

PROPOSED RULEMAKING

DEPARTMENT OF HEALTH

[4 PA. CODE CH. 263]

[28 PA. CODE CHS. 701 AND 715]

Drug and Alcohol Facilities and Services

The Department of Health (Department) proposes to amend narcotic addiction treatment standards for the approval of narcotic addiction treatment programs under the powers and duties contained in Articles IX and X of the Public Welfare Code (62 P. S. §§ 901—922, 1001—1031 and 1051—1059) and the Pennsylvania Drug and Alcohol Abuse Control Act (71 P. S. §§ 1690.101—1690.115).

The Department proposes to replace narcotic addiction treatment standards by adding Chapter 715 (relating to standards for approval of narcotic treatment program), amending § 701.1 (relating to definitions) and repealing 4 Pa. Code Chapter 263 (relating to methadone), to read as set forth in Annex A.

Purpose

The purpose of these amendments is to revise and update current narcotic addiction treatment standards for the approval of narcotic addiction treatment programs to conform with updated Federal regulations. The Federal regulations were revised in 1994 and treatment of the narcotic addict has changed over the past 25 years. Therefore, the need exists to amend State methadone regulations to more closely align with the Federal regulations, as well as incorporate current treatment practices for narcotic addicts.

The Department's Division of Drug and Alcohol Program Licensure (Division) inspects narcotic treatment programs on an annual basis.

Chapter 715 is being created to replace current narcotic addiction treatment regulations in 4 Pa. Code Chapter 263. Existing regulations as applied are not consistent with current health practices or Federal requirements. They are more burdensome than Federal regulations.

Requirements of the Regulations

A. Definitions

§ 701.1. General definitions.

The proposal would amend this section by adding nine definitions related to narcotic treatment. In addition, several definitions would be deleted. The new definitions encompass the deleted definitions and reflect the new and current practices related to narcotic addiction treatment. These definitions clarify and explain certain terms that are specific to narcotic treatment. For example, a narcotic or opiate dependent person is a specific type of drug dependent person. These proposed amendments directly address the special needs and requirements associated with treating narcotic dependents. These regulations are in addition to the general provisions required for treatment of all drug and alcohol dependent patients.

§ 715.1. General provisions.

This section would provide generally that these regulations would apply to any entity which operates a narcotic treatment program and uses approved opiod pharmacotherapy agents.

§ 715.2. Relationship of Federal and State regulations.

This section would require narcotic treatment programs to comply with Federal regulations and requirements and when there is a difference between State and Federal regulations, the stricter requirement applies.

§ 715.3. Approval of narcotic treatment programs.

This section would establish the general requirements for approval of all narcotic treatment programs, including existing programs. All programs would be subject to inspection and approval from both State and Federal regulators. Each year, all programs would be required to be in compliance with the regulations.

This section also addresses Department coordination with Federal agencies.

§ 715.4. Denial, revocation or suspension of approval.

This section would establish provisions for denying, tracking or suspending a license. This section would also establish a link to the Federal regulations whereby the states can recommend to the Federal agencies to initiate proceedings to revoke or deny Federal approval.

§ 715.5. Patient capacity.

This section would provide the Department with the ability to limit the number of patients that may be treated at a narcotic treatment program at any one time. A program may request an increase in the approved capacity from the Department in writing.

§ 715.6. Physician staffing.

This section would set forth the requirements, responsibilities and qualifications applicable to medical directors and physicians at narcotic treatment programs. It would set forth the qualifications that are required for one to serve as a medical director. It would also provide a mechanism for programs to obtain the services of a person as medical director who does not meet the qualifications. This section would also set forth the number of physician hours for which the physician must be onsite and also, availability for consultations and verbal medication orders, and allow for physicians' assistants or certified registered nurse practitioners to perform certain medical functions under the supervision of a physician.

§ 715.7. Dispensing or administering staffing.

This section would establish staffing requirements for the manual dispensing and administering of controlled substances by a narcotic treatment program. Also addressed would be the automatic dispensing system and corresponding staff requirements.

§ 715.8. Psychosocial staffing.

This section would require that narcotic treatment programs comply with staffing ratios in Chapter 704 (relating to staffing requirements for drug and alcohol treatment activities).

§ 715.9. Intake.

This section would require screening of narcotic treatment program applicants prior to admission. The criteria for acceptance of an applicant would be included. There would be the following three exceptions to the eligibility criteria: a 1 year history of physiologic dependency would not be required for detoxification or pregnant addicts, a physical examination and lab tests would not be required for a re-admitted patient who was out of treatment for

less than 6 months after a voluntary termination, and evidence of physiologic dependency would not be required for re-admission of patients previously admitted and voluntarily detoxified within the past 2 years.

§ 715.10. Pregnant patients.

This section would establish requirements for the admission and treatment of pregnant patients. This is subject matter that is not addressed in the regulations the Department is proposing for repeal. This would be included because of the increasing rate of heroin addiction among pregnant women. These programs are designed to take into account the special circumstances surrounding pregnant opiate addicts and to promote the health and safety of the babies. In addition, there are special restrictions for the use of LAAM with regard to pregnant patients. These restrictions and requirements are identified in this section.

§ 715.11. Confidentiality of patient records.

This section reiterates that narcotic treatment programs shall comply with Federal and State confidentiality requirements regarding patient records.

§ 715.12. Informed patient consent.

This section would require an informed, voluntary consent prior to the administering of an agent for other detoxification or maintenance treatment.

§ 715.13. Patient identification.

This section would require narcotic treatment programs to develop a system for patient identification. It is necessary to assure that the drug is being administered to the appropriate patient, that security of the agent is maintained and that improper doses are not being administered to the wrong individuals and that treatment progress is being accurately maintained.

§ 715.14. Urine testing.

This section would update urine testing procedures to conform with Federal standards and to current practices. It would require testing for certain specific substances. A program may choose to test for additional substances. However, to mandate additional testing, would be too costly and burdensome to programs and results in minimal additional benefits for purposes of narcotic addiction testing.

§ 715.15. Medication dosage.

This section would require narcotic treatment programs to meet various Federal standards relating to narcotic treatment medication dosage. The current State regulations require projects to obtain Department approval prior to increasing dosage above 80 mg. The process of obtaining waivers from the Department is time consuming, and inefficient. This process would be eliminated. The new regulation would permit the physician to make reduction changes and those in excess of the Federal requirement would require the physician to document in the patient's chart the rationale for dosages above the Federal requirements.

§ 715.16. Take-home privileges.

This section would establish requirements for patients to be eligible to take medication out of the program and self-administer outside the supervision of the program. A minimal time period of adherence to program rules, policies and procedures is established. Exceptions are provided for special circumstances that are determined on a case-by-case basis.

§ 715.17. Medication control.

This section would require programs to develop and implement policies and procedures relating to pharmaceutical services, verbal medication orders and medications.

§ 715.18. Rehabilitative services.

This section would revise the requirements for rehabilitative services. Prior requirements do not accurately reflect current practices. This section would establish a full range of services that are to be provided.

§ 715.19. Psychotherapy services.

This section would establish requirements for psychotherapy services to be provided to patients.

§ 715.20. Patient transfers.

This section would require each narcotic treatment program to develop policies regarding the transfer of patients to another narcotic treatment program or another treatment environment upon the request of the patient. The concern has been that once a patient requests a transfer, for whatever reason, facilities often attempt to keep the patient longer than the patient wishes or to talk to the patient out of transferring. This causes an adverse environment for both the facility and the patient.

§ 715.21. Patient termination.

This section would require narcotic treatment programs to establish policies regarding termination of clients from the program.

§ 715.22. Patient grievance procedures.

This section would establish procedures for reviewing and resolving any patient grievances.

§ 715.23. Patient records.

This section would establish the time period which records must be kept after a patient leaves the program. It would further establish minimum information requirements that must be kept in the patient file. This section would also require an annual evaluation of the patient's status by the counselor and medical director.

§ 715.24. Narcotic detoxification.

This section would establish minimum procedures for detoxification services provided by narcotic treatment programs. Minimum standards will be established, but programs are permitted to implement additional procedures, provided they are not in conflict with the minimum standards.

§ 715.25. Prohibition of medication units.

This section would prohibit medication units. Medication units are simply dispensing stations or places where patients receive medication without any accompanying treatment or counseling services. The full advantage of narcotic treatment cannot be realized when a patient merely receives medication. The patient must also have other psychosocial services in conjunction with dispensing of medication. Studies have shown that the success of treatment is greatly improved when other services are provided.

§ 715.26. Security.

This section would establish requirements for security of controlled substances and the requirement for a narcotic treatment program to develop a plan as to how the facility will address community concerns regarding activities of clients outside the program walls.

§ 715.27. *Readmission.*

This section would provide for priority consideration for re-admission into a narcotic treatment program to be given to patients who had voluntarily left the program. This consideration would provide incentive to seek re-admission to those who had success in the program but relapsed after termination.

§ 715.28. *Unusual incidents.*

This section would require a narcotic treatment program to develop a procedure to document and respond to unusual incidents.

§ 715.29. *Exceptions.*

This section would establish a procedure for exceptions to the regulations to be requested by a narcotic treatment program. Also, documentation of any exception action would be required.

§ 715.30. *Applicability.*

This section would establish that the regulations would apply to the use of any agent whether currently approved for use or subsequently approved after the promulgation of these regulations.

Affected Persons

All staff and clients of licensed and approved narcotic treatment programs would be affected. Over 6,000 individuals benefit from the provisions of these proposed amendments.

Fiscal Impact

It is anticipated that the proposed amendments to the narcotics addiction treatment program regulations would have no fiscal impact. In fact, it is anticipated that facilities, once in compliance, will experience savings as a result of these proposed amendments. There would be no measurable costs imposed upon local or State government.

Paperwork Requirements

There would be no measurable increase in paperwork since a paperwork system for the license and approval of narcotic addiction treatment programs is already in place. The current licensure forms might require slight modification to account for the regulatory changes.

Effective Date

The regulations will become effective immediately upon publication as final-form rulemaking.

Sunset Date

No sunset date is necessary. The Department will monitor the appropriateness of these regulations on a continuing basis.

Statutory Authority

Articles IX and X of the Public Welfare Code (relating to the licensure of facilities) as transferred to the Department by Reorganization Plan Number 2 of 1977 (71 P. S. § 751-25) (relating to the transfer of drug and alcohol facility licensure authority from the Department of Public Welfare to the Governor's Council on Drug and Alcohol Abuse), and Reorganization Plan No. 4 of 1981 (71 P. S. § 751-31) (relating to the transfer of the powers and duties of the Governor's Council on Drug and Alcohol Abuse to the Department of Health) and the Pennsylvania Drug and Alcohol Abuse Control Act (71 P. S. §§ 1690.101—1690.115) (relating to the control, prevention, treatment and rehabilitation aspects of drug and alcohol abuse problems).

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on July 18, 2000, the Department submitted a copy of these proposed amendments to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the House Committee on Health and Human Services and the Senate Committee on Public Health and Welfare. In addition to submitting the proposed amendments, the Department has provided IRRC and the Committees with a copy of a detailed Regulatory Analysis Form prepared by the Department in compliance with Executive Order 1996-1, "Regulatory Review and Promulgation." A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, if IRRC has objections to any portion of the proposed amendments, it will notify the Department within 10 days after expiration of the review period granted to the Standing Committees. The notification shall specify the regulatory review criteria which have not been met by that portion. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the regulation, by the Department, the General Assembly and the Governor, of objections raised.

Contact Person

Interested persons are invited to submit all comments, suggestions or objections regarding the proposed amendments to John C. Hair, Director, Bureau of Community Program Licensure and Certification, Department of Health, 132 Kline Plaza, Suite A, Harrisburg, PA 17104, (717) 783-8665, within 30 days after publication of this notice in the *Pennsylvania Bulletin*. Persons with a disability who wish to submit comments, suggestions or objections regarding the proposed amendments may do so by using V/TT (717) 783-6514 for speech and/or hearing impaired persons or the Pennsylvania AT&T Relay Service at (800) 654-5984 [TT]. Persons who require an alternative format of this document may contact John C. Hair so that necessary arrangements may be made.

ROBERT S. ZIMMERMAN,
Secretary

Fiscal Note: 10-159. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 4. ADMINISTRATION

PART XI. GOVERNOR'S COUNCIL ON DRUG AND ALCOHOL ABUSE

CHAPTER 263. (Reserved)

§§ 263.1—263.26. (Reserved).

(Editor's Note: The Department is proposing to delete the existing text of 4 Pa. Code Chapter 263 as it currently appears in the *Pennsylvania Code* at pages 263-1—263-17 (serial pages (235175)—(235191)).

Exhibits A—C. (Reserved).

TITLE 28. HEALTH AND SAFETY

PART V. DRUG AND ALCOHOL FACILITIES AND SERVICES

CHAPTER 701. GENERAL PROVISIONS

Subchapter A. DEFINITIONS

§ 701.1. General definitions.

The following words and terms, when used in this part, have the following meanings, unless the context clearly indicates otherwise:

* * * * *
Agent—Commonwealth approved opioid pharmacotherapy agent.

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Commonwealth-approved opioid pharmacotherapy agent—Methadone, LAAM or other approved controlled drug approved by the Department for the detoxification or maintenance of opiate addiction.

* * * * *
Controlled substance—A drug, substance, or an immediate precursor included in schedules I through V of The Controlled Substance, Drug, Device, and Cosmetic Act (35 P. S. §§ 780-101—780-149), or as added, deleted or rescheduled by regulation.

* * * * *
DEA—The Federal Drug Enforcement Administration

Detoxification of a narcotic dependent person utilizing a Commonwealth approved opioid pharmacotherapy agent—Dispensing of a Commonwealth approved opioid pharmacotherapy agent in decreasing doses to an individual to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of an opiate and for assisting patients in reaching and maintaining a narcotic drug-free state of detoxification.

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FDA—The Federal Food and Drug Administration

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Long term detoxification treatment—Detoxification treatment for a period of more than 30 days but not in excess of 180 days.

* * * * *
[Maintenance approach—The prescription of methadone or other Department approved substance in sufficient doses to achieve stabilization or prevent withdrawal symptoms. This approach differs from the drug free approach in that a maintenance substance is utilized throughout the treatment regimen. Slow withdrawal or outpatient detoxification of the client from the maintenance substance is considered as part of maintenance. The ultimate goal of maintenance is to assist the client in permanently discontinuing the use of dependency producing substances.

Maintenance substance—Methadone or other Department approved substance used in sufficient doses to achieve stabilization or prevent withdrawal symptoms.]

Maintenance treatment—Dispensing of a Commonwealth-approved opioid pharmacotherapy agent in sufficient doses to an individual on a continuing basis in conjunction with assessment, rehabilitation, treatment and ancillary services, to achieve stabilization or prevent withdrawal symptoms for treatment of an individual with an opiate dependency.

* * * * *
Medical director—A physician who meets the qualifying criteria in § 715.6(a)(1)(i)—(iii) (relating to physician staffing) and who assumes responsibility

ity for the administration of all medical services performed in the narcotic treatment program, including ensuring that the program is in compliance with all Federal, State, and local laws and regulations regarding the medical treatment of narcotic addiction with a Commonwealth-approved opioid pharmacotherapy agent.

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Narcotic or opioid dependent person—An individual who physiologically needs heroin or an opiate to prevent the onset of signs of withdrawal and who meets the accepted diagnostic criteria for opioid dependence.

Narcotic treatment physician—A physician who meets the qualifying criteria in § 715.6(a)(1)(i)—(iii) who is employed or contracted by a narcotic treatment program to provide medical services to patients.

Narcotic treatment program—A program for chronic opiate drug users that administers or dispenses Commonwealth-approved opioid pharmacotherapy agents under a physician's order either for detoxification purposes or for maintenance and when appropriate or necessary provides a comprehensive range of medical and rehabilitative services.

* * * * *
Physician—An individual who has a currently registered license to practice medicine or osteopathic medicine in this Commonwealth.

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Short term detoxification treatment—Detoxification treatment for 30 days or less.

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State authority—The agency designated by the Governor or other appropriate official to exercise the responsibility and authority for the treatment of narcotic addiction with a Commonwealth-approved opioid pharmacotherapy agent.

(Editor's Note: Chapter 715 is proposed to be added by the Department. It is printed in regular type to enhance readability).

CHAPTER 715. STANDARDS FOR APPROVAL OF NARCOTIC TREATMENT PROGRAM

- Sec.
- 715.1. General provisions.
- 715.2. Relationship of Federal and State regulations.
- 715.3. Approval of narcotic treatment programs.
- 715.4. Denial, revocation or suspension of approval.
- 715.5. Patient capacity.
- 715.6. Physician staffing.
- 715.7. Dispensing or administering staffing.
- 715.8. Psychosocial staffing.
- 715.9. Intake.
- 715.10. Pregnant patients.
- 715.11. Confidentiality of patient records.
- 715.12. Informed patient consent.
- 715.13. Patient identification.
- 715.14. Urine testing.
- 715.15. Medication dosage.
- 715.16. Take-home privileges.
- 715.17. Medication control.
- 715.18. Rehabilitative services.
- 715.19. Psychotherapy services.
- 715.20. Patient transfers.
- 715.21. Patient termination.
- 715.22. Patient grievance procedures.
- 715.23. Patient records.
- 715.24. Narcotic detoxification.
- 715.25. Prohibition of medical units.
- 715.26. Security.

- 715.27. Readmission.
- 715.28. Unusual incidents.
- 715.29. Exceptions.
- 715.30. Applicability.

§ 715.1. General provisions.

(a) An entity within this Commonwealth which uses Commonwealth-approved opioid pharmacotherapy agents for maintenance or detoxification of persons shall obtain the approval of the Department to operate a narcotic treatment program.

(b) Approval of a narcotic treatment program shall be contingent upon the program's compliance with the standards and conditions in this part. In addition, the program shall comply with applicable Federal laws and regulations.

§ 715.2. Relationship of Federal and State regulations.

(a) A narcotic treatment program shall comply with Federal regulations and requirements governing the administration, dispensing and storage of agents.

(b) This chapter is intended to complement the Federal regulations governing narcotic treatment programs in 21 CFR 291.505 and Parts 1300—1399 (relating to conditions for the use of narcotic drugs; appropriate methods of professional practice for medical treatment of the narcotic addiction of addicts under section 4 of the Comprehensive Drug Abuse Prevention and Control Act; and Drug Enforcement Administration, Department of Justice). When there is a conflict between this chapter and the Federal regulations, the stricter standard shall apply.

§ 715.3. Approval of narcotic treatment programs.

(a) An entity shall apply for and receive approval as required from the Department, the DEA and the FDA or designee prior to offering services within this Commonwealth as a narcotic treatment program. Application for approval shall be made simultaneously to the Department, DEA and FDA or designee. The Department will forward a recommendation for approval to the Federal officials after a review of policies and procedures and an onsite inspection by an authorized representative of the Department and after a determination has been made that the requirements for approval under this chapter have been met. The decision of the Federal officials as set forth in 21 CFR 291.505 and Parts 1300—1399 (relating to conditions for the use of narcotic drugs; appropriate methods of professional practice for medical treatment of the narcotic addiction of addicts under section 4 of the Comprehensive Drug Abuse Prevention and Control Act; and Drug Enforcement Administration, Department of Justice) or other Federal statutes shall constitute the final determination on the application for approval by DEA and FDA.

(b) A narcotic treatment program shall be licensed under the Department's regulations for drug and alcohol facilities as set forth in Chapter 157, 704, 709 or 711. When a licensee applies to operate a narcotic treatment program, the history component of the application of the licensee shall include the licensee's record of operation of any facility regulated by any state or Federal entity. A narcotic treatment program may not be recommended for approval unless licensure has been obtained under chapters 157, 704, 709 or 711.

(c) The Department will grant approval as a narcotic treatment program after an onsite inspection and review

of program policies, procedures and other material, when the Department determines that the requirements for approval have been met.

(d) A narcotic treatment program shall be inspected at least annually to determine compliance with State narcotic treatment program regulations. This inspection shall consist of an onsite visit and shall include an examination of patient records, reports, files, policies and procedures, and other similar items to enable the Department to make an evaluation of the approval status of the program. The Department may inspect the narcotic treatment program without notice, which shall occur during regular business hours of the program.

(e) A narcotic treatment program shall, during the inspection process, make available to the authorized staff of the Department full and free access to its premises, facilities, records, reports, files and other similar items necessary for a full and complete evaluation. The Department may make copies it deems necessary within the provisions of State and Federal confidentiality regulations.

(f) The authorized Department representative may interview patients and staff as part of the inspection process.

(g) The Department may grant conditional approval as a narcotic treatment program after an onsite inspection when it has been determined that a program satisfies the following:

- (1) It has substantially complied with applicable requirements for approval.
- (2) It is complying with a course of correction approved by the Department.
- (3) Its existing deficiencies will not adversely alter the health, welfare or safety of the facility's patients.

(h) Notification of deficiencies involves the following:

- (1) The authorized Department representative will provide the narcotic treatment program director with a record of deficiencies with instructions to submit plans of corrections.
- (2) The narcotic treatment program shall complete plans of corrections and submit them to the Department within 15 working days after the site inspection.
- (3) The Department will not grant approval of a narcotic treatment program until the Department receives and approves the plans of corrections.

§ 715.4. Denial, revocation or suspension of approval.

(a) The Department will deny, suspend or revoke approval of a narcotic treatment program if the applicant or program fails to comply with this chapter. Procedures for the revocation, suspension, or denial of Department approval, and appeals from these actions, shall be the same as procedures in §§ 709.17, 709.18, 711.17 and 711.18.

(b) The Department may recommend to the DEA or the FDA or designee to initiate proceedings to revoke or deny Federal approval under 21 CFR 291.505(h) (relating to conditions for the use of narcotic drugs; appropriate methods of professional practice for medical treatment of the narcotic addiction of addicts under section 4 of the Comprehensive Drug Abuse Prevention and Control Act).

(c) The Department may seek an injunction for the closure of a program in a court of competent jurisdiction.

§ 715.5. Patient capacity.

The Department may limit the number of patients a narcotic treatment program may treat at a given time. The Department may raise the permitted patient capacity upon the written request of the program with the written approval of the Department based upon periodic monitoring and review. The factors the Department will consider include:

- (1) Safety.
- (2) Physical facility.
- (3) Staff size and composition.
- (4) Ability to provide required services.
- (5) Availability/accessibility of service.

§ 715.6. Physician staffing.

(a) A narcotic treatment program shall designate a medical director to assume responsibility for administering all medical services performed by the program.

(1) A medical director shall be a physician and shall have obtained one of the following:

(i) Three years documented experience in the provision of services to persons who are addicted to alcohol or other drugs, including at least 1 year of experience in the treatment of narcotic addiction with a narcotic drug.

(ii) Certification in addiction medicine by the American Society of Addiction Medicine.

(iii) A certificate of added qualifications in addiction psychiatry by the American Board of Psychiatry and Neurology, Inc.

(2) When a program is unable to hire a medical director who meets the qualifications in paragraph (1), the program may hire an interim medical director. The program shall develop and submit to the Department for approval a training plan for the interim medical director, addressing the measures to be taken in order for the interim medical director to achieve minimal competencies/proficiencies until the interim medical director meets qualifications identified in paragraph (1) (i), (ii) or (iii). The interim medical director shall meet the qualifications within 24 months of being hired.

(3) The medical director's responsibilities include the following:

- (i) Supervision of all program physicians.
- (ii) Supervision of licensed practical nurses if the program does not employ a registered nurse to supervise the nursing staff. In addition, the medical director in these instances shall ensure that licensed practical nurses adhere to written protocols for dispensing and administration of medication.

(b) Narcotic treatment programs may employ narcotic treatment physicians to assist the medical director. A narcotic treatment program physician's responsibilities include: performing a medical history and physical exam, determining diagnosis, determining narcotic dependence, reviewing treatment plans, determining dosage and all changes in doses, ordering take-home privileges, discussing cases with the treatment team, issuing verbal orders pertaining to patient care, assessing coexisting medical and psychiatric disorders, and treating or making appropriate referrals for treatment of these disorders.

(c) A narcotic treatment program physician shall be available for consultation and verbal medication orders at all times when a program is open and a physician is not present.

(d) A narcotic treatment program shall provide physician services at least 1 hour per week onsite for every ten patients.

(e) Licensed or certified health care professionals may perform functions in narcotic treatment programs if authorized by Federal, State and local laws and regulations, and if these functions are delegated to them by the medical director, and records are properly countersigned by the medical director or a narcotic treatment physician. However, one-third of all required physician time shall be provided by a physician. Time provided by other licensed or certified health care professionals may not exceed two-thirds of the required physician time.

(f) A narcotic treatment program may utilize physician assistants or certified registered nurse practitioners if supervised by the medical director. Two hours of physician assistant or certified registered nurse practitioner time shall be equivalent to 1 hour of physician time.

§ 715.7. Dispensing or administering staffing.

(a) A narcotic treatment program shall be staffed as follows:

(1) If it operates an automated dispensing system, one full-time licensed nurse or other person authorized by law to administer or dispense a controlled substance shall be available for every 200 patients.

(2) If it operates a manual dispensing system, one full-time licensed nurse or other person authorized by law to administer or dispense a controlled substance shall be available for every 100 patients.

(b) Dispensing time shall be prorated for patient census. There shall be sufficient dispensing staff to ensure that all patients are medicated in a timely and orderly manner.

§ 715.8. Psychosocial staffing.

A narcotic treatment program shall comply with staffing ratios established in Chapter 704 (relating to staffing requirements for drug and alcohol treatment activities).

§ 715.9. Intake.

(a) Prior to administration of an agent, narcotic treatment program staff shall screen all individuals to determine eligibility for admission. The program shall:

(1) Verify that the individual has reached the age of majority.

(2) Verify the individual's identity, including name, address, date of birth, emergency contact and other identifying data.

(3) Obtain a drug use history and current drug use status of the individual.

(4) Include a determination by the program physician that the individual is currently physiologically dependent upon a narcotic drug and became physiologically dependent at least 1 year before admission for maintenance treatment. Documentation shall include the basis for the physician's determination of current dependency and evidence of a 1-year history of addiction.

(b) Exceptions to the requirements in subsection (a) are:

(1) A 1 year history of physiologic dependency is not required for detoxification or for pregnant patients.

(2) Upon readmitting a patient who has been out of a program for 6 months or less after a voluntary termination, the narcotic treatment program shall update the

information in and review the patient's file to show current opiate narcotic dependency, but need not conduct a physical examination and applicable laboratory tests. Privileges earned during the previous treatment may be reinstated at the discretion of the narcotic treatment program physician.

(3) A patient who has been treated and later voluntarily detoxified from comprehensive maintenance treatment may be readmitted to maintenance treatment, without evidence to support findings of current physiologic dependence, up to 2 years after discharge, if the program attended is able to document prior narcotic drug comprehensive maintenance treatment of 6 months or more, and the admitting program physician, exercising reasonable clinical judgment, finds readmission to comprehensive maintenance treatment to be medically justified.

(c) If an applicant has previously been discharged from treatment at another narcotic treatment program, the admitting program, with patient consent, shall contact the previous facility for the treatment history.

(d) A program shall explain to each patient treatment options; pharmacology of methadone, LAAM and other agents, including signs and symptoms of overdose and when to seek emergency assistance; detoxification rights; grievance procedures; and clinic charges, including the fee agreement signed by the applicant.

(e) A narcotic treatment program shall secure a personal history from the patient within the first week of admission which shall be made a part of the patient record.

§ 715.10. Pregnant patients.

(a) A narcotic treatment program may place a pregnant patient, regardless of age, who has had a documented narcotic dependency in the past and who may return to narcotic dependency, with all its attendant dangers during pregnancy, on a comprehensive maintenance regime. For these patients, evidence of current physiological dependence on narcotic drugs is not needed if a program physician certifies the pregnancy and, exercising reasonable clinical judgment, finds treatment to be medically justified. Evidence of all findings and the criteria used to determine the findings shall be recorded in the patient's record by the admitting program physician before the initial dose is administered to the patient.

(b) Programs shall give pregnant patients the opportunity for prenatal care either by the program or by referral to appropriate health-care providers.

(c) Counseling records and other appropriate patient records shall reflect the nature of prenatal support provided by the program.

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

(e) Dosage levels shall be maintained at the lowest effective dose of treatment as deemed necessary.

(f) Patients who are or become pregnant may not be started or continued on LAAM, except by the written order of a physician who determines that LAAM is the best therapy for that patient. An initial pregnancy test shall be performed for each prospective female patient of childbearing potential before admission to LAAM comprehensive maintenance treatment. A monthly pregnancy test shall be performed thereafter on female patients on LAAM.

§ 715.11. Confidentiality of patient records.

A narcotic treatment program shall physically secure and maintain the confidentiality of all patient records in accordance with applicable Federal and State statutes and regulations.

§ 715.12. Informed patient consent.

Narcotic treatment programs shall obtain an informed, voluntary consent before an agent may be administered to the patient for either maintenance or detoxification treatment.

§ 715.13. Patient identification.

(a) A narcotic treatment program shall develop a system for patient identification for the purpose of verifying the correct identity of a patient prior to administration of an agent.

(b) Program staff shall maintain onsite a photograph of each patient which includes the patient's name and birth date. The program shall ensure that the photograph is updated every 3 years.

§ 715.14. Urine testing.

(a) A narcotic treatment program shall complete an initial drug-screening urinalysis for each prospective patient and a random urinalysis shall be done at least monthly thereafter. Each test shall be for opiates, methadone, amphetamines, barbiturates, cocaine and benzodiazepines. In addition, if any other drugs have been determined by a program to be abused in that program's locality or have been identified in the patient's drug and alcohol history as being a drug of abuse or use, a program may conduct a test or analysis for any of those drugs as well.

(b) A narcotic treatment program shall develop and implement policies and procedures to ensure that urine collected from patients is unadulterated. These policies and procedures shall include random observation which shall be conducted professionally, ethically and in a manner which respects patient privacy.

(c) A narcotic treatment program shall develop and implement policies and procedures addressing chain of custody of a urine specimen to ensure that the tested specimen can be traced to the person to whom it belongs.

(d) A narcotic treatment program shall ensure that a laboratory that performs the testing required under this section shall be in compliance with all applicable Federal requirements, specifically the Clinical Laboratory Improvement Amendments of 1998 (42 U.S.C.A. §§ 201 note, 263a and 263 notes) and State requirements, specifically The Clinical Laboratory Act (35 P. S. §§ 2151—2165) and its regulations.

§ 715.15. Medication dosage.

(a) A narcotic treatment program may not administer an agent to a patient at a dose that exceeds that permitted by Federal regulations without the program physician's rationale documented in the patient chart. Prior to an increase in a patient's dose above the Federal limit, the program physician shall examine the patient and this examination shall be documented in the patient chart. Dosage levels shall be reviewed as least twice a year for the purpose of determining a patient's optimum dosage. These reviews shall be performed by the program's physician with each review occurring no less than 2 months apart.

(b) The narcotic treatment physician shall determine the proper dosage level for a patient, except as otherwise

provided in this section. If the program physician determining the initial dose is not the program physician who conducted the examination, the program physician shall consult with the physician who performed the examination before determining the patient's initial dose and schedule.

(c) Methadone shall be administered or dispensed only in oral form when administered at the program. Although tablets, syrup concentrate or other formulations may be distributed by the program, all oral medication is required to be administered or dispensed in liquid form.

(d) A narcotic treatment program shall label all take-home medication with the patient's name and the program's name, address and telephone number and shall be packaged as required by Federal regulation.

(e) A narcotic treatment program shall administer LAAM in a liquid form only. Although syrup concentrate or other formulations may be distributed by the program, all oral medication is required to be administered in a liquid form.

(f) A narcotic treatment program that administers LAAM, methadone or other agents shall take appropriate measures, including contrasting color and taste to ensure that dosage forms of each agent are easily distinguished.

(g) The program shall develop written policies and procedures relating to narcotic treatment medication dosage which includes the requirements of subsections (a)—(f).

§ 715.16. Take-home privileges.

(a) A narcotic treatment program shall determine whether a patient may be provided take-home medications. A program may give take-home medications only to patients who the physician has determined are responsible and able to handle narcotic drugs outside the program. The physician shall make this determination after consultations with appropriate staff within the program. The program physician shall document in the patient record the rationale for permitting take-home medication. The length of time in treatment is a minimum standard after which a patient may be eligible to receive take-home medication. A physician may rescind take-home medication privileges. A narcotic treatment program shall develop written policies and procedures relating to granting and rescinding take-home medication privileges.

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

- (1) Absence of recent abuse of drugs (narcotic or non-narcotic), including alcohol.
- (2) Regular program attendance.
- (3) Absence of serious behavioral problems at the program.
- (4) Absence of known recent criminal activity.
- (5) Stability of the patient's home environment and social relationships.
- (6) Length of time in comprehensive maintenance treatment.
- (7) Assurance that take-home medication can be safely stored within the patient's home.
- (8) Whether the rehabilitative benefit to the patient derived from decreasing the frequency of attendance outweighs the potential risks of drug diversion.

(c) A narcotic treatment program shall require a patient to come to the program for observation daily or at least 6 days a week for comprehensive maintenance treatment, unless a patient is permitted to receive take-home medication as follows:

(1) A program may permit a patient to reduce attendance at the program for observation to three times weekly and receive no more than a 2-day take-home supply of medication when, in the reasonable clinical judgment of the program physician, which is documented in the patient record:

(i) A patient demonstrates satisfactory adherence to program rules for at least 3 months.

(ii) A patient demonstrates substantial progress in rehabilitation.

(iii) A patient demonstrates responsibility in handling narcotic drugs.

(iv) A patient demonstrates that rehabilitation progress would improve by decreasing the frequency of attendance for observation.

(2) A program may permit a patient to reduce attendance at the program for observation to two times weekly and receive no more than a 3-day take-home supply of medication when in the reasonable clinical judgment of the program physician, which is documented in the patient record:

(i) A patient demonstrates satisfactory adherence to program rules for at least 2 years.

(ii) A patient demonstrates substantial progress in rehabilitation.

(iii) A patient demonstrates responsibility in handling narcotic drugs.

(iv) A patient demonstrates that rehabilitation progress would improve by decreasing the frequency of attendance for observation.

(3) A program may permit a patient to reduce attendance at the program for observation to one time weekly and receive no more than a 6-day take-home supply of medication when in the reasonable clinical judgment of the program physician, which is documented in the patient record:

(i) A patient demonstrates satisfactory adherence to program rules for at least 3 years.

(ii) A patient demonstrates substantial progress in rehabilitation.

(iii) A patient demonstrates responsibility in handling narcotic drugs.

(iv) A patient demonstrates that rehabilitation progress would improve by decreasing the frequency of attendance for observation.

(v) A patient demonstrates no major behavioral problems.

(vi) A patient is employed, is actively seeking employment, attends school, is a homemaker or is considered unemployable for mental or physical reasons.

(vii) A patient is not known to have abused alcohol or other drugs within the previous year.

(viii) A patient is not known to have engaged in criminal activity within the previous year.

(d) A program may make exceptions to the requirements in subsection (c) relating to the length of time of satisfactory adherence to program rules and number of

days of take-home medication when, in the reasonable clinical judgment of the program physician, which is documented in the patient record:

- (1) A patient has a permanent physical disability.
- (2) A patient has a temporary disability.
- (3) A patient has an exceptional circumstance which interferes with the ability to conform to the applicable mandatory attendance schedules. In all cases, the patient shall demonstrate an ability to responsibly handle narcotic drugs.
- (e) With an exception granted under subsection (d), in no case may a program permit a patient to receive more than a 2-week take-home supply of medication.
- (f) An exception granted under subsection (d) shall continue only for as long as the temporary disability or exceptional circumstance exists. In the case of a permanent disability, each case shall be reviewed at least annually to determine whether the need for the exception continues to exist.

§ 715.17. Medication control.

(a) Programs which provide pharmaceutical services shall comply with applicable Federal and State statutes and regulations regarding the storing, compounding, administering or dispensing of medication.

(b) A narcotic treatment program shall develop policies and procedures regarding verbal medication orders, including issuing and receiving of orders, identifying circumstances when orders are appropriate, and documentation of orders, in accordance with applicable Federal and State statutes and regulations.

(c) A narcotic treatment program shall develop and implement written policies and procedures regarding the medications used by patients which shall include, but not be limited to:

- (1) *Administration of medication.*
 - (i) A program physician shall determine the patient's initial and subsequent dose and schedule. The physician shall communicate the initial and subsequent dose and schedule to the person responsible for the administration of medication. Each medication order and dosage change shall be written and signed by the program physician.
 - (ii) An agent shall be administered or dispensed only by a practitioner licensed under the appropriate Federal and State laws to dispense agents to patients.
 - (iii) Only patients shall be permitted in the dispensing area.
 - (iv) There shall be only one patient permitted at a dispensing station at a given time.
 - (v) Each patient shall be observed when ingesting the agent.
- (2) *Drug storage areas.* A narcotic treatment program shall develop and implement written policies and procedures regarding where and how medications are stored and who has access to the medication storage area. Agents shall be stored in a locked safe that has been approved by the DEA.

(3) *Inspection of storage areas.* A narcotic treatment program shall inspect all drug storage areas and the dispensing station at least quarterly to ensure that the areas are maintained in compliance with Federal, State and local statutes and regulations. A narcotic treatment program shall develop and implement written policies and procedures regarding who performs the inspections,

how often, and in what manner the inspections are to be documented. The policies and procedures shall include the following:

- (i) Disinfectants and drugs for external use shall be stored separately from oral and injectable drugs.
- (ii) Drugs requiring special conditions for storage to insure stability shall be properly stored.
- (iii) Outdated and contaminated drugs shall be removed and destroyed according to Federal and State regulations.
- (iv) Administration of controlled substances shall be adequately documented.
- (v) Controlled substances and other abusable drugs shall be stored in accordance with Federal and State regulations.

(4) *Method for control and accountability of drugs.* A narcotic treatment program shall develop and implement written policies and procedures regarding who is authorized to remove drugs from the storage area and the method for accounting for all stored drugs. An agent or other drug prescribed or administered shall be documented on an individual medication record or sheet in a manner sufficient to maintain an accurate accounting of medication at all times and shall include:

- (i) The name of medication.
- (ii) The date prescribed.
- (iii) The dosage.
- (iv) The frequency.
- (v) The route of administration.
- (vi) The date and time administered.
- (vii) The name of staff administering medication.
- (viii) The take-home schedule, if applicable.

(5) *Security of all substances.* A narcotic treatment program shall develop and implement written policies and procedures to minimize the likelihood of loss, theft or misuse of an agent or another controlled substance as well as a plan of action if loss, theft or misuse does occur. In the event of loss, theft or misuse, the Federal and State statutes and regulations regarding reporting shall be followed.

(6) *Inventories.* A narcotic treatment program shall conduct monthly inventories of agents and other controlled substances stored. Each inventory shall include:

- (i) The date the inventory was conducted.
- (ii) The time of day it was conducted.
- (iii) The name and amount of each product on hand at the time of the inventory.
- (iv) The name of the individual conducting the inventory.

(7) *Drug reactions and medication errors.* A narcotic treatment program shall report any adverse drug reaction and medication errors to a narcotic treatment program physician immediately and initiate corrective action. The reaction or error shall be recorded in the drug administration record and the clinical chart, and all persons who are authorized to administer medication or supervise self-medication shall be informed of the reaction or error.

§ 715.18. Rehabilitative services.

A narcotic treatment program shall provide, either onsite or through referral agreements, a full range of

rehabilitative services, which shall include legal services, employment services, HIV education services, public health services, adult educational services and behavioral health services.

§ 715.19. Psychotherapy services.

A narcotic treatment program shall provide individualized psychotherapy services and shall meet the following requirements:

(1) A narcotic treatment program shall provide each patient an average of 2.5 hours of psychotherapy per month during the patient's first 2 years, 1 hour of which shall be individual psychotherapy.

(2) A narcotic treatment program shall provide each patient at least 1 hour per month of group or individual psychotherapy after 2 years.

(3) Psychotherapy is treatment, by psychological means, of the problems of an emotional nature in which a trained person deliberately establishes a professional relationship with the patient with the object of removing, modifying or retarding existing symptoms, mediating disturbed patterns of behavior, and promoting positive personality growth and development.

§ 715.20. Patient transfers.

A narcotic treatment program shall develop written transfer policies and procedures which shall require that the narcotic treatment program transfer a patient to another narcotic treatment program for continued maintenance, detoxification or another treatment activity within 7 days of the request of the patient. The transferring narcotic treatment program shall transfer patient files which include admission date, medical and psychosocial summaries, dosage level, urinalysis reports or summary, exception requests, and current status of the patient, and shall contain the written consent of the patient. The transferring narcotic treatment program shall document what materials were sent to the receiving narcotic treatment program. The receiving narcotic treatment program shall document in writing that it notified the transferring narcotic treatment program of the admission of the patient and the date of the initial dose given to the patient by the receiving narcotic treatment program.

§ 715.21. Patient termination.

A narcotic treatment program shall develop and implement policies and procedures regarding involuntary terminations. Involuntary terminations shall be initiated only when all other efforts at retention of the patient in the program have failed.

(1) A narcotic treatment program may involuntarily terminate a patient from the program if it deems that the termination would be in the best interests of the health or safety of the patient and others, or the program finds any of the following conditions to exist:

(i) The patient has committed or threatened to commit acts of physical violence in or around the program premises.

(ii) The patient possessed a controlled substance without a prescription or sold or distributed a controlled substance, in or around the program premises.

(iii) The patient has been excessively absent from the program.

(iv) The patient has failed to follow treatment plan objectives.

(2) A patient terminated involuntarily, except patients who commit or threaten to commit acts of physical violence, shall be afforded the opportunity to receive detoxification of not less than 7 days. The detoxification may take place at the facility or the patient may be referred to another narcotic treatment program or hospital licensed and approved by the Department for detoxification.

§ 715.22. Patient grievance procedures.

(a) A narcotic treatment program shall develop and utilize a patient grievance procedure.

(b) The procedure shall permit aggrieved patients a full and fair opportunity to be heard, to question and confront persons and evidence used against them and to have a fair review of their case by the narcotic treatment program director. If the grievance is filed against the narcotic treatment program director, the review of the case shall be conducted by the governing body.

(c) Penalties may not be initiated prior to final resolution with the exception of patients who have committed acts of physical violence or who have threatened to commit acts of physical violence in or around the program premises.

§ 715.23. Patient records.

(a) A narcotic treatment program shall maintain patient records in conformance with all applicable Federal and State statutes and regulations. A program shall maintain a complete file on the premises for each present and former patient of the narcotic treatment program for at least 4 years after the patient has completed treatment or treatment has been terminated. Files shall be updated regularly so that all information contained therein is current.

(b) Each patient file shall include the following information:

(1) A complete personal history.

(2) A complete drug and alcohol history.

(3) A complete medical history.

(4) The results of an initial intake physical examination.

(5) The results of all annual physical examinations given by the narcotic treatment program; examinations should include an annual reevaluation by the narcotic treatment program physician.

(6) Results of laboratory tests or other special examination given by the narcotic treatment program.

(7) Documentation of a 1-year history of narcotic dependency, if applicable.

(8) The patient's current and past narcotic dosage level.

(9) Other drugs prescribed by the narcotic treatment program physician and the reasons therefore.

(10) Urine testing results.

(11) Counselor notes regarding patient progress and status.

(12) Applicable consent forms.

(13) Patient record of services.

(14) Case consultation notes regarding the patient.

(15) Psychiatric, psychological or psychosocial evaluations of the patient.

(16) Treatment plans and applicable periodic treatment plan updates.

(17) Federal and State exceptions to this chapter granted to the project on behalf of the patient.

(18) Referrals to other projects or services.

(19) Take-home privileges granted to the patient.

(20) Annual evaluation by the counselor.

(21) Aftercare plan, if applicable.

(22) Discharge summary.

(23) Follow-up information regarding the patient.

(24) Documentation of patient grievances.

(c) An annual evaluation of each patient's status shall be completed by the patient's counselor and shall be reviewed, dated and signed by the medical director. The annual evaluation period shall start on the date of the patient's admission to a narcotic treatment program and shall address the following areas:

(1) Employment, education or training.

(2) Legal standing.

(3) Substance abuse.

(4) Financial management abilities.

(5) Physical and emotional health.

(6) Fulfillment of treatment objectives.

(7) Family and community supports.

(d) A narcotic treatment program shall prepare a treatment plan that outlines realistic short and long-term treatment goals which are mutually acceptable to the patient and the narcotic treatment program. The treatment plan shall identify the behavioral tasks a patient must perform to complete each short-term goal. The narcotic treatment program physician or the patient's counselor shall review, reevaluate, modify and update each patient's treatment plan as required by Chapters 157, 709 and 711 (relating to drug and alcohol services general provisions; standards for licensure of freestanding treatment activities; and standards for certification of treatment activities which are a part of a health care facility).

(e) Patient file records, information and documentation shall be legible, accurate, complete, written in English and maintained on standardized forms.

(f) In the event a narcotic treatment program keeps patient information in more than one file or location, it shall be the responsibility of the narcotic treatment program to provide the entire patient record to authorized persons conducting narcotic treatment program approval activities at the narcotic treatment program upon request.

§ 715.24. Narcotic detoxification.

If a narcotic treatment program provides narcotic detoxification services, the narcotic treatment program shall develop and implement narcotic detoxification policies and procedures which include the following:

(1) For detoxification from methadone or any other narcotic, the detoxification service may not exceed 180 days.

(2) For calculating the 1-year narcotic dependency history required for admission to maintenance treatment, the detoxification period may not be included.

(3) A 1-year physiologic dependence is not required for detoxification although documentation of current dependency is required.

(4) Minimum requirements for short-term detoxification treatment are as follows:

(i) Take-home medication is not allowed during a 30-day detoxification treatment. A narcotic treatment program shall observe the patient ingesting the medication 7 days per week.

(ii) The narcotic treatment program shall perform an initial drug screening test or analysis.

(iii) The narcotic treatment program shall develop a treatment plan. The patient's counselor shall monitor the patient's progress toward the goal of short-term detoxification and possible drug-free treatment referral.

(iv) No narcotic treatment program may provide short-term detoxification treatment to an individual until at least 7 days after the conclusion of any previous short-term detoxification treatment.

(5) Minimum requirements for long-term detoxification treatment are as follows:

(i) A narcotic treatment program shall administer medication to allow the regimen designed to reach a patient to attain drug-free status and to make progress in rehabilitation within 180 days or less.

(ii) A narcotic treatment program shall perform an initial drug screening test or analysis. A narcotic treatment program shall perform at least one additional random test or analysis monthly on each patient during long-term detoxification.

(iii) The narcotic treatment program shall develop an initial treatment plan, and update the plan monthly.

(iv) A narcotic treatment program shall observe the patient while ingesting the medication at least 6 days a week.

(v) No narcotic treatment program may provide long-term detoxification treatment to an individual until at least 7 days after the conclusion of any previous long-term detoxification treatment.

§ 715.25. Prohibition of medical units.

Narcotic treatment medication units as defined by Federal regulation are prohibited.

§ 715.26. Security.

(a) A narcotic treatment program shall meet the security standards for the distribution and storage of controlled substances as required by Federal and State statutes and regulations.

(b) Each narcotic treatment program shall provide the Department with a specific plan describing the efforts it will make to avoid disruption of the community by its patients and the actions it will take to assure responsiveness to the community. This plan shall include the designation of a staff member to act as community liaison.

§ 715.27. Readmission.

If a patient requests readmission to a narcotic treatment program after voluntary termination from that program, that person shall be provided with an evaluation interview and be given priority consideration for readmission.

§ 715.28. Unusual incidents.

(a) A narcotic treatment program shall develop and implement policies and procedures to respond to the following unusual incidents:

- (1) Physical assault by a patient.
- (2) Inappropriate behavior by a patient causing disruption to the narcotic treatment program.
- (3) Selling of drugs on premises.
- (4) Complaints of patient abuse (physical, verbal, sexual, emotional, financial).
- (5) Death or serious injury due to trauma, suicide, medication error or unusual circumstances.
- (6) Significant disruption of services due to disaster such as fire, storm, flood or other occurrence.
- (7) Incident with potential for negative community reaction or which the facility director believes may lead to community concern.
- (8) Theft, burglary, break-in or similar incident at the facility.
- (9) Other unusual incidents the narcotic treatment program believes should be documented.

(b) These policies and procedures shall include the following:

- (1) Documentation of the unusual incident.
 - (2) Prompt review and investigation.
 - (3) Implementation of a timely and appropriate corrective action plan, when indicated.
 - (4) Ongoing monitoring of the corrective action plan.
- (c) Narcotic treatment programs shall file a written Unusual Incident Report with the Department within 48 hours following the following unusual incidents:
- (1) Complaints of patient abuse (physical, verbal, sexual, emotional, financial).
 - (2) Death or serious injury due to trauma, suicide, medication error or unusual circumstances.
 - (3) Significant disruption of services due to disaster such as fire, storm, flood or other occurrence.
 - (4) An incident with potential for negative community reaction or which the facility director believes may lead to community concern.
 - (5) Drug related hospitalization of a patient.

§ 715.29. Exceptions.

A narcotic treatment program is permitted, at the time of application or any time thereafter, to request exception from specific regulations. The request for an exception from a specific regulation shall be in writing, with governing body approval, and shall state how the program will meet the intent of the regulation. The Department may withhold the granting of an exception and may

require a narcotic treatment program to be in actual operation to assess if the exception is appropriate. The Department will reserve the right to revoke any exception previously granted. The narcotic treatment program shall maintain documentation of the Department's approval of an exception. If the exception relates to a specific patient, the narcotic treatment program shall maintain documentation of the exception in the patient's record.

§ 715.30. Applicability.

This chapter applies to the use of any agent which may be approved by the Department for use in narcotic/opioid dependency medication therapy. This chapter applies to the administration of any agent which may be approved by the Department for use in the treatment of opioid dependency.

[Pa.B. Doc. No. 00-1280. Filed for public inspection July 28, 2000, 9:00 a.m.]

DEPARTMENT OF PUBLIC WELFARE

[55 PA. CODE CHS. 4225 AND 4226]

Early Intervention Services; Extension of Public Comment Period

The Department of Public Welfare (Department) published a notice of proposed rulemaking at 30 Pa.B. 27852 (June 3, 2000) seeking public comment on proposed rulemaking applicable to early intervention services. The notice of proposed rulemaking provided for a 60-day public comment period to end on August 2, 2000. The public comment period on the proposed regulations is hereby extended by 90 days.

Interested parties are invited to submit written comments, suggestions or objections regarding the proposed rulemaking to Mel Knowlton, Office of Mental Retardation, P. O. Box 2675, Harrisburg, PA 17105-2675, (717) 783-5764, fax (717) 787-6583.

The extension in the public comment period is being made because the Department wants to allow adequate opportunity for interested stakeholders to review and comment on this comprehensive regulatory proposal.

The Department is also adding two additional public hearings. They are scheduled as follows:

Western Region
October 13, 2000
State Office Building, Room 605
300 Liberty Avenue
Pittsburgh, PA 15222
10 a.m.—1 p.m.

Southeast Region
October 2, 2000
Philadelphia Office of MR Services
105 S. 7th Street, 4th Floor
Conference Room A1 & A2
Philadelphia, PA 19106
10 a.m.—1 p.m.

Request to provide verbal comments are to be addressed to:

Mary Puskarich
Western Region OMR
1403 State Office Building
300 Liberty Avenue
Pittsburgh, PA 15222
(412) 565-5144

Vicki Stillman-Toomey
Southeast Region OMR
306 State Office Building
1400 Spring Garden Street
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(215) 560-2247

FEATHER O. HOUSTOUN,
Secretary

[Pa.B. Doc. No. 00-1281. Filed for public inspection July 28, 2000, 9:00 a.m.]
