vol. 235, No. 15. This article, a copy of which is on file with the Hearing Clerk, Food and Drug Administration, discussed the provisions of the Narcotic Addict Treatment Act and indicated that HEW plans to establish narcotic treatment standards that would allow practitioners, in accordance with restrictive criteria, to use narcotic drugs other than methadone in the maintenance treatment of narcotic addicts. Explaining that there are no adequate estimates on the number of individuals being maintained on narcotic drugs other than methadone, nor on the drugs being used for this purpose, the article requested comments from the medical community on these two points and stated that comments from other professionals and the general public would be requested through a FEDERAL REGISTER notice. Therefore, to aid in the development of treatment standards that would become the criteria for the use of narcotic drugs other than methadone in maintenance or detoxification treatment FDA and NIDA now invite any interested person to submit information on certain issues set forth below. The information requested pertains only to the medical experience with the use of approved marketed narcotic drugs. It does not apply to narcotic new drugs being clinically investigated under a "Notice of Claimed Investigational Exemption for a New Drug." The issues on which information is requested are as follows:

1. The nature of and extent to which narcotic-dependent persons are now being maintained or detoxified by practitioners on narcotic drugs other than methadone;

2. The identity of narcotic drugs other than methadone which are being used for the maintenance or detoxification treatment of narcotic-dependent persons, and any data that support the use of these narcotic drugs in such treatment;

3. The clinical situations in which practitioners should be authorized to use narcotic drugs other than methadone in the treatment of narcotic addiction;

4. The circumstances in which it would be inappropriate to transfer a patient from another licit narcotic drug to methadone in the treatment of narcotic addiction;

5. The standards that should be applied to determine whether a practitioner is qualified to engage in narcotic addiction treatment with narcotic drugs other than methadone; and

6. Whether there should be a limit on the number of narcotic dependent persons whom a practitioner can maintain or detoxify with narcotic drugs other than methadone to prevent the diversion of narcotic drugs into illicit channels.

Received comments may be seen in the office of the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857, between 9 a.m. and 4 p.m., Monday through Friday. FDA will supply copies of all comments received to NIDA. Both the comments received on this notice and on the "Journal of American Medical Association" article will be used by FDA and NIDA in developing the appropriate standards.

Dated: October 13, 1977.

DONALD KENNEDY,
Commissioner of Food and Drugs.

Dated: October 19, 1977.

ROBERT DUPONT,
Director, National Institute on Drug Abuse.

[FR Doc.77-31071 Filed 10-27-77;8:45 am]

[4110–03]

[21 CFR Part 291]

[Docket No. 77N–0252]

METHADONE IN MAINTENANCE AND DETOXIFICATION

Joint Proposed Revision of Conditions for Use

AGENCY: Food and Drug Administration and the National Institute on Drug Abuse.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration and the National Institute on Drug Abuse are proposing revision of the conditions for use of methadone to allow greater flexibility of clinical standards and also to provide more specificity in areas in which the proposed clinical standards mandate levels of performance. This action is taken because a review of the current regulation, based on experience from both a regulatory and clinical perspective, revealed that clinical standards are too rigid in some cases and that patient care responsibilities are sometimes ambiguous. The proposed revisions would indicate clearly the minimum standards for the appropriate methods of professional practice in the medical treatment of narcotic addiction with methadone.

DATES: Comments by December 27, 1977.

ADDRESS: Written comments to the Hearing Clerk (HFC–20), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

Buddy F. Stonecipher, Bureau of Drugs (HFD–340), Food and Drug Administration, Department of Health Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301–443–3414. Or James R. Cooper, MD., National Institute on Drug Abuse, Alcohol, Drug Abuse and Mental Health Administration, Department of Health, Education, and Welfare, 11400 Rockville Pike, Rockville, Md. 20852, 301–443–4877.

SUPPLEMENTARY INFORMATION: Section 4 of Pub. L. 91–513 directs the Secretary of the Department of Health, Education, and Welfare (Secretary) to determine the appropriate methods of professional practice in the medical treatment of the narcotic addiction of various classes of narcotic addicts. The Secretary's authority under this section to determine the safety and effectiveness of drugs or to approve new drugs to be used in the treatment of narcotic addicts has been delegated to the Commissioner of the Food and Drug Administration (21 CFR 5.1). The Secretary's authority under this section relating to the determination of the appropriate methods of professional practice in the treatment of narcotic addicts has been delegated to the Administrator, Alcohol, Drug Abuse, and Mental Health Administration, who has redelegated his authority to the Director, National Institute on Drug Abuse (NIDA).

The Food and Drug Administration's (FDA) methadone regulation (21 CFR 291.505 (formerly § 310.505)) is the only regulatory standard which has been published under the Secretary's authority respecting the use of a narcotic drug in the maintenance or detoxification of narcotic addicts. This standard was originally published under section 505, the new drug provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and section 4 of Pub. L. 91–513 in the FEDERAL REGISTER of December 15, 1972 (37 FR 26790) and recodified on March 29, 1974 (39 FR 11680).

Under the Controlled Substances Act (21 U.S.C. 801 et seq.), practitioners are required to be registered annually with the Drug Enforcement Administration (DEA) of the Department of Justice in order to prescribe or dispense controlled drugs in schedule II, III, IV, or V. This is a general registration requirement. In 1974, after FDA issued its methadone regulation, the Controlled Substances Act was amended by the Narcotic Addict Treatment Act to require, among other things, that practitioners who dispense narcotic drugs for maintenance or detoxification treatment of narcotic-dependent individuals obtain an annual registration from DEA separate and distinct from the general registration. Section 303(g) of the Controlled Substances Act (21 U.S.C. 823(g)) states that in order to be specially registered, these practitioners must comply with secure storage and recordkeeping requirements regarding these drugs established by DEA and must be found to be qualified under treatment standards established by the Secretary.

The legislative history of the Narcotic Addict Treatment Act makes it clear that the Secretary's standards under that law were to be those standards published under the authority of section 4 of Pub. L. 91–513. In the Senate Committee on the Judiciary report (S. Rep. 93–192, 93rd Cong., 1st Sess., June 4, 1973), it is stated that:

> * * * an applicant must show that he or she is qualified to engage in the type of addict treatment for which registration is sought in accordance with the medical standards determined by the Secretary of Health, Education, and Welfare. Section 4 of Title 1 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (§ 4, Pub. L. 91–513) establishes authority for the Secretary to determine standards of treatment in this area. The current regulatory proposal published by the FDA on December 15, 1972, is an expression of this authority. (at 12).

The regulatory proposal to which the Committee report refers is, with several minor modifications, the currant FDA methadone regulation. In the FEDERAL REGISTER of April 29, 1976 (41 FR 17922), FDA issued a notice of proposed rule making which would amend § 291.505 (formerly § 310.505), to make the methadone regulation consistent with the requirements of the Narcotic Addict Treatment Act and the implementing regulations issued pursuant thereto by DEA. Those proposed amendments are expected to be published as final regulations shortly.

The current methadone regulation applies only to the use of methadone in the treatment of narcotic addiction. To date, methadone is the only drug which has been approved by FDA as safe and effective as labeled in the treatment of narcotic addiction. Nevertheless, the Secretary recognizes that there are an undetermined number of people throughout the country who are physiologically dependent upon licit narcotics other than methadone and who are receiving medical treatment for such dependence, which includes the dispensing of the narcotic drug to which the patient is addicted. Both NIDA and FDA recognize that in certain cases it may be medically inappropriate to require these persons to change from another licit narcotic drug to methadone. Therefore, in a separate notice published elsewhere in this issue of the FEDERAL REGISTER, FDA and NIDA are requesting data, information, and views concerning the use of narcotic drugs other than methadone in the maintenance or detoxification treatment of narcotic addicts (See Docket No. 77N–0253).

Experience, from both a regulatory and a clinical perspective, has made it apparent that significant revisions should be proposed in the FDA methadone regulation. At the time the methadone regulation was first promulgated, small numbers of physicians in several cities were excessively prescribing, and in some cases selling, methadone to heroin addicts. The methadone regulation was published, in part, to alleviate this problem by restricting the use of methadone to FDA-approved treatment programs and hospitals. To obtain registration as a treatment program, it was necessary to be able to comply with the requirements of the current regulation. The regulation, by detailing admission standards, staffing patterns, and services, attempted to ensure that only bona fide narcotic addicts would be admitted to methadone treatment and that those who were admitted to methadone treatment would be provided quality care.

While the Secretary believes that the methadone regulation has been responsible for upgrading the quality of treatment and for limiting methadone diversion, he now recognizes many of the requirements of the regulation, although appropriate for many individual patients, are not universally applicable to all maintenance patients at the present time.

This proposal would allow more flexibility in clinical standards, and it would clarify patient care responsibilities by clearly indicating the minimum standards for the appropriate methods of professional practice in the medical treatment of narcotic addicts. This proposal also contains many recommendations which, although not specific require-

ments, represent what the Secretary considers to be sound medical practice in the safe and effective treatment of narcotic addicts with methadone. Thus, the Secretary urges that these recommendations be followed.

In the FEDERAL REGISTER of April 29, 1976 (41 FR 17926), FDA proposed to amend the methadone regulation to adopt certain recommendations of the Methadone Treatment Policy Review Board (Board). The Board is an interagency committee consisting of representatives of NIDA, DEA, the Veterans Administration, and FDA established to review and recommend policy in connection with treatment of narcotic addiction with methadone. The Board's recommendations concerned requirements for physiologic dependence of patients, physician staffing, and urine testing in methadone maintenance programs. Since that proposal was published, review of the current methadone regulation revealed that significant revisions should be made, including revisions to the April 29, 1976 proposed provisions. In view of this proposal permitting even more flexibility in the clinical standards, along with setting forth recommended practices, action on the April 29 proposal will not be taken until the comments on this more extensive proposal are received and evaluated. The final regulations will summarize the comments of both proposals.

Received comments may be seen in the office of the Hearing Clerk, Food and Drug Administration, from 9 a.m. to 4 p.m., Monday through Friday. FDA will supply copies of all comments received to NIDA, and final regulations will be issued jointly by the two agencies.

A summary of the significant proposed revisions to § 291.505 (formerly § 310.505) are set forth below. The Secretary has expressed particular interest in comments on this proposal regarding the definition of a 1-year history of addiction (§ 291.505(d)(3)(i)), the opportunity to pregnant patients for prenatal care (§ 291.505(d)(3)(iii)(b)), the elimination of all mandatory urine testing, with the exception of the initial drug screening urinalysis (§ 291.505(d)(4)), and the recording in each patient's chart of the initial and periodic treatment plans including the review and updates (§ 291.505(d)(5)(v) and (vi)).

MINIMUM STANDARDS FOR ADMISSION

The current methadone regulation requires a 2-year history of addiction for entry to maintenance. That requirement was based upon the belief that methadone maintenance treatment should be reserved for treatment of the hard-core, chronic narcotic addict and that it was a treatment of "last resort." It was also based upon the fear that nonaddicted or those minimally dependent drug users would apply for treatment in the hope of obtaining freedrugs. Experience has indicated that the feared situations have not occurred with any degree of frequency. Therefore, some program directors have argued that the decision whether to admit an individual to maintenance treatment should be entirely within the clinical judgment of the program physician, and the Federal Government should not require a minimum period of addiction for eligibility.

The Secretary has concluded, however, that a 1-year history of addiction should be proposed as a necessary and reasonable precaution against the admission of nonaddicted persons. A 1-year history of addiction means that an applicant for admission to a maintenance program must have been physiologically addicted to a narcotic at a time at least 1 year prior to admission to a program and must have been so addicted, continuously or episodically, for most of the year immediately preceding admission to a program. This proposal would at the same time, allow the admission of the vast majority of truly dependent persons for treatment. This proposal would also allow the admission of persons who would meet the minimum standards for admission but for insufficient documentary evidence of the person's addiction history, if, in the clinical judgment of the program physician from the evidence presented, observed, and recorded in the patient's chart it is reasonable to conclude that there was continuous or episodic physiological addiction during most of the year immediately preceding the date of application for admission.

EXCEPTIONS TO MINIMUM ADMISSION CRITERIA

The current methadone regulation allows persons to be admitted to maintenance treatment, even though they were not currently physiologically addicted, prior to or within 1 week of release from a stay of 1 month or longer in a penal or chronic care institution, provided the person had a predetention history of addiction of at least 2 years. The 1-week period in the current regulation is now thought to be unwise in that it might encourage persons who would like to remain drug-free but are unsure of their ability to do so to enroll in methadone treatment.

This proposal would authorize admission to maintenance treatment within 14 days prior to release or discharge or within 6 months after release from a stay of 1 month or longer in a penal or chronic care institution. The longer time period is designed to afford a person an adequate period in which to adjust to his changed environment and to assure himself that he can do so without drugs. The transition is difficult enough without requiring the person to decide within 7 days whether to enter maintenance treatment.

This proposal would also expand the current provisions concerning the admission of pregnant women to maintenance treatment. If, in the clinical judgment of the program physician, maintenance treatment is justified, admission would be allowed regardless of length of addiction history or current physiologic dependence, if the patient is in jeopardy of returning to opiate use. The decision to allow maintenance treatment in this instance is based on the generally accepted finding that babies born to mothers maintained on methadone and receiving prenatal care have less morbidity than those born to mothers who use illicit heroin with its associated life style, e.g., intravenous use of nonsterile paraphenalia and adulterants. However, the patient must have been dependent upon opiates at some time in the past. This proposal requires the program to give a pregnant patient the opportunity for prenatal care. In addition, after termination of the pregnancy, the physician would be required to evaluate the patient's condition and indicate in the patient's record whether she should remain in maintenance treatment or be detoxified. The current requirement is that this be done within 6 weeks following termination of pregnancy; the proposal expands this to 3 months.

The current regulation requires that a person be currently physiologically dependent before readmission to maintenance treatment. The April 29, 1976 (41 FR 17926) proposed revision would have allowed persons who had been voluntarily detoxified from methadone maintenance treatment to be readmitted into maintenance treatment within 30 days after detoxification even though no longer currently physiologically dependent. This was designed to encourage patients who want to detoxify to do so without the fear that, if they are unable to remain drug free, they will have to revert to illicit drug use in order to be readmitted to methadone maintenance. A review of the current situation leads us to believe that 30 days is not a sufficiently long period of time. Available data suggest that 2 years is a critical point for relapse. Over 90 percent of the patients who return to drug use do so within the first 2 years. Accordingly, it is proposed to amend the current regulation to allow readmission to maintenance treatment for up to 2 years after voluntary detoxification from maintenance treatment provided that prior maintenance treatment was for a duration of 6 months or more. In view of the proposed expanded eligibility for readmission, it was thought necessary to impose the minimum period of prior treatment to be eligible for this exception.

The current methadone regulation regarding the admission to methadone maintenance treatment of persons between 16 and 18 years of age has not been changed substantively in this proposal. However, it is proposed that persons under 16 years of age may now be admitted to maintenance treatment in certain rare cases if prior approval is obtained from both FDA and the State authority. This change is proposed because clinical experience shows that detoxification of many of these younger patients has been insufficient, i.e., many return to the continued use of heroin and because morbidity with heroin is higher than morbidity with methadone.

MINIMUM URINE TESTINGS; USES AND FREQUENCY

It is recognized that there are advantages and disadvantages in mandating weekly drug urinalysis on all patients as is the current requirement. Some drug abuse clinicians believe that mandated weekly urine testing on all patients is a waste of time any money that could be more effectively used for additional counseling staff or other program needs. Furthermore, controlled blind proficiency testing has shown results that raise questions about the validity of urine testing. Some clinics have made minimal use of urine test results because of the questionable validity of the urinalysis results and/or the lengthy periods between urine testing and reports of the urinalysis.

Other drug abuse clinicians believe that weekly drug urinalysis is a valuable psychological aid and deterrent in helping reduce illicit drug use by patients. These clinicians contend that there are few reliable indicators to qualitatively evaluate illicit drug use among the patient population and that urine testing is one of these reliable indicators. Many clinicians believe that, as a minimum, urinalysis should be performed on all new patients during the stabilization phase of treatment, i.e., during the initial stage of treatment.

Despite the different views regarding urine testing, FDA and NIDA propose to eliminate all mandatory urine testing, with the exception of an initial screening urinalysis for new patients. FDA and NIDA do not wish to suggest that accurate and rapid urine test results are not important for certain patients even on a regular and continuing basis, thus it is recommended practice that monthly drug urinalysis be utilized but that the final decision be left to the medical director.

These proposed changes are intended to provide clinicians with greater flexibility regarding urinalyses for illicit drug use. These proposed changes in the urine testing schedule would not preclude a narcotic maintenance program from: (1) testing urine for illicit drugs on all or some patients on a weekly or more frequent basis; (2) collecting specimens weekly or more frequently, but performing analysis on some or all specimens on a less frequent basis; or (3) collecting and testing urine of anyone in the program suspect of illicit drug use. Nor would these proposed revisions preclude a State, if it were deemed appropriate by that State, from requiring additional urine tests. Urinalysis results should not, however, be used to force patients out of treatment.

PATIENT EVALUATION; MINIMUM ADMISSION AND PERIODIC REQUIREMENTS

This provision of the proposal is substantially similar to § 291.505(d)(3)(vi) of the current regulation, but has been renumbered and expanded to suggest the types of information that should be obtained at admission. As proposed, it will require the development of an initial treatment plan for each patient as soon as possible after admission and it will require a periodic review of the treatment plan. The details of the initial treatment plan and the requirement for periodic review of treatment plans are set forth in proposed § 291.505(d)(5)(v) and (vi).

Also, since an adequate physical examination should include an evaluation of body systems and provide evidence that an evaluation of these systems has occurred, the proposal would require the findings of specified results from a patient's physical examination to be recorded in the patient's chart.

It is recognized that there are advantages and disadvantages in mandating a number of laboratory tests for patients in methadone programs. Some drug abuse clinicians believe that a number of specific laboratory tests need to be performed to properly assess a patient's current health status, e.g., a tuberculin skin test, a serological test for syphilis, a liver function profile, a complete blood count and differential. These clinicians contend that coupled with a comprehensive physical examination such tests are essential in arriving at an appropriate treatment plan for a patient as well as determining what supportive services a patient may need.

Other drug abuse clinicians believe that the decision for ordering any laboratory tests should be left to the discretion of the program physician. These clinicians contend that many laboratory tests would not be necessary for each patient.

Despite these different views regarding mandatory laboratory tests, FDA and NIDA propose, as a minimum standard, that a serological test for syphilis and a tuberculin skin test be performed on each patient in the interest of the public health as well as the patient's health. The current regulation does not require these tests. The Secretary does not wish to suggest that other laboratory tests are not important for certain patients, thus it is recommended practice that other certain laboratory tests be performed where appropriate in the judgment of the program physician, e.g., a complete blood count and differential, routine and microscopic urinalysis, and liver function profile.

MINIMUM PROGRAM SERVICES

This provision intends to define the responsibilities of the program's medical director. Essentially, under this proposal, the medical director or other authorized licensed physicians are responsible for ensuring that the program is in compliance with all applicable Federal, State, and local laws and regulations regarding medical treatment of narcotic addiction. In addition, the medical director or other authorized physician must ensure that (1) evidence of current physiologic dependence, length of history of addiction, or exceptions to the admission criteria are documented in the patient's record before administration of the initial dose of methadone; (2) a medical evaluation including a medical history and physical examination have been performed before the patient receives the initial methadone dose (in an emergency the initial dose may be given before the physical examination); (3) appropriate laboratory studies have been performed and reviewed; (4) all medical orders are signed; (5) treatment plans are reviewed and countersigned at least annually; and (6) justification for take-home methadone is recorded in the patient's record.

The April 29, 1976 proposal would have allowed the use of physician assistants and other recognized health-care professionals to perform a number of functions which are normally performed by physicians, provided that the performance of these functions is authorized by State law. This proposal retains that revision. Because, however, this proposal would not mandate a specific physician-patient ratio, the April 29, 1976 proposed revision allowing the time spent by these health-care professionals to count toward the required physician time has been dropped.

Section 291.505(d)(5) of the current regulation requires each program to provide a comprehensive range of medical and rehabilitative services to its patients either at the primary treatment facility or through formal, documented agreements with other public and private organizations and institutions. Those provisions are retained in this proposal. In addition, the proposed regulation would require programs to enter into a written agreement with an accredited hospital for the purpose of providing necessary emergency, inpatient or ambulatory care for program patients. The proposed regulation also stipulates that the program shall provide opportunities for vocational rehabilitation and educational or employment services, either directly or through referral to community resources.

MINIMUM STAFFING PATTERNS

Section 291.505(d)(4) of the current regulation mandates detailed staffing patterns for physicians, nurses, and counselors. This proposed regulation eliminates these detailed requirements. The decision of what staff to employ and in what numbers is left to the judgment of the program physician or director. However, the proposal retains the requirement of a minimum of 4 counselors per 300 patients. Several criteria are set forth in the proposed regulation which the program director or physician would be required to consider in making staffing decisions.

DOSAGE AND RESPONSIBILITY FOR ADMINISTRATION

Unlike the current regulation, the proposed rule would impose limitations on the amount of methadone which could be given for the initial dosage as well as for the total first day's dosage. These changes are based upon most recent clinical experience in that very few patients need more than 40 mg and in fact most patients require between 15 and 30 mg to suppress withdrawal symptoms. The proposed rule would prohibit the dispensing of initial dosages of more than 30 mg and total first day dosages in excess of 40 mg, unless the program physician documents in the patient's chart

those rare cases where this maximum dose is insufficient to suppress withdrawal symptoms. This is the maximum permissible amount and is not intended to be a recommended dosage for all patients. In many instances, dosages one-half these amounts or less may be sufficient to mitigate abstinence syndromes. Daily dosages above 100 mg require prior approval of the State Methadone Authority and FDA. The current regulation allows up to 120 mg before prior approval is required. The FDA and NIDA have noted deaths and morbidity from the too generous dosages of methadone utilized on admission in some programs.

MAXIMUM TAKE-HOME MEDICATION

The proposed rule would retain, with minor modifications, the substance of the current regulatory requirements regarding take-home medication. However, unlike the current regulation, the proposed rule lists a number of criteria which the program physician would be required to consider in addition to evaluating the patient's responsibility in the handling of methadone.

The program physician would be required to consider whether the patient has satisfactorily adhered to the program's rules for at least 3 months and whether the patient has made substantial progress in rehabilitation. If these criteria are met and if the patient's rehabilitative progress would be enhanced by reducing the frequency of clinic attendance, the patient might be allowed up to 2 days of take-home medication earlier in the treatment course than is now the case.

The proposal retains the current provision that after 2 years of successful participation in the program, patients may be permitted twice-weekly visits to the clinic and 3-day take-home supplies. Individuals receiving more than 100 mg per day would not be eligible for more than 1 day per week take-home medication, as currently provided. In addition, the proposal includes a provision that would permit a patient to take home a 6-day supply under certain circumstances if the medical director has entered into the patient's record an evaluation that such patients have satisfactorily adhered to each of the criteria for measuring responsibility in handling methadone.

The proposal also retains the exceptions regarding take-home medications because in limited circumstances it may be difficult for some patients to adhere to the take-home schedule and pursue certain types of employment. As a result, some patients have been faced with discontinuing treatment because of their inability to adhere to take-home policies. The proposal also includes a specific provision permitting exceptions to the take-home limitations if, in the judgment of the program physician, the patient has a physical disability which makes it difficult for the patient to reasonably adhere to the required pick-up schedule or other exceptional circumstances arise which interfere with the patient's ability to conform to the applicable mandatory schedule.

The proposed revisions would eliminate the requirement in current § 291.505 (d)(8) for a 2-year evaluation of whether the patient should remain on methadone maintenance treatment. Many people have incorrectly interpreted this provision as requiring that patients be detoxified after 2 years. No specific reevaluation requirement is contained in the proposal because it is thought that this question of whether such a patient should remain on methadone maintenance treatment is one which should be continually under evaluation by the program physician and should be dealt with in the reevaluation of the treatment plan.

MINIMUM STANDARDS FOR DETOXIFICATION TREATMENT

Detoxification treatment would be required to be conducted over a period not to exceed 21 days. If treatment exceeds 21 days, it would be considered maintenance treatment. This limitation of 21 days, however, does not apply to the gradual withdrawal from methadone of a person on methadone maintenance; again, this terminology has been misinterpreted by many treatment program personnel. The provisions of the proposed rules regarding detoxification treatment are substantively changed from the detoxification section of the current methadone regulation. All the proposed mainenance treatment requirements apply to detoxification treatment except in those circumstances specifically excepted. The proposed rules on detoxification would apply to both inpatient and ambulatory detoxification treatment.

USE OF METHADONE IN HOSPITALS

The proposal would delete the reference to temporary maintenance in current § 291.505(f). This is proposed to make the regulation consistent with the regulations promulgated by DEA under the Narcotic Addict Treatment Act., i.e., that using methadone for the temporary maintenance treatment of addicts who are hospitalized for the treatment of medical conditions other than addiction is permitted.

CONFIDENTIALITY OF PATIENT RECORDS

The proposal would delete the reference to Part 1401 of this title to require compliance with the current Federal regulations on the confidentiality of alcohol and drug abuse patient records which are found at 42 CFR Part 2.

PROGRAM FORMS

The current regulation sets forth in § 291.505(k) several forms which must be filed simultaneously with both FDA and the State authority under § 291.505(c)(4) as a condition for approval of the use of methadone. The other forms in paragraph (k) deal with patient consent and hospital application.

Basically, these forms restate many of the minimum standards in § 291.505. The proposed changes to those forms conform to the proposed minimum standards in the methadone regulation. Also, reference to a patient identification system has been omitted from the forms to make the forms consistent with past changes in the methadone regulation (see 39 FR 37636).

MISCELLANEOUS PROVISIONS

Section 291.505(d)(10) of this proposal would mandate that programs develop a written policy and procedures regarding the involuntary termination of clients from treatment. This is considered essential to protect the due process rights of patients as well as to protect the program from legal liability if it is to terminate a client for failure to adhere to program rules. It is recommended that an adequate involuntary termination proceduce include an opportunity for patients to receive written notification of the program's intention to terminate them and the reasons for this decision, as well as an opportunity to contest this decision in an impartial forum.

Section 291.505(d)(15) would require that all programs comply with Federal and State reporting requirements and with regulations on the confidentiality of patient records.

Accordingly, the Commissioner of Food and Drugs and the Director of the National Institute on Drug Abuse jointly propose that the methadone regulation be revised as set forth below. The revised regulation constitutes the Secretary's standards under the Narcotic Addict Treatment Act of 1974.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 505, 701 (a), 52 Stat. 1052–1053, as amended, 1055 (21 U.S.C. 355, 371(a))), the Comprehensive Drug Abuse Prevention and Control Act of 1970 (sec. 4, 84 Stat. 1241 (42 U.S.C. 257a)), the Narcotic Addict Treatment Act of 1974 (sec. 3, 88 Stat. 124–125 (21 U.S.C. 823(g)), and applicable delegations of authority thereunder (37 FR 27616, December 19, 1972; 38 FR 27315–25316, October 2, 1973; (21 CFR 5.1)), it is proposed that § 291.505 be amended by revising paragraphs (b)(2)(iii) and (iv) and (d)(1), (3)(i) through (iv), (4) through (11); by adding paragraph (d)(14) through (16); and by revising paragraphs (f)(1), (2)(i) and (vi) through (viii), (g), and (k) to read as follows:

§ 291.505 Conditions for use of methadone.

* * * * *

(b) * * *

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(iii) *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 is responsible for assuring that the patient receives needed medical and social services at least monthly at the primary facility.

(iv) *Services.* Medication units are limited to the administering or dispensing of medication and the collection of urine for urine testing, following the procedures outlined in paragraph (d)(4) of this section. If a private practitioner

wishes to provide other services in addition to administering or dispensing medication and collecting urine samples, he shall be considered a program and shall be required to submit an application for seperate approval.

* * * * *

(d) * * *

(1) *Description of facilities.* Drug treatment services shall be provided through appropriate drug abuse treatment facilities at such site(s) as approved by Federal, State, and local authorities. A program shall have ready access to a comprehensive range of medical and rehabilitative services. The name, address, and description of each hospital, institution, clinical laboratory, or other facility available to provide the necessary services shall be given to the Food and Drug Administration and the State authority. This listing shall include the name and addres of each medication unit.

(3) *Minimum standards for admission*—(i) *History of addiction and current physical dependence.* (*a*) Each person selected as a patient for a maintenance program, regardless of age, shall be determined by a program physician to be currently physiologically dependent upon a narcotic drug and must have first become physiologically dependent at least 1 year prior to admission for maintenance treatment. A 1-year history of addiction means that an applicant for admission to a maintenance program must have been physiologically addicted to a narcotic at a time at least 1 year prior to admission to a program and must have been so addicted, continuously or episodically, for most of the year immediately preceding 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 reasonable clinical judgment, admit the person to methadone maintenance treatment, if from the evidence presented, observed, and recorded in the patient's chart, it is reasonable to conclude that there was physiologic dependence at a time approximately 1 year prior to admission.

(*b*) Although daily use of a narcotic for an entire year could satisfy the definition, 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 admission for application would be eligible for admission to a maintenance program:

(*1*) Physiologic addiction began in August 1976, and persisted to the date of application for admission in August 1977.

(*2*) Physiologic addiction began in January 1977, and persisted until April 1977. Physiologic addiction began again in July 1977 and persisted until the application for admission in January 1978.

(*3*) Physiologic addiction began in January 1976, and p ersisted until October 1976. The date of application for admission was January 1977, at which time the patient had been re-addicted for 1 month preceding his admission.

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

(*c*) In determining current physiologic dependence the physician should consider signs and symptoms of intoxication, a positive urine specimen for a narcotic drug, and old or fresh needle marks. Other evidence of current physiologic dependence could be obtained by noting early signs of withdrawal (lacrimation, rhinorrhea, pupilary dilatation, and piloerection) during the initial period of abstinence. Withdrawal signs may be observed during the initial period of abstinence. Withdrawal signs may be observed during the initial period of hospitalization or while the person is an outpatient undergoing diagnostic evaluation (e.g., medical and personal history, physical examination, and laboratory studies). Increased body temperature, pulse rate, blood pressure and respiratory rate are also signs of withdrawal, but their detection may require inpatient observation. It is unlikely but possible that a person could be currently dependent on narcotic drugs without having a positive urine test for narcotics. Thus, a urine sample that is positive for narcotics is not a requirement for admission to detoxification or maintenance treatment.

(*d*) The program physician or an appropriately trained staff member designated and supervised by the physician shall record in the patient's chart the criteria used to determine the patient's current physiologic dependence and history of addiction. In the latter circumstance, the program physician must review, date, and countersign the supervised staff member's evaluation to demonstrate his agreement with such evaluation. The final decision for determining physiologic dependence and history of addiction shall be made by the program physician. Therefore, in the chart there must be a signed and dated statement by the program physician, which indicates he has reviewed all the documented evidence to support a 1-year history of addiction and the current physiologic dependence and that in his reasonable clinical judgment the patient fulfills the requirements for admission to maintenance treatment. This review must be completed prior to the administration of the initial dose of methadone.

(ii) *Voluntary participation, informed consent.* The person responsible for the program shall ensure that: participation in a program is voluntary; all relevant facts concerning the use of methadone are clearly and adequately explained to the patient; all patients, with full knowledge and understanding of its contents, sign the "Consent for Methadone Treatment" form (FD–2635) set forth in paragraph (k)(4) of this section; the parents or guardian of patients under the age of 18 sign the second part of Form FD–2635.

(iii) *Exceptions to minimum admission criteria*—(*a*) *Penal or chronic case.* A person who has resided in a penal or chronic care institution for 1 month or longer may be admitted to methadone maintenance treatment within 14 days prior to release or discharge or within 6 months after release from such an institution without evidence to support findings of physiological dependence provided the person would have been eligible for admission prior to incarceration or institutionalization. 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 such findings shall be recorded in the patient's chart by the admitting program physician, or by program personnel superivsed by the admitting program physician. The admitting program physician shall date and sign the recordings or date, review, and countersign these recordings in the patient's chart prior to the administration of the initial methadone 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 be in direct jeopardy of returning to narcotic dependency, with all its attendant dangers during pregnancy, may be placed on a maintenance regimen. For such patients, evidence of current physiological dependence on narcotic drugs is not needed if a program physician certifies the pregnancy and, in his reasonable clinical judgment, finds such treatment to be medically justified. Evidence of all findings and the criteria used to determine such findings shall be recorded in the patient's chart by the admitting program physician, or by program personnel supervised by the admitting program physician. The admitting program physician shall date and sign the recordings, or date, review, and countersign such recordings in the patient's chart prior to the administration of the initial methadone dose to the patient. These pregnant patients shall be given the opportunity for prenatal care either by the methadone program or by referral to appropriate health care providers.

(*2*) If a program cannot provide direct prenatal care for pregnant patients in methadone treatment, it shall establish a system that provides for an opportunity to refer these patients for prenatal care which may be either publicly or privately funded. If there are no publicly funded prenatal referral opportunities, the program cannot provide such services, and the patient cannot afford them or refuses them, then the treatment program shall, at a minimum, offer these patients basic prenatal instruction on maternal, physical, and dietary care as a part of its counseling service.

(*3*) Counseling records and/or other appropriate patient records shall reflect the nature of prenatal support provided by the program. If referral for prenatal services is provided, the physician to whom the patient is referred shall be notified that the patient is in methadone

maintenance treatment, provided that such notification is in accordance with the Department of Health, Education, and Welfare's Confidentiality Regulations (42 CFR Part 2). In the event that a pregnant patient refuses direct treatment or appropriate referral for treatment, the treating program physician should consider the utilization of informed consent procedures, e.g., to have such 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. It is recognized that programs often request such information but for a variety of reasons do not always receive a response. In such situations, the program physician 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 indicate whether she should remain in the maintenance program or be detoxified.

(5) Caution shall be taken in the maintenance treatment of pregnant patients. Dosage levels shall be maintained as low as possible if continued methadone treatment is deemed necessary. It is the responsibility of the program sponsor to assure that each female patient is fully informed concerning the possible risks to a pregnant woman or her unborn child from the use of methadone, e.g., safe use in pregnancy has not been established in relation to possible adverse effects on fetal development.

(c) *Previously treated patients.* A patient who has been treated and subsequently detoxified from methadone maintenance treatment may be readmitted to methadone maintenance treatment without evidence to support findings of current physiologic dependence up to 2 years after discharge provided that prior methadone maintenance treatment of 6 months or more is documented from the program attended and that the admitting program physician, in his reasonable clinical judgment, finds readmission to methadone maintenance treatment to be medically justified. For patients meeting these criteria, the quantity of take-home medication shall be determined in the reasonable clinical judgment of the program physician but in no case shall the quantity of take-home medication be greater than would have been allowed at the time that person terminated previous treatment. Documented evidence of prior treatment and evidence of all other findings and criteria used to determine such findings shall be recorded in the patient's chart by the admitting program physician or program personnel under supervision of the admitting program physician. The admitting program physician shall date and sign the recordings, or date, review, and countersign such recordings in the patient's chart prior to the administration of the initial methadone does to the patient.

(iv) *Special limitation; treatment of patients under 18 years of age.* A person under the age of 18 shall have had two documented attempts at detoxification or drug-free treatment to be eligible for maintenance treatment. A 1-week waiting period is required after 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 one under the age of 16 is eligible for methadone maintenance treatment without the prior approval of the Food and Drug Administration and the State methadone authority. This shall not preclude a person under the age of 16 who is currently physiologically dependent on narcotic drugs from being detoxified with methadone if it's deemed medically appropriate by the program physician and is done in accordance with the requirements of paragraph (d)(9) of this section. No person under the age of 18 may be admitted to a maintenance treatment program unless a parent, legal guardian, or responsible adult designated by the State authority completes and signs consent form, Form FD–2635 "Consent to Methadone Treatment."

* * * * *

(4) *Minimum urine testing; uses and frequency.* (i) The person(s) responsible for a program shall ensure that an initial drug-screening urinaysis for opiates, barbiturates, amphetamines, cocaine, and other drugs as appropriate is completed for each prospective patient and that when urine is collected, specimens from each patient are collected in a manner that minimizes falsification. Each laboratory selected for urine testing must be incompliance with all applicable Federal proficiency testing and licensing standards and all State standards regarding such laboratories. Any changes made in laboratories used for urine testing shall have prior approval of the Food and Drug Administration.

(ii) It is recommended practice that after the initial drug screening urinalysis, urine specimens for each patient be collected and analyzed on a randomly scheduled basis at least monthly for opiates, methadone, amphetamines, cocaine, and barbiturates, as well as other drugs as indicated. It is recommended practice that more or less frequent testing for a specific drug(s) and for a specific individual occur when clinically indicated as determined by the reasonable clinical judgment of the medical director. It is recommended practice that results of urine testing be used as one clinical tool for the purposes of diagnosis, and in the determination of treatment plans, as well as utilized as one technique for overall prgoram evaluation by monitoring patient drug-using patterns before and uring treatment. The person(s) responsible for a program shall ensure that urine test results are not used to force a patient out of treatment but are used as a guide to change treatment approaches. He shall also ensure that when urine test results are utilized, presumptive laboratory results are distinguished from those results which are definitive. It is also recommended practice that the person(s) responsible for the program who utilizes the results of presumptive urinalysis for patient management show evidence of reasonable access to confirmatory laboratory analysis for use on occasions when this is necessary, e.g., for intake urine testing on all prospective methadone clients, for any loss of patient privileges based on urinalysis, for compiling criminal justice system records, and for indicating frequency of use of other drugs not detectable by a screening method.

(5) *Patient evaluation; minimum admission and periodic requirements*—(i) *Minimum contents of medical evaluation.* Each patient shall have a medical evaluation made by a program physician or an authorized health-care professional under the supervision of a program physician upon the patient's admission to a program. As a minimum, this evaluation shall consist of a medical history including a history of drug and/or alcohol dependence, a physical examination, and routine laboratory examinations including a serological test for syphilis, a tuberculin skin test and a urinalysis for drug determination. The physical examination shall 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 shall include a determination of the patient's vital signs (temperature, pluse, 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) *Recommended contents of medical evaluation.* (a) It is recommended practice that the following laboratory examinations be conducted for each patient at admission to a program in addition to the required examinations stated in paragraph (d)(5)(i) of this section.

(1) Complete blood count and differential;

(2) Routine and microscopic urinalysis;

(3) Liver function profile, e.g. SGOT, SGPT, etc.

(4) When the tuberculin skin test is positive, a chest X-ray;

(5) Australian Antigen Hb Ag Testing (HAA testing);

(6) When clinically indicated, an EKG; and

(7) When appropriate, pregnancy test and a pap smear.

(b) When a person is readmitted to a program, it is recommended that the decision for determining the appropriate laboratory tests to be conducted be based upon the intervening medical history and a physical examination.

(iii) *Recordings of findings.* The admitting program physician or an appropriately trained program staff member supervised by the admitting program physician shall record in the patient's chart all findings resulting from the admission medical evaluation. Both positive and negative results shall be recorded. In each case the admitting program physician shall date and sign these recordings, or date, review, and countersign these recordings in the patient's chart to signify his review of and concurrence with the history and physical findings.

(iv) *Admission evaluation.* (*a*) Each patient seeking admission or readmission for the purpose of obtaining treatment services shall be interviewed by a person who should be 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 shall include information relating to his educational and vocational achievements. In the event a patient has no such history, i.e., he has no formal education or has never had an occupation, this requirement shall be met by writing this information in the patient's history.

(*c*) It is recommended practice that a patient's history include information relating to his psychosocial, economic, and family background, and any other information deemed necessary by the program which is relevant to his application or which may be helpful in assessing the resources, e.g., psychological, economic, educational, and vocational strengths and weaknesses, that a patient brings to the treatment setting. It is recommended practice that each program establish its own methods for measuring such strengths and weaknesses to assess the severity of a patient's problem, establish realistic treatment goals, and develop an appropriate treatment plan to achieve these goals. Such assessments shall be performed on admission or as soon as a patient is stable enough for appropriate interviewing. Treatment plans should reflect individualization geared to a patient's needs.

(v) *Initial treatment plan.* (*a*) A primary person is one who shall be assigned by the person(s) responsible for a program to monitor a patient's progress in the patient's initial and periodic treatment plans. The name of this person shall be recorded in the patient's chart. The initial treatment plan shall contain realistic short-term goals which are mutually acceptable to the patient and the program (it is recommended practice that these short-term goals be designed to expect completion within a finite time period, e.g., 90 to 180 days). It shall also state the behavioral tasks expected of a patient which are necessary to complete each short-term goal and the medical, psychosocial, economic, legal, or other supportive services needed immediately by each patient, including the projected frequency with which these services will be provided. The contents of a patient's initial treatment plan along with the rationale used to determine such needs shall be recorded in the patient's chart by the primary person. It is recommended practice that this information be in sufficient detail to demonstrate that each patient has been assessed and that the services which are provided are based on the patient assessment findings and the available program and community services.

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

(*c*) Each patient's initial assessment, including the concomitant treatment plan reflecting the short-term mutually acceptable treatment goals, shall be documented in each patient's chart immediately after the patient is stabilized on a methadone dose or within 4 weeks after admission, whichever is sooner. 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 by this paragraph (d)(5)(v) to be recorded in each patient's chart.

(vi) *Periodic treatment plan evaluation.* (*a*) The program physician or the primary person 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 patients' chart and that it is signed and dated in the patients' chart by the primary person 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 chart and ensure that each patient's progress or lack of progress in achieving the treatment goals is entered in the patient's counseling record by the primary person. When appropriate, the treatment plan and progress notes shall deal with the patient's mental and physical problems, apart from drug abuse, and shall include reasons for prescribing any medication for emotional or physical problems.

(6) *Minimum program services*—(i) *Access to a range of services.* (*a*) A treatment program shall provide a comprehensive range of medical and rehabilitative services to its patients. These services normally should be provided at the primary facility, but the program sponsor may enter into formally documented agreements with other public or private agencies, institutions, or organizations to render these services. Such facilities must be located so as to provide ease of access to the patient. Also, for pregnant patients in a treatment program who were not admitted under paragraph (d)(3)(iii)(*b*) of this section, a treatment program shall give these pregnant patients the opportunity for prenatal care either by the methadone program or by referral to appropriate health-care providers. If a program cannot provide direct prenatal care for pregnant patients in methadone treatment, it shall establish a system that provides for an opportunity to refer these patients for prenatal care which may be either publicly or privately funded. If there are no publicly funded prenatal referral opportunities, the program cannot provide such services, and the patient cannot afford or refuses them, then the treatment program shall, at a minimum, offer these patients basic prenatal instruction on maternal, physical, and dietary care as a part of its counseling service.

(*b*) Counseling records and/or other appropriate patient records shall reflect the nature of prenatal support provided by the program. If referral for prenatal services is provided, the physician to whom the patient is referred shall be notified that the patient is in methadone maintenance treatment, provided that such notification is in accordance with the Department of Health, Education, and Welfare's Confidentiality Regulations (42 CFR Part 2). In the event that a pregnant patient refuses direct treatment or appropriate referral for treatment, the treating program physician should consider the utilization of informed consent procedures, i.e., to have such patient acknowledge in writing that she had 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. It is recognized that programs often request such information but for a variety of reasons do not always receive a response. In such situations, the program physician shall document in the record that such a request was made.

(*c*) Caution shall be taken in the maintenance treatment of pregnant patients. Dosage levels shall be maintained as low as possible if continued methadone treatment is deemed necessary. It is the responsibility of the program sponsor to ensure that each female patient is fully informed concerning the possible risks to a pregnant woman or her unborn child from the use of methadone, e.g., safe use in pregnancy has not been established in relation to possible adverse effects on fetal development.

(*d*) Any service not furnished at the primary facility shall be listed, and the agreements to furnish those services shall be documented, when application for approval is submitted to the Food and Drug Administration and the State authority. Modification of any program

services shall be reported in triplicate to the Food and Drug Administration before such services are added or deleted.

(ii) *Minimum medical services; designation of a medical director and responsibilities.* Each program shall have a designated medical director who assumes responsibility for the administration of all medical services performed by the program. The medical director and other authorized program physicians shall be licensed to practice in the jurisdiction in which the program is located. The medical director shall be 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 responsibilities of the medical director or other authorized physicians within the program shall include but not be limited to:

(*a*) Ensuring 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 methadone dose.

(*b*) Ensuring that a medical evaluation including a medical history and physical examination have been performed before the patient receives the initial methadone dose. However, in an emergency situation the initial dose of methadone may be given before the physical examination.

(*c*) Ensuring that appropriate laboratory studies have been performed and reviewed.

(*d*) Signing or countersigning 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 methadone for emergency situations.)

(*e*) Reviewing and countersigning treatment plans at least annually.

(*f*) Ensuring 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 physical 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 methadone treatment shall be made by the medical director or other designated program physician, it is recognized that physicians can train program personnel to detect and document narcotic abstinence symptoms and that some jurisdictions allow State-licensed or certified health-care professionals, e.g., physician's associates, physician's assistants, nurse practitioners, to perform certain functions—record medical histories perform physical examinations, and prescribe, administer, or dispense certain medications—that are ordinarily performed by a licensed physician. These regulations do not prohibit these licensed or certified health-care professionals from performing those functions in narcotic treatment clinics which are authorized by Federal, State, and local laws and regulations, and which are delegated to them by the medical director. However, if a health-care professional performs functions that the physician is required by these regulations to perform, any resulting written comments and evaluations shall be reviewed, signed, and dated by the physician. For example, if, in accordance with State law, a health-care professional rather than physician records a medical history, performs a physical examination, or determines current physiological dependence and length of history of addiction, the physician shall review and countersign all work performed before the initial methadone dose may be administered to the patient. In all instances the responsibilities and duties of the health care professional shall be in accordance with State enabling legislation and regulations which govern the practice of health-care professionals.

(iv) *Emergency or other medical services.* Each program shall enter into a written agreement with a licensed and accredited hospital in the community for the purpose of providing necessary emergency, inpatient, and ambulatory care for program patients. Neither the program sponsor nor the hospital are required to assume financial responsibility for the patient's medical care.

(v) *Vocational rehabilitation, education, and employment.* (*a*) Each program shall provide opportunities directly, or through referral to community resources, for those patients who either desire or who have been deemed by the program staff ready to participate in educational job-training programs or to obtain gainful employment as soon as possible. Each program shall maintain a list of references that may be used for referral purposes if rehabilitative activities are not provided directly. The references shall include the opportunities for vocational training, education, and employment as well as the community resources that may be available to provide assistance for such activities.

(*b*) The patient's needs and readiness for vocational rehabilitation, education, and employment shall be evaluated and recorded in the patient's records during the preparation of the initial treatment plan and reviewed and updated as appropriate in subsequent treatment plan evaluations. It is recognized that some patients are either not ready for or are not in need of these services. Such a statement in the patient's record shall suffice to meet the requirement in this paragraph (d)(6)(v). For those patients who are deemed ready and are referred for such services, a program staff member designated and supervised by the admitting program physician shall document in the patient's record the type of referral made and the results. These results shall be periodically updated as appropriate.

(7) *Minimum 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 methadone 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.

(iii) *Minimum staff.* The person(s) responsible for a program shall ensure that there are at least four counselors per 300 patients.

(8) *Frequency of attendance; quantity of take-home medication; dosage of methadone; initial and stabilization*—(i) *Dosage and responsibility for administration.* (*a*) The person(s) responsible for the program shall ensure that the initial dose of methadone does not exceed 30 mg and that the total dose for the first day does not exceed 40 mg, unless the program medical director documents in the patient's chart that 40 mg did not suppress opiate abstinence symptoms.

(*b*) It is recommended practice that the initial dose of methadone be given in attempts to control or mitigate abstinence symptoms concomitant to withdrawal of narcotic drugs. Presently there is no absolute method available to determine individuals' narcotic tolerance levels. Therefore, in order to achieve this goal, it is recommended practice that the drug be given empirically in very small doses and the initial dose be adjusted on an individual basis to the narcotic tolerance of the new patients. Methadone dosages which are less than equivalent to the patient's current level of narcotic tolerance will result in his experiencing withdrawal symptoms. Therefore, it is important that the initial dose be adjusted on an individual basis to the narcotic tolerance of the new patient. If the patient has been a heavy user of heroin up to the day of admission, he may require an initial does of 15 to 30 mg with additional smaller increments 4 to 8 hours later. It is recommended practice that if the patient enters treatment with little or no narcotic tolerance (e.g., recently released from jail or using poor quality heroin), the initial dose may be one-half these quantities. When there is any doubt, the smaller dose should be used initially. The patient may be kept under observation, and if the symptoms of absti-

nence are distressing, an additional 5- to 10-mg dose should be administered as needed. Subsequently, the dosage should be adjusted individually as tolerated and required. The stabilization dose frequency, but not necessarily, is higher than the dose needed to attenuate abstinence. The range of methadone maintenance dosages in the country today is between 40 and 100 mg daily.

(c) A licensed physician shall resume responsibility for the amounts of methadone administered or dispensed and shall record and sign in each patient's chart each change in the dosage schedule.

(*d*) The administering licensed physician shall ensure that a daily dosage of 100 mg or more is justified in the medical record of each patient's chart and that a daily dose greater than 100 mg of methadone is not given to a new patient admitted to a program after (effective date of the final regulation) without the prior approval of the State methadone authority and the Food and Drug Administration.

(*e*) It is recommended practice that a regular review of each patient's dosage level be made by the responsible physician with careful consideration given for both increasing or decreasing the dosage as indicated. It should be noted that according to the official labeling, therapeutic doses of meperidine have precipitated severe reactions in patients currently receiving monoamine oxidase inhibitors or those who have received such agents within 14 days. Similar reactions thus far have not been reported with methadone, but if the use of methadone is necessary in such patients, it is recommended that a sensitivity test be performed in which repeated small incremental doses are administered over the course of several hours while the patient's condition and vital signs are under careful observation. Likewise, physicians should also be aware that according to the official labeling, concurrent administration of rifampin may possibly reduce the blood concentration of methadone to a degree sufficient to produce withdrawal symptoms. The mechanism by which rifampin may decrease blood concentrations of methadone is not fully understood, although enhanced microsomal drug-metabolized enzymes may influence drug disposition.

(ii) *Authorized dispensers of methadone; responsibility.* Methadone will be administered or dispensed by a practitioner licensed or registered under appropriate State or Federal law to order narcotic drugs for patients or by an agent of the practitioner, supervised by and pursuant to the order of the practitioner. This agent may only 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 methadone administered or dispensed and all changes in dosage schedule will be recorded and signed by the licensed practitioner.

(iii) *Form.* The methadone shall 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 in the attending physican's professional judgment it is deemed advisable. Although tablet, syrup concentrate, or other formulaions are permitted to be distributed to the program, all oral medication shall be administered or dispensed in a liquid formulation. The dosage will be formulated in such a way as to reduced its potential for parenteral abuse and accidental ingestion and packaged for outpatient use in special packaging as required by 16 CFR 1700.14. Any take-home medication shall be labeled with the treatment center's name, address and telephone number. Exceptions may be granted when any of the provisions of this subsection are in conflict with State law with regard to the administering or dispensing of drugs.

(iv) *Maximum take-home medication; evidence in support of a finding of responsibility in the handling of methadone and frequency of take-home medication.* (a) Take-home methadone shall only be given to a patient who, in the reasonable clinical judgment of the program physician, is responsible in the handling of methadone. Prior to reducing the frequency of clinic visits, the rationale for this decision shall be recorded in the patient's chart by the program physician or one of his designated staff. In the latter situation, a program physician shall review, countersign, and date the patient's record where this information is recorded. Additionally, take-home methadone shall be dispensed solely in an oral/liquid form so as to minimize its potential for abuse and shall be packaged in accordance with the Poison Prevention Packaging Act (Pub. L. 91–601).

(b) It is recommended practice that this liquid vehicle be nonsweetened and contain a preservative so that patients can be instructed to keep take-home methadone out of the refrigerator in an attempt to minimize the likelihood of accidental overdoses by children and fermentation of the vehicle.

(c) The program physician shall, in the exercise of his reasonable clinical judgment, consider the following in determining whether or not a patient is responsible in the handling of methadone.

(1) Background and history of the patient;

(2) General and special characteristics of the patient and the community in which the patient resides;

(3) Absence of past abuse of nonnarcotic drugs, including alcohol;

(4) Absence of current abuse of nonnarcotic drugs and alcohol and narcotic drugs, including methadone;

(*5*) Regularity of clinic attendance;

(*6*) Absence of serious behavioral problems in the clinic;

(7) Stability of the patient's financial condition;

(*8*) Stability of the patient's home environment;

(*9*) Stability of the patient's family and other relationships;

(*10*) Absence of past and/or current criminal activity;

(*11*) Length of time in methadone maintenance treatment; and

(*12*) Assurance that take-home medication can be safely stored within the patient's home.

(v) *Take-home requirements.* (*a*) In maintenance treatment a patient shall ingest the drug under observation daily or at least 6 days a week, for a minimum of the first 3 months. If, in the reasonable clinical judgment of the program physician, a patient demonstrates satisfactory adherence to program rules for at least 3 months, substantial progress in rehabilitation, responsibility in handling of methadone (see paragraph (d) (8) (iv) (*c*) (*1*)–(*12*) of this section), and his rehabilitative progress would be enhanced by decreasing the frequency of his clinic attendance, the patient may be permitted to reduce his clinic attendance, for drug ingestion under observation to three times weekly. Such a patient shall receive no more than a 2-day take-home supply of methadone. If, in the reasonable clinical judgment of the program physician, a patient demonstrates satisfactory adherence to program rules for at least 2 years from his entrance into the program, substantial progress in rehabilitation, responsibility in the handling of methadone (see paragarph (d) (8) (iv) (c) (*1*)–(*12*) of this section), and his rehabilitative progress would be enhanced by decreasing the frequency of his clinic attendance, the patient may be permitted to reduce his clinic attendance for drug ingestion under observation to twice weekly. Such a patient shall receive no more than a 3-day take-home supply of methadone.

(*b*) In calculating 2 years of methadone maintenance treatment, the period shall be considered to begin upon the first day of administration of methadone, or upon readmission of a patient who has had a continuous absence of 90 days or more. Cumulative time spent by the patient in more than one program shall be counted toward the 2 years of treatment unless there has been a continuous absence of 90 days or more. For patients maintained on methadone for 3 consecutive years who have demonstrated for at least the last year responsibility in handling of methadone, and the absence of major behavioral problems, a 6-day supply of take-home medication may be granted providing the medical director has entered into the patient's record an evaluation that such patients have satisfactorily adhered to each of the criteria for measuring responsibility in handling methadone as set forth in paragraph (d) (8) (iv) (*c*) (*4*)–(*12*) of this section. Each patient whose daily dose is above 100 mg shall ingest the medication under observation 6 days per week irrespective of the length of time in treatment, unless the program has received prior approval from the State authority and the Food and Drug Administration.

(vi) *Exceptions to take-home requirements.* The rationale for an exception

to a mandatory schedule shall be based on the reasonable clinical judgment of the program physician and shall be recorded in the patient's chart 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 chart where this rationale is recorded. In any event, a patient shall not be given more than a 2-week supply of methadone at one time. If in the reasonable clinical judgment of the program physician:

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

(*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, he may be permitted a temporarily reduced schedule provided he is also found to be responsible in the handling of methadone.

(9) *Minimum standards for detoxification treatment.* (i) For detoxification from narcotic drugs (not the gradual withdrawal of methadone from patients on methadone maintenance), methadone shall be administered by the program physician daily under close observation in reducing dosages over a period not to exceed 21 days. All requirements pertaining to maintenance treatment apply to detoxification treatment with the following exceptions:

(*a*) Take-home medication shall not be allowedt during detoxification.

(*b*) A history of 1 year physiologic dependence shall not be required for admission to detoxification.

(*c*) Patients who have been determined by the program physician to be currently physiologically narcotic dependent may be detoxified with methadone, regardless of age.

(*d*) The recommended initial dose is 15 to 20 mg.

(ii) A waiting period of at least 1 week shall be required between detoxification attempts. Before a 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)(9)(i) of this section, are applicable to both inpatient and ambulatory detoxification treatment.

(10) *Discontinuation of methadone use*—(i) *Involuntary termination from treatment.* The person(s) responsible for a program shall develop and prominently post about the program premises at least one copy of a written policy establishing criteria for involuntary termination from treatment which describes patients' rights as well as the responsibilities and rights of the program staff. At the time a patient enters treatment, an appropriate program staff member designated by the person(s) responsible for the program shall inform the patient where such copy is posted and shall inform him of the reasons for which he might be terminated from treatment, his rights to due process under involuntary termination procedure, and the fact that information about him shall be kept confidential.

(ii) *Voluntary withdrawal from methadone use.* All patients in treatment shall be given careful consideration for discontinuation of methadone use. Social rehabilitation shall have been maintained for a reasonable period of time. Patients should be encouraged to pursue the goal of eventual withdrawal from methadone and becoming completely drug free whenever possible. Upon successfully reaching for a drug-free state the patient should be retained in the program for as long as necessary to assure stability in the drug-free state, with the frequency of his required visits adjusted at the discretion of the medical director.

(11) *Inspections of programs; patient confidentiality.* Inspection of a program may be undertaken by the State authority, by the Food and Drug Administration, and by the Drug Enforcement Administration, Department of Justice, and in the case of federally funded programs by the National Institute on Drug Abuse, in accordance with Federal controlled substances laws and Federal confidentiality laws.

* * * * *

(14) *Research.* When a program conducts research on human subjects or provides subjects for research, there shall be written policies and review to assure the rights of the patients involved. Appropriate informed consent forms must be signed and must be present in the patient's records. All research, development, and related activities in which human subjects are involved which are funded by the Department of Health, Education, and Welfare grants or contracts must comply with the Department of Health, Education, and Welfare regulations on the protection of human subjects, 45 CFR Part 46.

(15) *Patient record system*—(i) *Patient care.* The person(s) responsible for a program shall establish for that program a record system to document and monitor patient care. This system shall comply with all Federal and State reporting requirements relevant to methadone. All records shall be kept confidential and must be 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 shall be maintained showing dates, quantity, and batch or code marks of the drug dispensed. These records shall be retained for a period of 3 years.

(iii) *Patient's clinical record.* An adequate clinical record will be maintained for each patient. The record will contain a copy of the signed consent form(s), the date of each visit, the amount of methadone administered or dispensed, the results of each urinalysis, a detailed account of any adverse reactions, which will also be reported within 2 weeks to the Food and Drug Administration on Form FD-1639. "Drug Experience Report," 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 so noted in the clinical 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 so noted in the clinical record. This method of recordkeeping helps assure the easy detection of sporadic attendance and decreases the possibility of administering inappropriate doses of methadone (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 will be recorded in the clinical record(s).

(16) *Security of drug stocks.* Adequate security shall be maintained over stocks of methadone, 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 security standards for the distribution and storage of controlled substances as required by the Drug Enforcement Administration, Department of Justice (§§ 1301.72-1301.76 of this title) shall be met by the program.

* * * * *

(f) *Conditions for use of methadone in hospitals for detoxification treatment*—(1) *Form.* The drug may be administered or dispensed in either oral or parenteral form.

(2) *Use of methadone in hospitals*—(i) *Approved uses.* Methadone for narcotic addict treatment is permitted to be administered or dispensed only for detoxification treatment of hospitalized patients. If methadone is administered for treatment of heroin dependence for more than 3 weeks, the procedure passes from treatment of the acute withdrawal syndrome (detoxification) to maintenance treatment. Maintenance treatment is permitted to be undertaken only by approved methadone programs. This does not preclude the maintenance treatment of an addict who is hospitalized for treatment of medical conditions other than addiction and who requires temporary maintenance treatment during the critical period of his stay or whose enrollment in a program which has approval for maintenance treatment using methadone has been verified. Any hospital which already has received approval under this paragraph (f) may be permitted to serve as a temporary methadone treatment program when an ap-

proved methadone treatment program has been terminated and there is no other facility immediately available in the area to provide methadone 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.

* * * * *

(vi) *Inspection.* The Food and Drug Administration and the State authority may inspect supplies of the drug and evaluate the uses to which the drug is being put. The identity of the patient will be kept confidential in accordance with confidentiality requirements of 42 CFR Part 2. Records relating to the receipt, storage, and distribution of narcotic medication shall also be subject to inspection as provided by 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 methadone for detoxification treatment will be submitted to the Food and Drug Administration and the State authority and shall receive approval from both, except as provided for in paragraph (h)(5) of this section. Within 60 days after receipt of the application by the Food and Drug Administration, the applicant will receive notification of approval or denial or a request for additional information, when necessary.

(viii) *Approval of shipments to hospital pharmacies.* Before a hospital pharmacy may lawfully receive shipments of methadone for detoxification treatment, a responsible official shall complete, sign, and file in triplicate with the Food and Drug Administration and the State authority Form FD–2636, "Hospital Request for Methadone for Detoxification Treatment" set forth in paragraph (k)(5) of this section and shall receive a notice of approval thereof from the Food and Drug Administration.

* * * * *

(g) *Confidentiality of patient records.* (1) Except as provided in paragraph (g)(2) of this section, disclosure of patient records maintained by any program shall be governed by the provisions of 42 C FR Part 2, and every program shall comply with the provisions of that part. Records relating to the receipt, storage, and distribution of narcotic medication shall also be subject to inspection as provided by 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. In addition to the restrictions upon disclosure in 42 CFR Part 2, and in accordance with the authority conferred by section 303(a) of the Public Health Service Act (42 U.S.C. 242a(a)), every program is hereby further authorized to protect the privacy of patients therein by withholding from all persons not employed by such program or otherwise connected with the conduct of its operations the names or other identifying characteristics of such patients under any circumstances under which such program has reasonable grounds to believe that such information may be used to conduct any criminal investigation or prosecution of a patient. Programs may not be compelled in any Federal, State, or local civil, criminal, administrative, or other proceedings to furnish such information, but this subparagraph does not authorize the withholding of information authorized to be furnished pursuant to 42 CFR Part 2 nor does it invalidate any legal process to compel the furnishing of information in accordance with 42 CFR Part 2. Records relating to the receipt, storage, and distribution of narcotic medication shall also be subject to inspection as provided by 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 relating to the use of methadone in accordance with the provisions of 42 CFR Part 2 and shall reveal them only when necessary in a related administrative or court proceeding.

* * * * *

(k) *Program forms*—(1) *Treatment program application.*

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

FOOD AND DRUG ADMINISTRATION

Form FD–2632 Application for Approval of Use of Methadone in a Treatment Program

Name or other identification of program---

Address ---

Name of program sponsor---

Commissioner,
Food and Drug Administration,
Bureau of Drugs (HFD–106),
Rockville, MD 20857.

DEAR SIR: As the person responsible for this program, I submit this request for approval of a treatment program using methadone to provide detoxification and maintenance treatment for narcotic addicts in accordance with § 291.505 of the regulations. I understand that failure to abide by the requirements described below may cause revocation of approval on my application, seizure of my drug supply, an injunction, and criminal prosecution.

I. Attached is the name, complete address, and summary of the scientific training and experience of each physician and all other professional personnel having major responsibilities for the program and rehabilitative efforts, and a signed Form FD–2633 "Medical Responsibility Statement for Use of Methadone in a Treatment Program" for every licensed practitioner authorized to prescribe, dispense, or administer methadone under the program. (If the Medical Director of this program has been listed for a program in a previous application, the feasibility of serving as Medical Director for this program must be documented and this documentation attached to this application.)

II. Attached is a description of the organizational structure of this program and the name and complete address of any central administration or larger organizational structure to which this program is responsible.

III. Attached is a listing of the sources of funding for this program. (The name and address for each governmental agency providing funding must be provided.)

IV. The program shall have ready access to a comprehensive range of medical and rehabilitative services. Attached is the name, address, and description of each hospital, institution, clinical laboratory facility, or other facility available to provide the necessary services and a statement for each facility as to whether or not methadone will be administered or dispensed at that facility. These facilities shall comply with any guidelines established by Federal or State authorities. (This listing should include the address of each medication unit. If any medical or rehabilitative service is not available at the primary facility, there must be a formal, documented agreement with private or public agencies, organizations, or institutions for these services.)

V. Attached is a statement of the approximate number of addicts to be included in the program

VI. The following minimum treatment standards shall be followed:

A. A statement shall be given to the addicts to inform them about the program. A voluntary request and consent Form FD–2635 "Consent to Methadone Treatment" shall be signed by each patient. Participation in the program shall be voluntary.

B. I concur that the mere use of a narcotic drug, even if periodic or intermittent, cannot be equated with narcotic addiction. Care shall be exercised in the selection of patients to prevent the possibility of admitting a person who was not first dependent upon heroin or other morphine-like drugs at least 1 year prior to admission to maintenance treatment (see § 291.505(d)(3)(i)). This drug history and evidence of current physiologic dependence on morphine-like drugs shall be documented. Evidence of physical dependence should be obtained by noting early signs of withdrawal (lacrimation, rhinorrhea, pupillary dilation, and piloerection) during the initial period of abstinence. (Withdrawal signs may be observed during an initial period of hospitalization or while the individual is an outpatient undergoing diagnostic evaluation—(medical and personal history, physical examination, and laboratory studies). Loss of appetite and increased body temperature, pulse rate, blood pressure, and respiratory rate are also signs of withdrawal, but their detection may require inpatient observation. It is unlikely that an individual would be currently dependent on narcotic drugs without having a positive urine test for one or more of these drugs. Additional evidence can be obtained by noting the presence of old and fresh needle marks, and by obtaining additional history from relatives and friends.)

C. An exception to the requirement for evidence of current physiologic dependence on narcotic drugs or to the age limitation will be allowed under the following exceptional circumstances: (1) Methadone treatment may be initiated within 14 days of release from a stay of 1 month or longer in a penal or chronic care institution, or within 6 months of release from such institution if an individual would have been eligible for admission prior to institutionalization (see § 291.505(d)(3)(iii)(a)), or (2) pregnant patients, regardless of age with a documented prior addiction history, may be eligible for maintenance treatment, if the Medical Director certifies the pregnancy and, in his judgment, such treatment is medically justified

(see § 291.505(d)(3)(iii)(b)). Within 3 months after the termination of the pregnancy, the physician shall enter an evaluation of the patient's treatment state into the patient's records indicating whether the patient should remain in a maintenance program or be detoxified. Justification for any such exception shall be noted on the patient's record.

D. Persons under 18 years of age may be eligible for maintenance treatment after two documented attempts at detoxification or drug-free treatment (see § 291.505(d)(3)(iv)). In addition, no one under the age of 16 is eligible for methadone maintenance treatment without the prior approval of the Food and Drug Administration and the State methadone authority.

No person under the age of 18 may be admitted to a maintenance treatment program unless a parent, legal guardian or responsible adult designated by the State authority completes and signs consent form, Form FD-2635 "Consent to Methadone Treatment."

VII. An admission evaluation and record shall be made and maintained for each patient upon admission to the program. This evaluation and record shall consist of a medical history, a physical examination, and laboratory examinations as indicated in § 291.505(d)(5).

A. A patient's history record will include at least age, sex, educational level, employment history, criminal history, past history of drug abuse of all types, and prior treatment for drug abuse as well as that required by § 291.505(d)(5)(iv).

B. Medical history. A thorough medical history record will be completed for each patient accepted for admission.

C. Physical examination. The findings of a comprehensive physical examination will be recorded.

VIII. I understand that there is a danger of drug dependent persons attempting to enroll in more than one methadone treatment program to obtain quantities of methadone either for the purpose of self-administration or illicit marketing. Therefore, except in an emergency situation, methadone will not be provided to a patient who is known to be currently receiving the drug from another treatment program using methadone. Except as provided in item XV of this form, information that could identify the patient will be kept confidential in compliance with 42 CFR Part 2.

IX. The following minimum procedures will be used for ongoing care.

A. Dosage and administration for detoxification and maintenance treatment:

1. Methadone shall be administered or dispensed in oral form only when used in a treatment program. Hospitalized patients under care for medical or surgical condition are permitted to receive methadone in parenteral form, when in the attending physician's professional judgment it is deemed advisable. Although tablet, sirup concentrate, or other formulations are permitted to be distributed to the program, all oral medication shall be administered or dispensed in a liquid formulation. The dosage shall be formulated in such a way as to reduce its potential for parental abuse and accidental ingestion, and packaged for outpatient use in special packaging as required by 16 CFR 1700.14. Any take-home medication shall be labeled with the treatment center's name, address, and telephone number. Exceptions may be granted when any of the provisions of this subsection are in conflict with State law with regard to the administering or dispensing of drugs.

2. In tetoxification, the patient may be placed on a substitutive methadone administration schedule when there are significant symptoms of withdrawal. The methadone shall be administered by the program physician daily under close observation in reducing dosages over a period not to exceed 21 days. All requirements pertaining to maintenance treatment apply to detoxification treatment with the following exceptions:

i. Take-home medication shall not be allowed during detoxification.

ii. A history of 1 year physiologic dependence shall not be required for admission to detoxification.

iii. Patients who have been determined by the program physician to be currently physiologically narcotic dependent may be detoxified with methadone, regardless of age.

iv. The recommended initial dose is 15 to 20 mg. Stabilization can be continued for 2 to 3 days and then the amount of methadone will normally be gradually decreased. The rate at which methadone is decreased will be determined separately for each patient. The dose of methadone can be decreased on a daily basis or in 2-day intervals, but the amount of intake shall always be sufficient to keep withdrawal symptoms at a tolerable level. In hospitalized patients a daily reduction of 20 percent of the total daily dose usually will be tolerated and will cause little discomfort. In ambulatory patients, a somewhat slower schedule may be needed. If methadone is administered for more than 3 weeks, the procedure is considered to have progressed from detoxification or treatment of the acute withdrawal syndrome to maintenance treatment, even though the goal and intent may be eventual total withdrawal.

3. In maintenance treatment the initial dosage of methadone should control the abstinence symptoms that follow withdrawal of narcotic drugs but should not be so great as to cause sedation, respiratory depression, or other effects of acute intoxification. It is important that the initial dosage be adjusted on an individual basis to the narcotic tolerance of the new patient. (The person(s) responsible for the program shall ensure that the initial dose of methadone does not exceed 30 mg and that the total dose for the first day does not exceed 40 mg, unless the program medical director documents in the patient's chart that 40 mg did not suppress opiate abstinence symptoms.) If the patient has been a heavy user of heroin up to the day of admission, he may require an initial dose of 15 to 30 mg with additional smaller increments 4 to 8 hours later. It is recommended practice that if the patient enters treatment with little or no narcotic tolerance (e.g., recently released from jail or using poor quality heroin), the initial dose may be one-half these quantities. When there is any doubt, the smaller dose should be used initially. The patient may be kept under observation, and if the symptoms of abstinence are distressing, an additional 5- to 10-mg dose should be administered as needed. Subsequently, the dosage should be adjusted individually as tolerated and required. The stabilization dose frequently, but not necessarily, is higher than the dose needed to attenuate abstinence. The range of methadone maintenance dosages in the conutry today is between 40 and 100 mg daily.

A licensed physician shall assume responsibility for the amounts of methadone administered or dispensed and shall record and sign in each patient's chart each change in the dosage schedule.

The administering licensed physician shall ensure that a daily dose of 100 mg or more is justified in the medical record of each patient's chart and that a daily dose greater than 100 mg of methadone is not given to a new patient admitted to a program after (effective date of the final regulation) without the prior approval of the State methadone authority and the Food and Drug Administration. A regular review of dosage level should be made by the responsible physician with careful consideration given for reduction of dosage as indicated on an individual basis. A new dosage level is only a test level until stability is achieved.

4. Caution shall be taken in the maintenance treatment of pregnant patients. Dosage levels shall be maintained as low as possible if continued methodane treatment is deemed necessary. It is the responsibility of the program to assure that each female patient is fully informed concerning the possible risks to a pregnant woman or her unborn child from the use of methadone.

5. Methadone will be administered or dispensed by a practitioner licensed or registered under appropriate State or Federal law to order narcotic drugs for patients or by an agent of the practitioner, supervised by and pursuant to the order of the practitioner. This agent may 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 methadone administered or dispensed and all changes in dosage schedule shall be recorded and signed by the licensed practitioner.

6. For detoxification, the drug shall be administered daily under close observation. In maintenance treatment the patient initially will ingest the drug under observation daily, or at least 6 days a week, for the first 3 months. It is recognized that diversion occurs primarily when patients take medication from the clinic for self-administration. It is also recognized, however, that daily attendance at a program facility may be incompatible with gainful employment, education, and responsible homemaking. After demonstrating satisfactory adherence to the program regulations for at least 3 months and showing substantial progress in rehabilitation by participating actively in the program activities and/or by participation in educational, vocational, and homemaking activities, those patients whose employment, education, or homemaking responsibilities would be hindered by daily attendance may be permitted to reduce to 3 times weekly the times when they must ingest the drug under observation. They shall receive no more than a 2 day take-home supply. With continuing adherence to the program's requirements and progressive rehabilitation for at least 2 years after entrance into the program, such patients may be permitted twice weekly visits to the program for drug ingestion under observation with a 3 day take-home supply.

In calculating 2 years of methadone maintenance treatment, the period shall be considered to begin upon the first day of administration of methadone, or upon readmission of a patient who has had a continuous absence of 90 days or more. Cumulative time spent by the patient in more than one program shall be counted toward the 2 years of treatment unless there has been a continuous absence of 90 days or more. For patients maintained on methadone for 3 consecutive years who have demonstrated for at least the last year responsibility in handling of methadone, and the absence of major behavioral problems, a 6-day supply of take-home medication may be granted providing the medical director has entered into the patient's record an evaluation that such patients have satisfactorily adhered to each of the criteria for measuring responsibility in handling methadone as set forth in § 291.505(d)(8)(iv)(c)(4)-(12). Each patient whose daily dose is above 100 mg shall ingest the medication under observation 6 days per week irrespective of the length of time in treatment, unless the program has received

prior approval from the State authority and the Food and Drug Administration.

The rationale for an exception to a mandatory schedule shall be based on the reasonable clinical judgment of the program physician and shall be recorded in the patient's chart 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 chart where this rationale is recorded. In any event, a patient shall not be given more than a 2-week supply of methadone at one time.

If in the reasonable clinical judgment of the program physician a patient is found to have a physicial disability that interferes with such patient's ability to conform to the applicable mandatory schedule, he or she may be permitted a temporarily or permanently reduced schedule provided he or she is also found to be responsible in the handling of methadone; or 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, he or she may be permitted a temporarily reduced schedule provided he or she is also found to be responsible in the handling of methadone (see § 291.505(d)(8)(iv)).

B. In maintenance treatment an initial drug-screening urinalysis will be performed upon admission for opiates, cocaine, barbiturates, amphetamines, and other drugs as appropriate. The urine shall be collected in a manner which minimizes falsification of the samples. The reliability of this collection procedure shall be demonstrated. Those patients receiving their doses of the drug from medication units will also adhere to this minimum standard. Each laboratory selected for urine testing must be in compliance with all applicable Federal proficiency testing and licensing standards and all State standards regarding such laboratories. Any changes in laboratories used for urine testing shall have prior approval of the Food and Drug Administration.

C. An adequate clinical record will be maintained for each patient. The record will contain a copy of the signed consent form(s), the date of each visit, the amount of methadone administered or dispensed, the results of each urinalysis, a detailed account of any adverse reactions, which will also be reported within 2 weeks to the Food and Drug Administration on Form FD-1639, "Drug Experience Report", any significant physical or psychologic disability, the type of rehabilitative and counseling efforts employed, an account of the patient's progress, and other relevant asepcts 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 so noted in the clinical 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 so noted in the clinical record. This method of recordkeeping helps assure the easy detection of sporadic attendance and decreases the possibility of administering inappropriate doses of methadone (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 treatment plan will be recorded in the clinical record and signed by the program physician (see § 291.505(d)(5)(vi)).

D. All patients in maintenance treatment will be given careful consideration for discontinuance of methadone, especially after reaching a 10-20 milligram dosage level. Social rehabilitation shall have been maintained for a reasonable period of time. Patients should be encouraged to pursue the goal of eventual withdrawal from methadone and becoming completely drug-free. Upon successfully reaching a drug-free state the patient should be retained in the program for as long as necessary to assure stability in the drug-free state, with the frequency of required visits adjusted at the discretion of the medical director.

X. To prevent diversion into illicit channels, adequate security shall be maintained over stocks of methadone and over the manner in which it is distributed, as required by the Drug Enforcement Administration, Department of Justice.

XI. Accurate records traceable to patients shall be maintained showing dates, quantity, and batch or code marks of the drug used. These records shall be retained for a period of 3 years.

XII. The program director may establish geographically dispersed medication units of reasonable size for administering and dispensing medication to patients stabilized at their optimal dosage level. The approval of such units for any geographic area shall be based upon the number and distribution of such units within the area. No more than 30 patients shall be under care at a medication unit at any one time. These units shall be responsible only for administering and dispensing medication. Private practitioners and community pharmacies may serve as medication units. Only after patients have been stabilized at their optimal initial dosage level may they be referred to a medication unit. Subsequent to such referral, the program director shall retain continuing responsibility for the patient's care and the patient shall be seen at the primary program facility at least monthly for medical evaluation and ancillary service. If a private practitioner wishes to provide other service in addition to administering and dispensing medication and collecting urine samples, the practitioner is considered a program component or a separate program, depending upon the type of services provided. In such case the restrictions on the number of patients served shall be determined by the staffing pattern and resources available.

XIII. All representations in this application are currently accurate, and no changes shall be made in the program until they have been approved by the Food and Drug Administration and the State authority.

XIV. If the program or any individual under the program is disapproved, the program director shall recall the methadone from the disapproved sources and return the drug to the manufacturer in a manner prescribed by the Drug Enforcement Administration, Department of Justice.

XV. Inspections of this program may be undertaken by the State authority, by the Food and Drug Administration and by the Drug Enforcement Administration, Department of Justice, and, in the case of federally funded programs, by the National Institute on Drug Abuse, in accordance with Federal controlled substances laws and Federal confidentiality laws.

Signature _____
(Program Sponsor)

(2) *Medical responsibility statement.*

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

FOOD AND DRUG ADMINISTRATION

Form FD-2633 Medical Responsibility Statement for Use of Methadone in a Treatment Program

(To be completed by each physician licensed to dispense or administer methadone under an approved program.)

Date _____
Name of program _____
Address _____
Telephone number _____

Medical Director for this facility (licensed by law to administer or dispense drugs and responsible for all medication administered or dispensed at this facility).

_____
Address of this facility _____
Telephone number of this facility _____

I. The undersigned agrees to assume responsibility for the administration and dispensing of methadone under the above identified program and to abide by the minimum standards for methadone detoxification and maintenance treatment.

II. The name of each patient treated at a facility and the frequency of visits shall be registered with the medical director. An annual report Form FD-2634 "Annual Report for Treatment Program Using Methadone" shall be submitted to the program sponsor for submission to the Food and Drug Administration. The patient shall always report to the same facility unless prior approval is obtained from the medical director for treatment at another operation.

III. The following minimum treatment standards shall be followed.

A. A statement shall be given to the addicts to inform them about the program. A voluntary request and consent Form FD-2635 "Consent to Methadone Treatment" shall be signed by each patient. Participation in the program shall be voluntary.

B. The mere use of a narcotic drug, even if periodic or intermittent, cannot be equated with narcotic addiction. Care shall be exercised in the selection of patients to prevent the possibility of admitting a person who was not first dependent upon heroin or other morphine-like drugs at least 1 year prior to admission to maintenance treatment (see § 291.505(d)(3)(i)). This drug history and evidence of current physiologic dependence on morphine-like drugs shall be documented. Evidence of physical dependence should be obtained by noting early signs of withdrawal (lacrimation, rhinorrhea, pupillary dilation, and piloerection) during the initial period of abstinence. Withdrawal signs may be observed during an initial period of hospitalization or while the individual is an outpatient undergoing diagnostic evaluation (medical and personal history, physical examination, and laboratory studies). Loss of appetite and increased body temperature, pulse rate, blood pressure, and respiratory rate are also signs of withdrawal, but their detection may require inpatient observation. It is unlikely that an individual would be currently dependent on narcotic drugs without having a positive urine test for one or more of these drugs. Additional evidence can be obtained by noting the presence of old and fresh needle marks, and by obtaining additional history from relatives and friends.

C. An exception to the requirement for evidence of current physiologic dependence on narcotic drugs or to the age limitations will be allowed under the following exceptional circumstances: (1) Methadone treatment may be initiated within 14 days of release from a stay of 1 month or longer in a penal or chronic care institution, or within 6 months of release from such institution if an individual would have been eligible for admission prior to institutionalization (see § 291.505(d)(3)(iii)(a)), or (2) pregnant patients, regardless of age with a documented prior addiction history, may be eligible for maintenance treatment if the Medical Director certifies the pregnancy and, in his or her judgment, such treatment is medically justified (see § 291.505(d)(3)(iii)(b)). Within 3 months after the termination of

the pregnancy, the physician shall enter an evaluation of the patient's treatment state into the patient's records indicating whether the patient should remain in a maintenance program or be detoxified. Justification for any such exception shall be noted on the patient's record.

D. Persons under 18 years of age may be eligible for maintenance treatment after two documented attempts at detoxification or drug-free treatment (see § 291.505(d)(3)(iv)). In addition, no one under the age of 16 is eligible for methadone maintenance treatment without the prior approval of the Food and Drug Administration and the State methadone authority.

No person under the age of 18 may be admitted to a maintenance treatment program unless a parent, legal guardian or responsible adult designated by the State authority completes and signs consent form, Form FD-2635 "Consent to Methadone Treatment."

IV. An admission evaluation and record shall be made and maintained for each patient upon admission to the program. This evaluation and record shall consist of a medical history, a physical examination, and laboratory examinations as indicated in § 291.505(d)(5).

A. A patient's history record will include at least age, sex, educational level, employment history, criminal history, past history of drug abuse of all types, and prior treatment for drug abuse, as well as that required by § 291.505(d)(5)(iv).

B. Medical history. A thorough medical history record will be completed for each patient accepted for admission.

C. Physical examination. The findings of a comprehensive physical examination will be recorded.

V. I understand that there is a danger of drug dependent persons attempting to enroll in more than one methadone treatment program to obtain quantities of methadone either for the purpose of self-administration or illicit marketing. Therefore, except in an emergency situation, methadone will not be provided to a patient who is known to be currently receiving the drug from another treatment program using methadone. Except as provided in item XI of this form, information that could identify the patient will be kept confidential in compliance with 42 CFR Part 2.

VI. The following minimum procedures will be used for ongoing care.

A. Dosage and administration for detoxification and maintenance treatment:

1. Methadone shall 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 in the attending physician's professional judgment it is deemed advisable. Although tablet, syrup concentrate, or other formulations are permitted to be distributed to the program, all oral medication shall be administered or dispensed in a liquid formulation. The dosage shall be formulated in such a way as to reduce its potential for parenteral abuse and accidental ingestion, and packaged for outpatient use in special packaging as required by 16 CFR 1700.14. Any take home medication shall be labeled with the treatment center's name, address and telephone number. Exceptions may be granted when any of the provisions of this subsection are in conflict with State law with regard to the administering or dispensing of drugs.

2. In detoxification, the patient may be placed on a substitutive methadone administration schedule when there are significant symptoms of withdrawal. The methadone shall be administered by the program physician daily under close observation in reducing dosages over a period not to exceed 21 days. All requirements pertaining to maintenance treatment apply to detoxification treatment with the following exceptions:

i. Take-home medication shall not be allowed during detoxification.

ii. A history of 1 year physiologic dependence shall not be required for admission to detoxification.

iii. Patients who have been determined by the program physician to be currently physiologically narcotic dependent may be detoxified with methadone, regardless of age.

iv. The recommended initial dose should be 15 to 20 mg. Stabilization can be continued for 2 to 3 days and then the amount of methadone will normally be gradually decreased. The rate at which methadone is decreased will be determined separately for each patient. The dose of methadone can be decreased on a daily basis or in 2 day intervals, but the amount of intake shall always be sufficient to keep withdrawal symptoms at a tolerable level. In hospitalized patients a daily reduction of 20 percent of the total daily dose usually will be tolerated and will cause little discomfort. In ambulatory patients, a somewhat slower schedule may be needed. If methadone is administered for more than 3 weeks, the procedure is considered to have progressed from detoxification or treatment of the acute withdrawal syndrome to maintenance treatment, even though the goal and intent may be eventual total withdrawal.

3. In maintenance treatment the initial dosage of methadone should control the abstinence symptoms that follow withdrawal of narcotic drugs but should not be so great as to cause sedation, respiratory depression, or other effects of acute intoxification. It is important that the initial dosage be adjusted on an individual basis to the narcotic tolerance of the new patient. (The person(s) responsible for the program shall ensure that the initial dose of methadone does not exceed 30 mg and that the total dose for the first day does n otexceed 40 mg, unless the program medical director documents in the patient's chart that 40 mg did not suppress opiate abstinence symptoms.) If the patient has been a heavy user of heroin up to the day of admission, he may require an initial dose of 15 to 30 mg with additional smaller increments 4 to 8 hours later. It is recommended practice that if the patient enters treatment with little or no narcotic tolerance (e.g., recently released from jail or using poor quality heroin), the initial dose may be one-half these quantities. When there is any doubt, the smaller dose should be used initially. The patient may be kept under observation, and if the symptoms of abstinence are distressing, an additional 5- to 10-mg dose should be administered as needed. Subsequently, the dosage should be adjusted individually as tolerated and required. The stabilization dose frequently, but not necessarily, is higher than the dose needed to attenuate abstinence. The range of methadone maintenance dosages in the country today is between 40 and 100 mg daily.

A licensed physician shall assume responsibility for the amounts of methadone administered or dispensed and shall record and sign in each patient's chart each change in the dosage schedule.

The administering licensed physician shall ensure that a daily dose of 100 mg or more is justified in the medical record of each patient's chart and that a daily dose greater than 100 mg of methadone is not given to a new patient admitted to a program after (effective date of the final regulation) without the prior approval of the State methadone authority and the Food and Drug Administration. A regular review of dosage level should be made by the responsible physician with careful consideration given for reduction of dosage as indicated on an individual basis. A new dosage level is only a test level until stability is achieved.

4. Caution shall be taken in the maintenance treatment of pregnant patients. Dosage levels shall be maintained as low as possible if continued methadone treatment is deemed necessary. It is the responsibility of the program sponsor to assure that each female patient is fully informed concerning the possible risks to a pregnant woman or her unborn child from the use of methadone.

5. Methadone will be administered or dispensed by a practitioner licensed or registered under appropriate State of Federal law to order narcotic drugs for patients or by an agent of the practitioner, supervised by and pursuant to the order of the practitioner. This agent may only 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 methadone administered or dispensed and all changes in dosage schedule shall be recorded and signed by the licensed practitioner.

6. For detoxification, the drug shall be administered daily under close observation. In maintenance treatment the patient initially will ingest the drug under the observation daily, or at least 6 days a week, for the first 3 months. It is recognized that diversion occurs primarily when patients take medication from the clinic for self-administration. It is also recognized, however, that daily attendance at a program facility may be incompatible with gainful employment, education, and responsible homemaking. After demonstrating satisfactory adherence to the program regulations for at least 3 months and showing substantial progress in rehabilitation by participating actively in the program activities and/or by participation in educational, vocational, and homemaking activities, those patients whose employment, education or homemaking responsibilities would be hindered by daily attendance may be permitted to reduce to three times weekly the times when they must ingest the drug under observation. They shall receive no more than a 2-day take-home supply. With continuing adherence to the program's requirements and progressive rehabilitation for at least 2 years after entrance into the program, such patients may be permitted twice weekly visits to the program for drug ingestion under observation with a 3-day take-home supply.

In calculating 2 years of methadone maintenance treatment, the period shall be considered to begin upon the first day of administration of methadone, or upon readmission of a patient who has had a continuous absence of 90 days or more. Cumulative time spent by the patient in more than one program shall be counted toward the 2 years of treatment unless there has been a continuous absence of 90 days or more. For patients maintained on methadone for 3 consecutive years who have demonstrated for at least the last year responsibility in handling of methadone, and the absence of major behavioral problems, a 6-day supply of take-home medication may be granted providing the medical director has entered into the patient's record an evaluation that such patient's have satisfactorily adhered to each of the criteria for measuring responsibility in handling methadone as set forth in § 291.505(d)(8)(iv)(c)(4)-(12). Each patient whose daily dose is above 100 mg shall ingest the medication under observation 6 days per week irrespective of the length of time in

treatment, unless the program has received prior approval from the State authority and the Food and Drug Administration.

The rationale for an exception to a mandatory schedule shall be based on the reasonable clinical judgment of the program physician and shall be recorded in the patient's chart 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 chart where this rationale is recorded. In any event a patient shall not be given more than a 2-week supply of methadone at one time.

If in the reasonable clinical judgment of the program physician: a patient is found to have a physical disability which interferes with his ability to conform to the applicable mandatory schedule, he may be permitted a temporarily or permanently reduced schedule provided he is also found to be responsible in the handling of methadone; or 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, he may be permitted a temporarily reduced schedule provided he is also found to be responsible in the handling of methadone (see § 291.505 (d) (8) (iv)).

B. In maintenance treatment an initial drug-screening urinalysis will be performed upon admission for opiates, cocaine, barbiturates, amphetamines and other drugs as appropriate. The urine shall be collected in a manner which minimizes falsification of the samples. The reliability of this collection procedure shall be demonstrated. Those patients receiving their doses of the drug from medication units will also adhere to this minimum standard. Each laboratory selected for urine testing must be in compliance with all applicable Federal proficiency testing and licensing standards and State standards regarding such laboratories. Any changes in laboratories used for urine testing shall have prior approval of the Food and Drug Administration.

C. An adequate clinical record will be maintained for each patient. The record will contain a copy of the signed consent form(s), the date of each visit, the amount of methadone administered or dispensed, the results of each urinalysis, a detailed account of any adverse reactions, which will also be reported within 2 weeks to the Food and Drug Administration on Form FD–1639, "Drug Experience Report," any significant physical or psychologic 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 so noted in the clinical 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 so noted in the clinical record. This method of recordkeeping helps assure the easy detection of sporadic attendance and decreases the possibility of administering inappropriate doses of methadone (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 treatment plan will be recorded in the clinical record and signed by the program physician (see § 291.505(d) (5) (iv)).

D. All patients in maintenance treatment will be given careful consideration for discontinuance of methadone especially after reaching a 10 to 20 milligrams dosage level. Social rehabilitation shall have been maintained for a reasonable period of time. Patients should be encouraged to pursue the goal of eventual withdrawal from methadone and becoming completely drug-free. Upon successfully reaching a drug-free state the patient should be retained in the program for as long as necessary to assure stability in the drug-free state, with the frequency of required visits adjusted at the discretion of the medical director.

To prevent diversion into illicit channels, adequate security shall be maintained over stocks of methadone and over the manner in which it is distributed, as required by the Drug Enforcement Administration, Department of Justice.

VII. Accurate records traceable to patients shall be maintained showing dates, quantity, and batch or code marks of the drug used. These records shall be retained for a period of 3 years.

VIII. The program director may establish geographically dispersed medication units of reasonable size for administering and dispensing medication to patients stabilized at their optimal dosage level. The approval of such units for any geographic area shall be based upon the number and distribution of such units within the area. No more than 30 patients shall be under care at a medication unit at any one time. These units shall be responsible only for administering and dispensing medication. Private practitioners and community pharmacies may serve as medication units. Only after patients have been stabilized at their optimal initial dosage level may they be referred to a medication unit. Subsequent to such referral, the program director shall retain continuing responsibility for the patient's care and the patient shall be seen at the primary program facility at least monthly for medical evaluation and ancillary service. If a private practitioner wishes to provide other service in addition to administering and dispensing medication and collecting urine samples, the practitioner is considered a program component or a separate program, depending upon the type of services provided. In such case the restrictions on the number of patients served shall be determined by the staffing pattern and resources available.

IX. All representations in this application are currently accurate, and no changes shall be made in the program until they have been approved by the Food and Drug Administration and the State authority.

X. If the program or any individual under the program is disapproved, the program director shall recall the methadone from the disapproved sources and return the drug to the manufacturer in a manner prescribed by the Drug Enforcement Administration, Department of Justice.

XI. Inspections of this program may be undertaken by the State authority, by the Food and Drug Administration and by the Drug Enforcement Administration, Department of Justice, and, in the case of federally funded programs, by the National Institute on Drug Abuse, in accordance with Federal controlled substances laws and Federal confidentiality laws.

Signature _____

(3) *Annual report form.*

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

FOOD AND DRUG ADMINISTRATION

Form FD–2634 Annual Report for Treatment Program Using Methadone

This form shall be completed in triplicate by the program sponsor for each calendar year.

One copy is to be sent to the Food and Drug Administration and one copy to the State authority on or before Januray 30.

I. Name or other identification of program _____

Address _____

II. Total Treatment Capacity _____

III. Amount of methadone dispensed (in grams) during the year: _____

IV. Number of individuals who applied to the program but were not admitted or given admission evaluation _____

V. Number of individuals who were provided only detoxification one or more times _____

VI. Census of patients provided methadone maintenance treatment _____

A. Number under care at the beginning of the year being reported _____

B. Of those in treatment at the beginning of the year:

1. Number continuously under care through the year being reported (still under care) _____

2. Number discharged or transferred to other types of programs and not readmitted _____

3. Number discharged or transferred to other types of programs and readmitted (still under care) _____

4. Number discharged and readmitted (no longer under care) _____

C. Number admitted to care during year ____, not previously treated in this program:

1. Number still under care at the end of the year _____

2. Number discharged or transferred to other types of programs and not readmitted _____

3. Number discharged or transferred to other types of programs and readmitted (still under care) _____

4. Number discharged and readmitted (no longer under care) _____

D. Number admitted to care during the year ____, previously treated in this program prior to the past year:

1. Number still under care at the end of the year _____

2. Number discharged or transferred to other types of programs and not readmitted _____

3. Number discharged and transferred to other types of programs and readmitted (still under care) _____

4. Number discharged and readmitted (no longer under care) _____

VII. Demographic and treatment characteristics of patients under care at the end of the year being reported:

A. By age and sex:

Age	Total	Male	Female
Under 14			
14–15			
16–17			
18–20			
21–25			
26–35			
36–45			
46+			

B. For the year being reported, give the number of patients who have been under continuous care for the following periods of time:

Under 3 months _____

3 months to 1 year _____

1 to 2 years _____

2 to 5 years _____

Over 5 years _____

C. Total number of individuals treated to date _____

D. For the year being reported, give the number of patients stabilized at each dosage level:

Daily dosage, mgm.	*Number of patients*
Under 20	
20 to 39	
40 to 59	
60 to 79	
80 to 99	
100 to 119	
Over 120	

E. When applicable, for the year being reported, give the number of patients seen in the past 8 weeks who have fallen in the following categories:

No positive urinalysis for morphine for 2 months or more_____

Occasional positive urinalysis for morphine (monthly or less)_____

Frequent positive urinalysis for morphine (more than once per month)_____

In program for less than 2 months_____

For the year being reported, give the number of patients treated who were pregnant _____

VIII. Give the number of patients having significant adverse reactions, particularly reactions related to hematopoietic, cardiovascular, endocrine, neurologic, and immunological functions (attach a completed copy of Form FD–1639, "Drug Experience Report," for each incident not previously reported to the Food and Drug Administration):

Type of reaction	*Number of patients*

IX. Give the number of patients who have died while under methadone care (attach a completed copy of Form FD–1639, "Drug Experience Report," for each incident not previously reported to the Food and Drug Administration):

	Number of patients
A. Definitely methadone-related	
B. Not methadone-related	

Signature _____

(Program sponsor)

* * * * *

(5) *Hospital application.*

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

FOOD AND DRUG ADMINISTRATION

Form FD–2636 Hospital Request for Methadone for Detoxification Treatment

Name of hospital_____
Address _____

Commissioner,
Food and Drug Administration,
Bureau of Drugs (HFD–106),
Rockville, MD 20857.

DEAR SIR: As hospital administrator, I submit this request for approval to receive supplies of methadone to be used for detoxification treatment in accord with § 291.505 of the regulations. I understand that the failure to abide by the requirements described below may result in revocation of approval to receive shipments of methadone, seizure of the drug supply on hand, injunction, and criminal prosecution.

I. The name of the individual (pharmacist) responsible for receiving and securing supplies of methadone is _____.

II. There are a total of _____ beds in the hospital.

III. A general description of the hospital and nature of patient care undertaken is attached.

IV. The anticipated quantity of methadone needed for narcotic addict treatment per year is _____ (Gms.).

V. Methadone for narcotic addict treatment is permitted to be administered or dispensed only for detoxification treatment of hospitalized patients. If methadone is administered for treatment of heroin dependence for more than 3 weeks, the procedure passes from treatment of the acute withdrawal syndrome (detoxification) to maintenance treatment. Maintenance treatment is permitted to be undertaken only by approved methadone programs. This does not preclude the maintenance treatment of an addict 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 methadone has been verified.

VI. Accurate records shall be maintained showing dates, quantity, and batch or code marks of the drug for inpatient treatment. The records shall be retained for a period of 3 years.

VII. Inspections of supplies of the drug and an evaluation of the use to which the drug is being put may be undertaken by the State authority, by the Food and Drug Administration, by the Drug Enforcement Administration, Department of Justice, and, when appropriate, by the National Institute on Drug Abuse, in accordance with Federal controlled substances laws and Federal confidentiality laws.

Signature_____
(Hospital Official)

Interested persons may, on or before December 27, 1977 submit to the Hearing Clerk (HFC–20), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville Md. 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

The Food and Drug Administration and the National Institute on Drug Abuse have determined that this document does not contain a major proposal requiring preparation of an economic impact statement under Executive Order 11821, as amended by Executive Order 11949, and OMB Circular A–107. A copy of the economic impact assessment is on file with the Hearing Clerk, Food and Drug Administration.

Dated: October 13, 1977.

DONALD KENNEDY,
Commissioner, Food and Drug Administration.

Dated: October 19, 1977.

ROBERT DUPONT,
Director, National Institute on Drug Abuse.

[FR Doc.77–31163 Filed 10–27–77;8:45 am]

[4110–03]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Alcohol, Drug Abuse, and Mental Health Administration

[Docket No. 77N–0252]

METHADONE IN MAINTENANCE AND DETOXIFICATION

Joint Proposed Revision of Conditions for Use

CROSS REFERENCE: For a document setting forth the Food and Drug Administration and the National Institute on Drug Abuse proposed revision of the conditions for use of methadone to allow greater flexibility of clinical standards and to provide more specificity in areas in which the proposed clinical standards mandate levels of performance, see FR Doc. 77–31163 appearing at page 56897 in this issue of the FEDERAL REGISTER.

[4110–03]

[Docket No. 77N–0253]

NARCOTIC TREATMENT PROGRAM STANDARDS

Use of Narcotic Drugs Other Than Methadone by Narcotic Treatment Programs; Joint Notice of Intent To Propose Regulations and Request for Data, Information, and Views

CROSS REFERENCE: For a document announcing the intent of the Food and Drug Administration and the National Institute on Drug Abuse to propose regulations and their request for data, information, and views on several specific issues concerning the use of narcotic drugs other than methadone, see FR Doc. 77–31071 appearing at page 56896 in this issue of the FEDERAL REGISTER.