ARKANSAS REGISTER

Transmittal Sheet

W. J. "Bill" McCuen
Secretary of State
State Capitol Rm. 010
Little Rock, Arkansas 72201-1094

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Name of Agency Bureau of Alcohol and Drug Abuse Prevention

Department Department of Health

Contact Person Garland S. Ferguson Telephone: (501) 778-8820

Statutory Authority for Promulgating Rules Arkansas Act 644 of 1977; the Division of of Alcohol and Drug Abuse Prevention's Policies and Procedures, page v. Item 9; 21 CFR Pt. 291 CFR Pt. 291.505 (b)(2)(i),(c)(5), Food and Drug Administration, HHS Regulation

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Adopted by State Agency . . . . . Oct. 1, 1993

CERTIFICATION OF AUTHORIZED OFFICER

I Hereby Certify That The Attached Rules Were Adopted In Compliance with Act 434 of 1967 As Amended.

Joe M. Hill
Signature

Arkansas Department of Health
Bureau of Alcohol & Drug Abuse Prevention
Title

August 6, 1993
Date

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CERTIFICATION

This will certify the Methadone Treatment Program Standards were adopted according to the Arkansas Administrative Procedures Act after a Public Hearing on the 26th day of August, 1993 held in Little Rock, Arkansas at the State Health Building and review by the Subcommittee on Administrative Rules and Regulations on the 8th day of September, 1993 in a meeting at the State Capitol.

Interim Director,
Arkansas Department of Health

The foregoing Standards having been filed in my office are hereby adopted on this 4 day of October, 1993.

Jim Guy Tucker,
Governor

FILED
AR. REGISTER DIV.
93 OCT -6 PM 1:41
W.J. "BILL" McCUEN
SECRETARY OF STATE
LITTLE ROCK, ARKANSAS
BY

03.25.93-001

JIM GUY TUCKER
GOVERNOR

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Bureau of Alcohol and Drug Abuse Prevention
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October 4, 1993

W.J. "Bill" McCuen
Secretary of State
State Capitol
Little Rock, AR 72201

Dear Mr. McCuen:

Please publish the attached Rules and Regulations in the Arkansas Register. If there are any questions please call or write.

Sincerely,

Joe M. Hill

Joe M. Hill,
Director
Bureau of Alcohol and Drug Abuse Prevention

JMH:sw

Enclosures

METHADONE TREATMENT PROGRAM STANDARDS

ARKANSAS DEPARTMENT OF HEALTH

BUREAU OF ALCOHOL AND DRUG ABUSE PREVENTION

October 1, 1993

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METHADONE TREATMENT PROGRAM STANDARDS

§ I. INTRODUCTION

The Bureau of Alcohol and Drug Abuse Prevention (ADAP) has developed standards for the administration of Methadone Treatment Programs in Arkansas.

The goal of methadone treatment is total rehabilitation of the patient. While eventual withdrawal from the use of drugs, including methadone, may be an appropriate treatment goal, some patients may remain on methadone maintenance for relatively long periods of time. Periodic consideration of withdrawing from methadone maintenance is appropriate only if it is in the individual patient's interest. Such considerations are between the patient and the treatment facility.

The Program shall be progressive in nature, addressing the patient's individual needs with methadone as only one component of comprehensive treatment services.

§ II. REGULATORY AUTHORITY

The authority for these rules is A.C.A. §§ 20-64-602, 20-64-704, and 20-64-903.

Persons, partnerships, associations or corporations applying for approval as a treatment program providing methadone services shall meet the requirements of these Standards. In addition, the Bureau of Alcohol and Drug Abuse Prevention shall accredit Arkansas programs providing methadone services in accordance with A.C.A. § 20-64-901, et seq.

The treatment program providing methadone services, hereinafter referred to as "Program," shall comply with applicable federal, state and local laws and regulations including those under the jurisdiction of the Food and Drug Administration, the Drug Enforcement Administration and the State Authority, as well as laws and regulations governing equal employment opportunity and non-discrimination of patients.

§ III. DEFINITIONS:

The following definitions apply to Programs.

A. Accreditation

Accreditation is the process by which the the Bureau of Alcohol and Drug Abuse Prevention determines if a person, partnership, association, or corporation may operate an alcohol and drug abuse treatment program as provided by A.C.A. § 20-64-901, et seq.

B. Accreditation Standards for Alcohol and Other Drug Abuse Treatment Programs

Accreditation Standards for Alcohol and Drug Abuse Treatment Programs are the standards developed by the Bureau of Alcohol and Drug Abuse Prevention which accredited treatment programs shall meet.

C. Administrative Detoxification

Administrative Detoxification is the gradual, medically controlled withdrawal of methadone from a patient for violation or infraction of a Program policy.

D. Applicant Screening

Applicant Screening is the act of determining eligibility for treatment.

E. Alcohol and Drug Management Information System (ADMIS)

Alcohol and Drug Management Information System (ADMIS) is the management information system for the collection and reporting of patient related data prescribed by the State Authority.

F. Counselor

A Counselor is one of the following:

1) A Certified Substance Abuse Counselor recognized by the Arkansas Substance Abuse Certification Board;
2) A Social Worker licensed by the State of Arkansas, and who by virtue of education, training or experience, provides treatment, which includes advice, opinion, or instruction to an individual or in a group setting to allow opportunity for a person to explore his or her problems related directly or indirectly to alcohol and or other drug abuse or dependence;
3) An individual who has at least a Bachelor's Degree in a behavioral science, and who by virtue of education, training or experience, provides treatment, which includes advice, opinion, or instruction to an individual or in a group setting to allow opportunity for a person to explore his or her problems related directly or indirectly to alcohol and or other drug abuse or dependence.

G. Definitive Laboratory Results

Definitive Laboratory Results are confirmatory tests done by a National Institute of Drug Abuse (NIDA) certified laboratory.

H. Detoxification Treatment

Detoxification Treatment means the dispensing of a narcotic drug in decreasing doses to an individual to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period.

I. Family

Family means individuals who claim relationship to others either by heredity or by law.

J. Medical Director

A Medical Director is a physician licensed to practice medicine in the State of Arkansas who assumes responsibility for the administration of medical services performed by the Program, including ensuring that the Program is in compliance with federal, state and local laws and regulations regarding the medical treatment of narcotic addiction with a narcotic drug.

K. Methadone Maintenance

Methadone Maintenance means the dispensing of methadone for more than 180 days in the treatment of an individual for dependence on heroin or other morphine-like drug.

L. Narcotic Dependent

A Narcotic Dependent is an individual who physiologically needs heroin or a morphine-like drug to prevent the onset of signs of withdrawal.

M. Presumptive Laboratory Results

Presumptive Laboratory Results are screening test results that have not been confirmed by a National Institute of Drug Abuse (NIDA) certified laboratory.

N. Program

A Program is an entity that:

1) Administers or dispenses an approved narcotic drug to a narcotic addict for maintenance or detoxification treatment; and
2) Provides a comprehensive range of medical and rehabilitative services; and
3) Is approved by the State Authority and the Food and Drug Administration; and
4) Is registered with the Drug Enforcement Administration to use a narcotic drug for the treatment of narcotic addiction; and
5) Is open at least six (6) days a week.

O. Program Sponsor

A Program Sponsor is a person (or representative of an organization) who is responsible for the operation of a Program and who assumes responsibility for its employees, including practitioners, agents or other persons providing services at the Program (including its medication units) and is knowledgeable of substance abuse treatment issues.

P. Services

Services are program components rendered to patients which shall include, but are not limited to:

1) Medical evaluations; and
2) Counseling; and
3) Rehabilitative and other social programs (e.g., vocational and educational guidance, employment placement) which shall help the patient become a productive member of society.

Q. Significant Other

A Significant Other is an individual who has an intimate relationship with another, but who is not related by heredity or law.

R. State Authority

State Authority means the Director, or designee, of the Arkansas Department of Health - Bureau of Alcohol and Drug Abuse Prevention, or its successor.

S. Take-Home Medication

Take-Home Medication refers to those doses of methadone consumed by the patient under conditions of no direct observation by a medical provider.

§ IV. ACCREDITATION

The Bureau of Alcohol and Drug Abuse Prevention shall accredit persons, partnerships, associations or corporations establishing, conducting, managing, or operating an alcohol and drug abuse treatment program as provided by A.C.A. § 20-64-901, et seq.

§ V. CONFIDENTIALITY OF ALCOHOL AND DRUG ABUSE PATIENT INFORMATION

The Program shall comply with state and federal regulations governing confidentiality of alcohol and drug abuse patient records and other patient identifying information. Existing federal regulation (42 CFR, Part 2) provides for safeguarding files or other patient identifying information from access by unauthorized individuals, and requires that records be maintained in a secure manner. The ADAP may review records for the purpose of monitoring execution of the standards. The Program shall

make records available to the ADAP upon request. In addition, access by the Food and Drug Administration and the Drug Enforcement Administration is also allowed for determination of compliance with FDA or DEA regulations.

§ VI. APPLICANT SCREENING

Applicant screening shall be extensive and thorough and shall form the basis for effective, long-term treatment planning. It shall include a staff assessment as to appropriateness of treatment, that admission is voluntary, and that the patient understands the risks, benefits, and options. Prescription methadone is a highly addictive substance and entry into a Program is a critical decision for both the patient and the Program. Before admitting an applicant to methadone treatment, the Program shall satisfy itself that the applicant fully understands the reasons for and ramifications of administrative detoxification and that the applicant voluntarily enters the program with that knowledge.

§ VII. ADMISSION CRITERIA

A. The Program shall verify the applicant's name, address, date of birth and other critical identifying data.

B. The Program shall document a one (1) year history of addiction and current physiologic dependence. A one (1) year history of addiction means a period of continuous or episodic addiction for the one (1) year period immediately prior to application for admission to the Program. Documentation may consist of the applicant's past treatment history, presence of clinical signs of addiction, such as old and fresh needle marks, constricted or dilated pupils, or an eroded or perforated nasal septum.

C. For applicants who are under the age of eighteen (18), the Program shall document two (2) unsuccessful attempts at drug-free treatment prior to being considered for admission to a Program. Note: Admit no person under the age of sixteen to a Program without the prior approval of the State Authority.

D. The Program shall give admission priority to pregnant women (see § X.).

The Medical Director may refuse treatment with a narcotic drug to a particular patient if, in the reasonable clinical judgement of the Medical Director, the patient would not benefit from such treatment. Prior to such a decision, appropriate staff may be consulted, as determined by the Medical Director.

§ VIII. READMISSION CRITERIA

Readmission to a Program depends on whether a patient who is seeking readmission previously withdrew from methadone on a voluntary basis or as a result of an administrative decision due to the patient's violation of Program policies.

A. A patient, treated and later voluntarily detoxified from methadone maintenance treatment, may be readmitted to the Program without evidence to support findings of current physiologic dependence, up to two (2) years after discharge, if the Program attended is able to document prior methadone maintenance treatment of six (6) months or more, and the admitting physician, in his or her reasonable clinical judgment, finds readmission to methadone maintenance treatment medically justified.

B. Patients seeking readmission to a Program after an administrative detoxification shall at a minimum wait thirty (30) days prior to applying for readmission. If a Program administratively detoxifies a patient twice in a year then the patient shall wait twelve (12) months to reapply for admission.

§ IX. EXCEPTIONS TO MINIMUM ADMISSION REQUIREMENTS:

A. An applicant who has been residing in a correctional institution for one (1) month or longer may enroll in a Program within fourteen (14) days before release or discharge or within six (6) months after release from such an institution without evidence of current physiologic dependence on narcotics provided that prior to his or her institutionalization the patient would have met the one (1) year admission criteria (see § VII. B.).

B. A Program may place a pregnant applicant on a maintenance regimen, regardless of age, if the applicant has had a documented narcotic dependency in the past and may be in direct jeopardy of returning to narcotic dependency, with its attendant dangers during pregnancy. The applicant need not show evidence of current physiologic dependence on narcotic drugs if a Program physician certifies the pregnancy and, in his or her reasonable clinical judgment, justifies medical treatment.

§ X. SERVICES TO WOMEN

The Program shall test women of childbearing age for pregnancy at the time of admission unless medical personnel determine that the test is unnecessary.

In addition to federal laws and regulations regarding pregnant patients, the Program shall implement written policies and procedures to ensure the accessibility of services to pregnant women. The Program shall:

A. Give priority to pregnant women in its admission policy;

B. Arrange for medical care during pregnancy by appropriate referral, and verify that the patient receives medical care as planned.

§ XI. TREATMENT STRUCTURE

The Program shall provide the patient a full range of treatment and rehabilitative services. The absence of the use of controlled substances, except as medically prescribed; social, emotional, behavior and vocational status; and other individual patient needs shall determine the frequency and extent of the services.

The assessment and treatment team shall consist of a Medical Director, medical staff and counselors who shall assess the patient's needs and, with the patient's input, develop a treatment plan. The primary counselor shall sign the treatment plan. As part of developing a treatment plan, the patient shall have input in establishing or adjusting dosage levels. The assessment and treatment team shall staff each case at least once each thirty (30) days during the first ninety (90) days of treatment and at least once each ninety (90) days thereafter. The Medical Director shall sign off on the initial treatment plan when developed and the comprehensive treatment plan on an annual basis.

A. Services to each patient shall include individual, group and family counseling at the following minimum levels:

Phase I

Phase I consists of a minimum ninety (90) day period in which the patient attends the Program for observation daily or at least six (6) days a week.

Phase I requires at least four (4) hours of counseling per week during the initial three (3) months following admission or until the patient achieves two (2) day take-home medication status, whichever is longer. The counseling sessions at a minimum shall consist of three (3) hours of group therapy sessions and one (1) hour of individual counseling per week. The assessment and treatment team and the patient shall determine the patient's assignment of group therapy attendance. The issues to be discussed in group therapy sessions shall consist of at a minimum but not be limited to the following:

1) Family or Significant Others; and
2) Living Skills; and
3) Methadone Maintenance; and
4) Peer Confrontation; and
5) Positive Drug Screen; and
6) Educational Training; and
7) Vocational Training and or Employment; and
8) Acquired Immunodeficiency Syndrome (AIDS) Education as Related to Human Immunodeficiency Virus (HIV).

In addition, patients shall attend at least one (1) self-help 12-step type meeting per week. The assessment and treatment team and the patient shall negotiate a methadone detoxification plan with potential target

dates for implementation in Phase V. Such a plan may be short-term or long-term in nature based on the patient's need and may include intermittent periods of methadone maintenance between detoxification attempts.

Prior to a patient moving to Phase II or receiving take-home medication, the patient shall demonstrate a level of stability as evidenced by the following:

1) Absence of alcohol and other drug abuse; and
2) Regularity of Program attendance; and
3) Absence of significant behavior problems; and
4) Absence of recent criminal activities; and
5) Employment, actively seeking employment or attending school if not retired, disabled or functioning as a homemaker.

In addition, the patient shall provide assurance to the Program regarding the safe transportation and storage of take-home medication (see § XIII.G.).

Phase II

A patient, admitted more than three (3) months but less than two (2) years and successfully completing Phase I, shall attend the Program no less than three (3) times weekly. The Program may issue no more than two (2) take-home doses at a time and no more than a total of four (4) take-home doses in a week.

During the first three (3) months of Phase II a patient shall attend at least two (2) hours of counseling (one of which shall be individual) and two (2) self-help group meetings per week. For the remainder of Phase II, or until the patient achieves three (3) day take-home medication status, whichever is longer, the patient and primary counselor shall determine a patient's counseling and self-help activities provided that the minimum level of service delivery shall be one (1) hour of counseling per week and two (2) self-help group meetings per week.

Phase III

A patient, admitted more than two (2) years but less than three (3) years and successfully completing Phase II, shall attend the Program no less than two (2) times weekly. The Program may issue no more than three (3) take-home doses at a time and no more than a total of five (5) take-home doses in a week.

Phase III requires at least one (1) hour counseling per month in addition to attendance at one (1) self-help group meeting per week for three (3) years following admission or until the patient achieves a six (6) day take-home medication status, whichever is longer. The one (1) hour counseling may be either individual counseling or group therapy, as determined by staff and patient.

Phase IV

The Program may provide a six (6) day supply of methadone if a patient, admitted for three (3) years, has successfully completed Phase III.

Phase IV requires at least one (1) hour counseling per month in addition to attendance at two (2) self-help group meetings per month as long as the patient maintains a six (6) day take-home medication status.

Phase V

During the above four (4) phases a patient, in consultation with the assessment and treatment team, may elect to enter Phase V.

This phase implements the methadone detoxification plan. The Program physician determines the take-home dosage schedule for the patient. The primary counselor determines the number of counseling sessions provided during this phase based on the clinical judgment of the primary counselor with input from the patient. At the onset of Phase V, the patient may require an increased level of support services (i.e., increased levels of individual, group counseling, etc.). Prior to successful completion of Phase V the primary counselor and patient shall develop a plan that shall integrate the patient into a drug-free treatment regimen for ongoing support.

B. The patient's use of controlled substances except as medically prescribed, deterioration of social, emotional, vocational or behavioral status; and or other individual needs shall result in increased frequency and extent of treatment and rehabilitation services.

C. The Program shall assess each patient for referral, if appropriate, to Employment Security Division, vocational training and or enrollment in school. The Program shall conduct a follow-up at least every thirty (30) days.

§ XII. SPECIAL STAFFING

The Program shall conduct a special staffing to determine an appropriate response whenever a patient has two (2) or more urinalyses in a one (1) year period that are positive for drugs other than methadone. The Medical Director shall use test results as a guide to change treatment approaches and not as the sole criteria to force a patient out of treatment. When using test results, the Medical Director shall distinguish presumptive laboratory results from definitive laboratory results.

§ XIII. PROGRAM RESPONSIBILITIES

A. Admission

Upon admission the Program shall:

1. Obtain the applicant's signature on a voluntary agreement admitting the applicant to the program.

2. Verify the applicant's identification, including name, address, date of birth and other critical identifying data from social security card, birth certificate, driver's license, etc. Copies of this identifying information shall become a part of the patient's record.

3. Obtain a complete medical history from each patient being admitted to treatment. The medical and laboratory examination of each patient shall include:

   a) Investigation of the possibility of infectious disease and possible concurrent surgery problems; and
   b) The complete blood count and differential; and
   c) Serological test for syphilis; and
   d) Routine and microscopic urinalysis toxicology screening for drugs; and
   e) Multiphasic chemistry profile; and
   f) Intramural PPD, administered and interpreted by the medical staff; and
   g) A chest x-ray, Pap smear, biological test for pregnancy or screening for sickle cell disease if the examining medical personnel request these tests.

   The Program shall not require a medical examination for a patient transferring to a new Program who received a medical and laboratory examination within three (3) months prior to admission to the new Program. The Program physician may request a medical and laboratory examination for a transferring patient. However, the new Program physician shall have, as part of the transfer summary, a medical summary and statement from the patient's previous Program that indicates a significant medical problem. The transferred record shall include copies of the previous examination prior to admission.

4. Conduct and complete a counseling intake interview and develop a narrative psychosocial history within thirty (30) days of the patient's admission. This psychosocial narrative shall form the basis for preparing future treatment plans.

5. Develop a written statement, signed by the Medical Director, that the applicant is competent to sign the voluntary agreement admitting them to the Program.

6. Verify that the patient is not currently enrolled in another methadone treatment program.

B. **Program Policies**

1. The Program shall implement a written policy that states the Program shall not deny treatment to a person based on his or her actual or perceived sero status, HIV related condition, or AIDS.

2. Program staff shall receive training on the subject of HIV infection and treatment of HIV infected patients.

3. The Program shall have written policies for infection control which are not in conflict with the Center for Disease Control Guidelines.

4. The Program shall provide AIDS education to patients and shall provide or refer patients for HIV pre-test counseling and voluntary HIV testing. If the Program does test for AIDS, it shall be with the informed consent of the patient. The Program shall assure the provision of pre- and post-test counseling for the patients.

5. The Program shall provide medical evaluations to patients periodically and at least annually

6. The Program shall provide or refer patients for tuberculosis and sexually transmitted disease (STD) testing upon admission and at least annually thereafter.

7. The Program shall develop written policies and procedures for continued methadone treatment in the event of an emergency or natural disaster.

8. The Program shall have hours which provide for early morning and late evening services.

9. The Program shall implement written policies and procedures to ensure positive identification of the patient before methadone is administered.

10. The Program shall develop written policies regarding the recording of patient medication intake and a daily methadone inventory.

11. The Program shall require a six (6) day Program attendance when the patient receives a daily dose greater than 100 milligrams.

12. The Program shall develop and implement written policies and procedures to contact other methadone treatment programs within a 200 mile radius to prevent duplication of services to an individual. The policy shall be in accordance with Federal Confidentiality Regulations (42 CFR, Part 2).

13. The program shall monitor a patient's progress and shall satisfy itself that the patient is continuing to benefit from treatment.

C. **Program Security**

Programs are subject to Drug Enforcement Administration regulations concerning the Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances (Chapter II Parts 1301 - 1307). Patients shall be physically separated from the narcotic storage and dispensing area. The Program shall not allow patients to congregate or loiter on the grounds or around the facility wherein the Program operates.

D. **Patient Records**

Patient records shall contain at a minimum:

1) Documents and test results as generated by activities in § XIII.A.; and
2) Patient progress in treatment case notes; and
3) Results of case staffings; and
4) Results of drug screening tests; and
5) Such treatment plan reviews as required by § XI, herein; and
6) Any other patient related material deemed appropriate by the Program.

E. **Urinalysis**

The Program shall complete an initial drug screening test or analysis for each patient upon admission. The Program shall conduct new patient urine drug screening weekly for the first three (3) months in treatment. The Program may place a patient who completes three months of urine drug screening showing no indications of drug abuse on a monthly urine testing schedule. Programs shall implement procedures, including the random collection of samples, to effectively minimize the possibility of falsification of the sample. The Program shall use urine testing as a clinical tool for the purposes of diagnosis and the development of treatment plans. After admission, the results of a single urine screening report shall not determine significant treatment decisions. Patients on a monthly schedule for whom urine screening reports indicate positive results for drugs other than methadone shall return to a weekly schedule for a period of time clinically indicated by the physician.

The Program shall analyze each urine sample for opiates, methadone, amphetamines, cocaine, benzodiazephines, barbiturates, marijuana and other drugs as may be indicated by patient's use patterns. Laboratories that perform the testing required under this regulation shall be in compliance with applicable Federal proficiency testing and licensing standards and applicable state standards.

F. Dosage Reporting Requirements

The Medical Director may order methadone dosages in excess of 100 milligrams but less than 120 milligrams only where medically indicated. The Medical Director shall fully document the reasons for the dosage level and report to the State Authority such orders. The Medical Director shall obtain prior written approval from the State Authority for methadone dosage orders in excess of 120 milligrams.

G. Take-Home Medication

The requirement of time in treatment is a minimum reference point after which a patient may be eligible for take-home medication privileges. The time reference does not mean that a patient in treatment for a particular time has a specific right to take-home medication. Since the use of take-home privileges creates a danger of not only diversion, but also accidental poisoning, the Medical Director must make every attempt to ensure that take-home medication is given only to patients who will benefit from it and who have demonstrated responsibility in handling methadone. Thus, regardless of time in treatment, a Medical Director may, in his or her reasonable judgment, deny or rescind the take-home medication privileges of a patient. Concurrently, the patient shall provide assurance to the Program that take-home medication can be safely transported and stored by the patient for the patient's use only.

H. 24-Hour Emergency Services

Patients shall have access to the Program in case of an off-hour emergency. The Program shall maintain a 24-hour Emergency Hot-Line with individuals designated as on-call to deal with patient emergencies.

I. Transferring or Visiting Patients

When a patient transfers from one Program to another, the transferring Program shall send copies of the transferring patient's records to the accredited receiving Program prior to admission. Transferring patients shall enter Phase I for a minimum of two (2) weeks. With successful completion of Phase I, they shall enter the appropriate treatment phase.

Individuals visiting the State of Arkansas who are part of a methadone treatment program, shall have their home program provide information to an accredited Program prior to the individual's arrival in the state. The Arkansas Program shall provide qualified visiting patients up to twenty-eight (28) days of methadone medication. However, take-home privileges shall not be greater than the privileges accorded by the home program, and in no case for longer than six (6) days.

J. Discharge Procedures

In order to remain in the Program and to successfully move through treatment, patients shall be in compliance with Program rules or risk administrative detoxification from methadone. For the purpose of these standards, an infraction means threats of violence or actual bodily harm to staff or another patient, disruptive behavior, community incidents (loitering, diversion of methadone, sale or purchase of drugs), continued unexcused absences from counseling and other support services, involvement in criminal activities and other serious rule violations. Patients may also be discharged for failure to benefit from the Program (see § XIII.B.13.). When a Program determines to discharge a patient, the Program shall provide a written statement containing:

1) The reason(s) for discharge; and
2) Written notice of his or her right to request review of the decision by the Program director or his or her designee; and
3) A copy of the appeal procedures.

K. Community Liaison and Concerns

1. A Program shall instruct patients not to cause unnecessary disruption to the community by loitering in the vicinity of the Program, or engaging in disorderly conduct or harassment. The Program may discharge patients who cause such disruption to the community pursuant to § XIII.J. of these Standards.

2. Each Program shall provide the State Authority with a specific plan to avoid disrupting the community and the actions it shall take to assure responsiveness to community needs. The State Authority may require that such plan include forming a committee of representative members of the community. Such committee shall meet on a regular basis.

3. Further actions to assure responsiveness may include, but are not limited to, the assignment of a staff member to act as community liaison, the establishment of a hot line between the community and the Program administration, the assignment of staff to patrol the Program vicinity, and the provision of educational material to the immediate community regarding methadone treatment.

L. Staff Training

In an effort to maintain quality care, the Program shall develop a training plan for personnel that fosters consistency of care in accordance with rapidly evolving knowledge in the methadone treatment field. Treatment staff shall receive at a minimum thirty (30) clock hours of training per year. In addition, the Program shall develop a method of rapidly disseminating information about pharmacological issues and other advances in the field.

§ XIV. RECORD KEEPING AND REPORTING REQUIREMENTS

A. The Program shall report patient admissions, environment changes and discharges to the Program to the Bureau of Alcohol and Drug Abuse Prevention using the Alcohol and Drug Management Information System (ADMIS). The Program shall complete and submit reports by the 7th day of the following month.

B. The Program shall keep such records and make such reports as required by the Drug Enforcement Administration (DEA) as required by § 1304.01 - 1304.38 of Chapter II - Drug Enforcement Administration, Department of Justice, Part 1304 Records and Reports of Registrants.

C. The Program shall adhere to record keeping and reporting requirements of the Food and Drug Administration, HHS, § 291.505(d)(13). These records shall include but not be limited to (i) Patient Care, (ii) Drug Dispensing, (iii) Patient's Record.

D. The Program shall provide the State Authority with records as required by Drug Enforcement Administration and Food and Drug Administration regulations.

E. The Program shall provide other reports as required by the State Authority.

F. The Program shall maintain Program records for at least five (5) years. The Program shall not destroy records that are part of an unresolved audit or investigation.

§ XV. APPEAL PROCESS

A. <u>Patient Appeal Rights</u>

Decisions regarding a patient's treatment by staff are subject to appeal. The Program shall develop appeal procedures that allow direct appeal to the State Authority. The State Authority shall approve these procedures. In addition, procedures shall include a provision that a central file of patient appeals be maintained at the Program site for review by the State Authority staff. The Program shall post a list of patient rights in a conspicuous place.

B. <u>Program Appeal Rights</u>

1. An entity may appeal the disapproval of an application or Program closure to the State Authority. § 2.05 of the Bureau of Alcohol and Drug Abuse Prevention's Policies and Procedures Manual contains the steps for the Appeal Process for Adverse Action.

2. If the Federal Drug Administration revokes approval of an application to receive shipments of narcotic drugs, the Program may appeal to the Federal Drug Administration as outlined in 21 CFR, Part 291, Drugs Used For Narcotic Addicts, 291.505(h)(5).

§ XVI. PROGRAM CLOSURE

Failure of the Program to adhere to Food and Drug Administration or Drug Enforcement Administration regulations or Standards of the State Authority may result in revocation of accreditation and closure of the Program.

The State Authority shall report Programs recommended for closure to the Federal Drug Administration for revocation of the right to receive shipments of narcotic drugs in accordance with 21 CFR, 291.505(h).