Regulatory Analysis Form	This space for use by IRRC
(1) Agency Department of Health	
(2) I.D Number (Governor's Office Use) 10-159	IRRC Number: 2134

(3) Short Title

Standards for Approval of Narcotic Treatment Programs

(4) PA Code Cite	(5) Agency Contacts & Telephone Numbers
4 Pa. Code Chapter 263 28 Pa. Code Chapters 701 and 715	Primary Contact: John C. Hair, Director Bureau of Community Program Licensure and Certification (717) 783-8665 Secondary Contact:

(6) Type of Rulemaking (Check One)	(7) Is a 120-Day Emergency Certification Attached?
Proposed Rulemaking	✓ No
√ Final Order Adopting Regulation	Yes: By the Attorney General
Final Order, Proposed Rulemaking Omitted	Yes: By the Governor

(8) Briefly explain the regulation in clear and non-technical language.

The Department of Health, by this final rulemaking, amends the regulations which govern the approval and monitoring of narcotic treatment programs in the Commonwealth of Pennsylvania. The regulations being amended, 4 Pa. Code Chapter 263, were enacted approximately 25 years ago, as required by federal regulation. Chapter 263 requires that all programs within the Commonwealth which use methadone in treatment, maintenance, or detoxification of individuals, obtain approval of the Department to operate such a program. These regulations direct projects to comply with all federal regulations concerning administration, dispensing and storage of methadone. Chapter 263 supplemented the federal regulations in order to provide additional direction to methadone programs. The federal regulations were revised in May, 2001, and methods for the treatment of the narcotic addict has changed over the past 25 years. Thus, there is a need to amend Pennsylvania's state narcotic treatment program regulations to more closely align with the requirements of the federal regulations, as well as conform with the current best practices of the treatment of narcotic addicts. This amendment is in conformance with the Governor's

Policy Directive (Executive Order 1996-1) to have state regulations consistent with federal regulations.

(9) State the statutory authority for the regulation and any relevant state or federal court decisions.

Articles IX and X of the Pennsylvania Public Welfare Code, 62 P.S. §§901-922, 1001-1087, the Pennsylvania Drug and Alcohol Abuse Control Act, 71 P.S. §1690.101-115, and federal regulations 42 CFR 8.1-8.34.

(10) Is the regulation mandated by any federal or state law or court order, or federal regulation? If yes, cite the specific law, case or regulation, and any deadlines for action.

Federal regulation (42 CFR 8.2) states that the State Authority is the agency to exercise the responsibility and authority within the state for governing the treatment of narcotic addictions with a narcotic drug. It further states that before a narcotic treatment program may be lawfully operated, the program shall submit an application simultaneously to the Federal Drug Enforcement Agency, the Center for Substance Abuse Treatment and the State Authority and receive approval of all In order to fulfill this requirement, applicable state regulations are required to establish procedures for approval.

(11) Explain the compelling public interest that justifies the regulation. What is the problem it addresses?

The Department is amending these regulations because the treatment of the narcotic addict has changed considerably since the current state methadone regulations were published in the early 1970's. The current state methadone regulations are specific to methadone treatment programs and do not allow for the use of other drugs in narcotic treatment. Since the 1970s, medications other than methadone have been found to be effective in treating the narcotic addict, i.e., LAAM, and thus the revised regulations, as do the new federal regulations, refer to Narcotic Treatment Programs and incorporate regulations reflecting other medications. With the increasing prevalence of infectious diseases, specifically HIV, within the narcotic addicted population, there is a need to address public health concerns. Patients with HIV are sicker and more in need of medical and psychosocial intervention. Many of the previously known sequelae of injecting drug use (TB, hepatitis B) are exacerbated by HIV infection. Also, studies show that HIV seroprevalence is much lower among patients who have been on long-term methadone maintenance and entered treatment prior to the onset of increasing seroprevalence within the local addict populations. The amended regulations require HIV education and counseling to all patients in narcotic treatment programs, thus impacting upon some of these public health issues

In addition, the federal regulations were revised causing some contradiction and conflict with current state regulations. Examples include the following: (1) federal regulations now require a

one-year history of narcotic addiction for admission while current state regulations require a two-year history, (2) federal regulations no longer require a two-year justification for methadone maintenance while the current state regulations do, (3) federal regulations allow for a maximum dose of 40 mg. within the first 24 hour period while the current state regulations allow for a maximum dose of 30 mg. within the first 24 hour period, (4) federal regulations do not specify a maximum dose, while the current state regulations allow for a maximum dose of 80 mg., (5) federal regulations allow for the admission of a pregnant female who has a documented history of narcotic dependency, while the current state regulations do not allow it, (6) federal regulations allow for a six day medication take-home schedule while the state regulations prohibit a six day medication take-home schedule.

The amended regulations will correct these inconsistencies and will bring the state regulations into alignment with the federal regulations. These amended regulations reflect changes in the revised federal narcotic treatment regulations as discussed earlier, by not specifying a maximum dose versus the current state regulation of 80 mg. and in allowing for the use of LAAM, which the current state regulations do not. The need to increase the maximum allowable dose is based upon availability of purer street heroin, thus increasing the individual's tolerance to narcotics. Another reason includes the fact that other medications being administered to a number of methadone patients, medication for treatment of TB, increases the metabolism of the methadone, thus necessitating a higher dose.

The State Methadone Maintenance Treatment Guidelines issued by the U.S. Department of Health and Human Services in 1992 provides extensive research analysis, and recommendations on all aspects of narcotic treatment, including public health issues, clinical issues, admission criteria, dose determination, urinalysis, take-home medication, pregnancy, HIV and other infectious diseases. This document contains additional detailed information.

(12) State the public health, safety, environmental or general welfare risks associated with non-regulation.

From both treatment management and public health perspective, non-regulation is not an option. Regulation is essential to control and monitor this field. Regulation also helps control and monitor public health risks. Refer to #11 above.

(13) Describe who will benefit from the regulation. (Quantify the benefits as completely as possible and approximate the number of people who will benefit.)

Benefits to be derived from these amended regulations include flexibility in a number of areas; i.e., use of physician assistants and certified registered nurse practitioners, expansion in medications to be used, allowing for pro-rating of dispensing hours, provision for higher dosing as necessitated, less frequent drug testing, requirement of a one year versus two year history of opiate addiction for admission, waiver on the one year history for pregnant females, elimination of a two year medical justification, inclusion of requirements for aftercare planning, inclusion of HIV education and counseling. This flexibility will allow for decreased expenditures by the program in some instances which should be passed on to the patient (self pay) or managed care (public or private) entities. At the same time, modifications in the regulations reflect current treatment/healthcare issues, (i.e., allowance for a higher dose, as needed, HIV education, testing, and counseling resulting in earlier detection and treatment of those who are HIV positive with a decreased incidence of HIV in the narcotic addicted population), and as a consequence, decreased medical costs as well as improved health and quality of life for these patients. The amended regulations allow for and support the provision of a higher quality service to individuals receiving treatment in a narcotic treatment program.

(14) Describe who will be adversely affected by the regulation. (Quantify the adverse effects as completely as possible and approximate the number of people who will be adversely affected.)

It is anticipated that no individual or entity will be adversely affected by this regulation.

(15) List the persons, groups or entities that will be required to comply with the regulation. (Approximate the number of people who will be required to comply.)

All licensed and approved Pennsylvania narcotic treatment programs will be required to comply with the regulation. At this time there are approximately 30 licensed and approved narcotic treatment programs in Pennsylvania. These programs treat approximately 9000 individuals.

(16) Describe the communications with and input from the public in the development and drafting of the regulation. List the persons and/or groups who were involved, if applicable.

Narcotic treatment programs have provided suggestions over the past several years on the need to modify these regulations, such as the need to reduce the frequency of required drug testing, to increase dosage, and to eliminate the two-year justification for continued maintenance. Recently, the Department conducted three workgroup sessions with a large stakeholders group. Suggestions and comments from the group have been incorporated into these regulations.

(17) Provide a specific estimate of the costs and/or savings to the regulated community associated with compliance, including any legal, accounting or consulting procedures which may be required.

There are no anticipated cost increases to the regulated community associated with compliance. Programs may see savings in reduced number of urine testing required and increased use of physician assistants. The amended regulations will afford cost savings in several areas:

(1) Current regulations require a full-time nurse for 100 patients or fewer. The amended regulations will allow for pro-rating of nursing time based upon patient census. For example, pro-rating will allow for a quarter time nurse for 25 patients. This will significantly reduce nursing costs for small programs and new programs building a census.

(2) Current regulations require weekly urinalysis while the proposed regulations require monthly urinalysis. This change will allow for significant cost savings in drug testing.

(3) These amended regulations allow for elimination of a two-year justification to continue methadone maintenance by the medical director, allowing the intent of this regulation to be met through the annual evaluation regulation. This change will result in cost reduction for physician time.

(4) Amended regulations allow for the use of physician assistants and certified registered nurse practitioners, in lieu of licensed physicians, for routine medical functions. Again, this change will reduce the cost of physician time.

(5) The amended regulations allow for a one-year versus a two-year history of opiate addiction prior to admission for treatment, and thus, earlier detection and treatment of patients at risk for infectious disease including HIV, TB, hepatitis, syphilis, and other STDs. Earlier identification and medical treatment of these diseases should reduce overall medical costs.

Also, less administrative time will be spent in consulting with the Department on medication dose changes since this requirement is being eliminated. No additional reporting, record keeping or other paperwork is required to implement the amended regulations. The exact amount of savings is difficult to estimate since each program's savings will depend upon the number of patients being treated.

(18) Provide a specific estimate of the costs and/or savings to local governments associated with compliance, including any legal, accounting or consulting procedures which may be required.

There are no anticipated costs or savings to local government associated with compliance.

(19) Provide a specific estimate of the costs and/or savings to state government associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required.

Specific estimates of savings to state government are difficult to assess. However, there are some savings anticipated to the state regulatory division as a result of having to perform a few less regulatory functions. One example in particular is that the Department will no longer be required to use administrative time for review and consideration of waivers to daily methadone dose regulations.

(20) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government and state government for the current year and five subsequent years.

NOT APPLICABLE

	Current FY Year	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
SAVINGS:	$	$	$	$	$	$
Regulated Community	$0	0	0	0	0	0
Local Government	$ 0	0	0	0	0	0
State Government	$ 0	0	0	0	0	0
Total Savings	$0	0	0	0	0	0
COSTS:						

Regulated Community	$0	0	0	0	0	0
Local Government	$ 0	0	0	0	0	0
State Government	$0	0	0	0	0	0
Total Costs	$0	0	0	0	0	0
REVENUE LOSSES:						
Regulated Community	$ 0	0	0	0	0	0
Local Government	$ 0	0	0	0	0	0
State Government	$0	0	0	0	0	0
Total Revenue Losses	$0	0	0	0	0	0

(20a) Explain how the cost estimates listed above were derived.

NOT APPLICABLE

(20b) Provide the past three year expenditure history for programs affected by the regulation.

NOT APPLICABLE

Program	FY - 3	FY - 2	FY - 1	Current FY
Planning	$			
Licensure (Hospital)	$			

(21) Using the cost-benefit information provided above, explain how the benefits of the regulation outweigh the adverse effects and costs.

There are no anticipated adverse affects and costs. The anticipated benefits are described above. Therefore, anticipated benefits outweigh anticipated costs.

(22) Describe the nonregulatory alternatives considered and the costs associated with those

alternatives. Provide the reasons for their dismissal.

None. No other alternatives exist which will achieve the desired effect. Regulations are required to implement state and federal provisions as well as to protect the public interest.

(23) Describe alternative regulatory schemes considered and the costs associated with those schemes. Provide the reasons for their dismissal.

No other alternative regulatory schemes were considered. These amendments will achieve the greatest cost savings while maintaining public health interests.

(24) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulation.

Yes. The State regulation limits take-home amounts to 6 days while the Federal regulations allow for 14 and 30 day take-home amounts. Dispensing hours and physician hours are not addressed by the Federal regulations. State regulations specify hours for both dispensing and physicians. The Department believes the high risk of diversion justifies stricter oversight. Higher incidence of co-morbidity justifies more stringent physician hours.

(25) How does this regulation compare with those of other states? Will the regulation put Pennsylvania at a competitive disadvantage with other states?

Each state regulates programs according to its own laws and regulations and within the framework of the federal regulations. These amendments are designed to bring Pennsylvania's regulations in alignment with federal standards and current best practices. The regulations do not put Pennsylvania at a competitive disadvantage.

(26) Will the regulation affect existing or proposed regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

No.

(27) Will any public hearings or information meetings be scheduled? Please provide the dates, times, and locations, if available.

The Department's review of the existing regulations and drafting of the proposed amendments

entailed extensive meetings with a workgroup composed of many stakeholders from providers, law enforcement and government. These regulations are a culmination of that process. No further meetings or hearings are contemplated.

(28) Will the regulation change existing reporting, record keeping, or other paperwork requirements? Describe the changes and attach copies of forms or reports which will be required as a result of implementation, if available.

There are no additional reporting, record keeping or other paperwork requirements associated with the implementation of the proposed amended regulations. In fact, programs might experience a decrease in paperwork in various areas (such as urine testing).

(29) Please list any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, elderly, small businesses, and farmers.

None.

(30) What is the anticipated effective date of the regulation; the date by which compliance with the regulation will be required; and the date by which any required permits, licenses or other approvals must be obtained?

It is anticipated that the regulations will become effective immediately upon publication as final rulemaking. Compliance is expected to be immediate, but certainly no later than the first annual licensing inspection after the effective date.

(31) Provide the schedule for continual review of the regulation.

The Department will continue to review these regulations on a periodic basis as required by Executive Order 1996-1. In addition, should additional issues arise, such as a change in the federal regulations, in the treatment of narcotic addiction, these regulations will be reviewed to determine whether any changes are necessary.

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

#2134

DO NOT WRITE IN THIS SPACE

Copy below is hereby approved as to form and legality Attorney General	Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by	Copy below is hereby approved as to form and legality Executive or Independent Agencies
BY _____ DEPUTY ATTORNEY GENERAL	DEPARTMENT OF HEALTH (AGENCY)	BY _____
_____ DATE OF APPROVAL	DOCUMENT/FISCAL NOTE NO 10-159	_____ DATE OF APPROVAL
	DATE OF ADOPTION _____	(Deputy General Counsel) ~~(Chief Counsel, Independent Agency)~~ (Strike inapplicable title)
☐ Check if applicable Copy not approved Objections attached	BY Robert S. Zimmerman, Jr. TITLE Secretary of Health	☐ Check if applicable No Attorney General approval or objection within 30 days after submission

FINAL RULEMAKING
DEPARTMENT OF HEALTH

TITLE 4. ADMINISTRATION

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

[4 PA. CODE CHAPTER 263]

AND

TITLE 28. HEALTH AND SAFETY

PART V. DRUG AND ALCOHOL FACILITIES AND SERVICES

28 PA. CODE CHAPTERS 701 AND 715

The Department of Health (Department) herby amends the standards for approval of narcotic treatment programs by repealing 4 Pa. Code Chapter 263 (relating to methadone), amending 28 Pa. Code § 701.1 (relating to general definitions) and adding 28 Pa. Code Chapter 715 (relating to standards for approval of narcotic treatment program), as set forth in Annex A hereto.

A. PURPOSE OF THE REGULATION

The purpose of these regulations is to revise and update current narcotic treatment standards for the approval of narcotic treatment programs to conform with updated Federal regulations and requirements. The Federal regulations were revised in 1994, and again several years ago, 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 to 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 replaces the repealed methadone treatment regulations in 4 Pa. Code Chapter 263. Those regulations as applied were not consistent with current health practices or Federal requirements. They were more burdensome than Federal regulations.

B. COMMENTS

Chapter 701. General Provisions

Subchapter A. Definitions

Section 701.1 (relating to general definitions). This section defines terms used in Part V.

Comment

The definition of the term "agent" should not contain within its parameters the term being defined, rather, the word "agent" should be replaced with a more appropriate term such as "controlled substance."

Response

The Department agrees. The word "agent" has been removed from the definition and replaced with the word "substance."

Comment

The proposed definition of "controlled substance" includes the phrase "or as added, deleted or rescheduled by regulation." This phrase renders the definition inconsistent with this statutory definition and should be removed from the definition.

Response

The Department agrees. The phrase "or as added, deleted or rescheduled by regulation" has been deleted.

Comment

The lengthy phrase "Commonwealth approved opioid pharmacotherapy agent" included in the proposed term and definition of "detoxification of a narcotic dependent person utilizing a Commonwealth approved opioid pharmacotherapy agent" should be changed to the single word "agent" which is already defined in this subchapter.

Response

The Department agrees. The phrase "Commonwealth approved opioid pharmacotherapy agent" has been replaced with the term "agent" to provide clarity. The Department has made this substitution throughout the final regulations.

Comment

According to the proposed definition of "maintenance treatment," the goal of maintenance is to achieve stabilization or prevent withdrawal symptoms for treatment of an individual with opiate dependency rather than to assist the client in permanently discontinuing the use of dependency producing substances. The Department should explain the rationale behind the change in the goal of the Commonwealth's maintenance program. Further, the proposed definition is inconsistent with the Federal regulations at 42 CFR § 8.2, which provide two types of treatment: comprehensive maintenance treatment and interim maintenance treatment. The definition should be consistent with the Federal definition of "maintenance treatment."

Response

According to research by Alan Leshner, Ph.D., Director of the National Institute on Drug and Abuse, National Institute of Mental Health Addiction and the Brain, addiction is a disease of the brain requiring long-term maintenance for many individuals, and possibly permanent maintenance for some. In addition, the Department has decided to limit the definition as proposed to only provide for comprehensive maintenance treatment. The Department does not believe that it is in the best interest of patients to receive "interim maintenance treatment" because that would allow for medicating patients without counseling or treatment. Accordingly, the Department does not believe its definition of "maintenance treatment" is inconsistent with Federal regulations.

Other Changes

The Department has added a definition for the term "medication unit" since § 715.25 (relating to prohibition of medication units) prohibits the use of medication units and the term had not been defined in the proposed regulation. This definition is in line with the Federal definition of "medication unit."

The Department has added the words "narcotic treatment" before the words "physician" and "program" for clarity and consistency throughout the regulations.

The Department has also added a definition for "psychotherapy" since that term has been added in § 715.19 (relating to psychotherapy services).

The Department has also deleted the definition of and reference to "Federal Food and Drug Administration (FDA)" and added a definition for the "Center For Substance Abuse Treatment (CSAT)" since the functions previously performed by the FDA are now performed by CSAT.

Chapter 715. Standards for Approval of Narcotic Treatment Program

Section 715.1. General provisions. This section requires approval from the Department to operate a narcotic treatment program and such approval is contingent upon compliance with all applicable State and Federal laws and regulations. The Department received no comment on this section. It made a minor revision to clarify that the section relates to narcotic treatment programs.

Section 715.2. Relationship of Federal and State regulations. This section provides that a narcotic treatment program must comply with Federal regulations and requirements governing the administration, dispensing and storage of agents.

Comment

Subsection (b) of the proposed regulation should be amended to delete the last sentence. If the Department is or becomes aware of conflicts with Federal requirement, the Department should amend its regulations to address the conflicts rather than state, "when there is a conflict between this chapter and the Federal regulations, the stricter standard shall apply." Also, the term "complement" in subsection (b) should be replaced with

"supplement" or "supercede" to provide clarity as to what the Department is intending to convey by the phrase "this chapter is intended to complement the Federal regulations... ."

Response

The Department agrees. The phrase "when there is a conflict between this chapter and the Federal regulation, the stricter standard shall apply" has been deleted from subsection (b) of the regulation. The word "supplement" in subsection (b) has replaced the word "complement."

Section 715.3. Approval of narcotic treatment programs. This section sets forth the process by which a narcotic treatment program shall obtain and maintain licensure and approval for operation within the Commonwealth.

Comment

The Department should define and explain its intent in using the term "designee" in the phrase "an entity shall apply for and receive approval as required by the Department, the DEA and the FDA or designee" in subsection (a). It is not clear from the regulation who a "designee" may be under the proposed regulation.

Response

The Department agrees. The term "designee" has been replaced by the phrase "an organization designated by the Substance Abuse and Mental Health Services

Administration under the authority of 21 U.S.C. 823; 42 U.S.C. 257a, 290aa(d), 290dd-2, 300x-23, 300x-27(a) and 300y-11."

Comment

Proposed subsection (d) provides that the Department may inspect the narcotic treatment program without notice whereas the existing regulation at 4 Pa. Code Section 263.3(e) states that "inspections will occur without notice to the methadone project." The Department should explain the rationale behind removing mandatory no-notice inspections from the regulation. Subsection (d) does not articulate what standards will be used by the Department to determine which narcotic treatment programs will be inspected without notice and with notice.

Response

The Department has not revised the proposed regulation. The regulation provides that inspections may occur without notice to the methadone project and shall occur during any regular business hours of the methadone project. The general standards for all drug and alcohol treatment facilities is that notice is provided for annual renewal inspections. The Department is being consistent in this section. The Department may still conduct inspections without notice when it investigates complaints or conducts a plan of correction follow-up, for example.

Comment

The phrase "within the provisions of State and Federal confidentiality regulations" contained in proposed subsection (e) of the proposed regulation is a vague reference which does not afford notice of the specific requirements which must be satisfied under State and Federal regulations.

Response

The Department agrees. The specific citations 42 CFR Part 2, § 2.53 (relating to audit and evaluation activities) and 28 Pa. Code §§ 709.15 and 711.15 (both relating to right to enter and inspect) are referenced in subsection (e).

Comment

Proposed subsection (g) removes the 60-day time limit for programs to correct deficiencies. The Department should explain its rationale and the benefits to be derived from the removal of the maximum time limit.

Response

The Department does not wish to be bound by a specific time frame, rather, it wishes to examine each case on a deficiency-by-deficiency basis. Adopting the language of subsection (g)(2) permits flexibility in the time in which deficiencies must be corrected. Also, the word "conditional" has been removed. There is no provision for, or definition of, "conditional" approval. The Department will either approve or not approve pursuant to this section.

Comment

Proposed subsection (h)(2) is not clear as to when the Department would require the submittal of plans of correction: within 15 working days after onsite inspection or within 15 working days after the program receives the results of the onsite inspection. Also, the exact meaning of "working days" is unclear in the proposed regulation.

Response

The Department agrees and has changed the regulation. Results of site inspections are distributed to a program on the last day of the inspection. The methadone treatment program will have 21 days from the last day of the site inspection to submit its plan of correction to the Department.

Other Changes

The Department has added a reference to 28 Pa. Code Chapter 705 (relating to physical plant standards) in subsection (b). Chapter 705 became effective on March 2, 2002, and also applies to narcotic treatment programs.

Section 715.4. Denial, revocation or suspension of approval. This section outlines when approval will be denied, revoked or suspended due to noncompliance by an applicant or a program.

Comment

Proposed subsection (a) does not allow any opportunity for providers to appeal issues related to noncompliance, expansion, or capacity. The proposed regulations only address denial or revocation of approval. The Department should preserve an option for approval comparable to that in the existing standard. Also, providers should have the opportunity to appeal to another entity rather than resubmitting their appeal to the same entity that initially gave a negative response.

Response

The Department has not changed the regulation in response to this comment. An appeal mechanism currently exists for narcotic treatment programs to appeal overall Department approval decisions. See Section 715.3 (relating to approval of narcotic treatment programs). A formal appeal process on issues relating to matters of noncompliance where the Department requests a plan of correction is inappropriate because a request for a plan of correction is not a final agency decision. If a program does not comply with a request for a plan of correction, the Department will take administrative action. If that administrative action is adverse to the facility, it may appeal from that decision.

Section 715.5. Patient capacity. This section sets out the criteria to be used by the Department in reviewing a request by a program for an increase in patient capacity.

Comment

The phrase "may limit" in the first sentence is too broad. The Department should clarify whether it intends to use this section for any other purpose such as lowering the permitted patient capacity of the program and, if so, amend the first sentence accordingly. The Department should also examine whether this section can supercede the staffing ratios in proposed § 715.7 (relating to dispensing or administering staffing). This section would require written approval of the Department to be "based upon periodic monitoring and review." It is unclear as to the exact time frame intended by the term "periodic." Lastly, criteria for the evaluation of the factors in proposed paragraphs (1) through (4) should be established.

Response

The Department agrees with these recommendations. The phrase "may limit" in the first sentence of this section has been replaced with the phrase "may increase or decrease." This section does not supercede § 715.7. The Department would not approve an increase in capacity that would conflict with the required ratios.

The following criteria will be used by the Department in evaluating the factors in paragraphs (1) through (5): (1) *Safety* -- considerations include dispensing time, internal patient flow and external traffic patterns; (2) *Physical facility* -- considerations include number and size of counseling office, waiting area, restrooms, and dispensing and nursing windows; (3) *Staff size and composition* -- considerations include the number of

physician, dispensing and counseling staff; (4) *Ability to provide required services* -- considerations include compliance with licensing and narcotic treatment program regulations as determined during licensing, monitoring and special visits to the program; and (5) *Availability and accessibility of service* -- considerations include the location of the narcotic treatment program and the hours of operation. These criteria are reflected in the final amendments.

Section 715.6. Physician staffing. This section establishes the staffing ratios and requirements for narcotic treatment physicians providing treatment to patients in methadone treatment programs.

Comment

Proposed subsection (a)(2) provides that "the interim medical director shall meet the qualifications within 24 months of being hired." The 24 month time limit is unreasonable and should be amended. Examinations by the American Society of Addiction Medicine are held roughly every two years. To sit for an exam, a physician must document 1-year full time equivalent (FTE) experience in addiction medicine. Further, for many narcotic treatment programs, physicians are recruited from the community. They may not have sufficient time dedicated in a field to be able to comply with this regulation and sit for the exam within 24 months after being hired. A training program documenting specific education in addiction and narcotic treatment should suffice to guarantee that the narcotic treatment program has a current and up-to-date practitioner.

Response

The Department accepts this recommendation in part. The Department has changed the 24-month time limit to a more reasonable 36-month time period in order for the narcotic treatment program physician to meet all the qualification requirements contained in the regulation. However, the Department will not accept training in lieu of compliance with the regulations.

Comment

Proposed subsection (a)(3)(i) requires a medical director to supervise "program physicians." Proposed subsection (b) states that programs may employ "narcotic treatment physicians to assist the medical director." The regulation is unclear as to whether the two positions are interchangeable or serve separate functions. The Department should use either of the terms consistently throughout the regulations and amend the definitions section 701.1 accordingly.

Response

The Department agrees that the use of "physicians" and "narcotic treatment physician" in proposed subsection (a)(3)(i) and (b) was unclear and inconsistent. Additionally, there were many other places in the proposed regulations where there was inconsistent use of these terms. The Department now uses the term "narcotic treatment physician" consistently throughout the regulations. Also, there was inconsistent use of the terms "narcotic treatment program," "treatment program" and "program." The term "narcotic treatment program" is now used consistently throughout.

Comments

Proposed subsections (d) and (e) contain the staffing ratios for physicians and other licensed and certified health care professionals providing treatment to patients in narcotic treatment programs. The 1:10 physician-hour per week per patient ratio in subsection (d) is excessive, unnecessary, costly and unreasonable. The economics of narcotics addiction treatment for smaller clinics simply does not allow for such a large and unnecessary allocation to physician services. Further, other states impose no physician-patient requirements on narcotic treatment programs. The Department should consider amending the ratio to a maximum of 1:25 or a minimum of 1:15. If the Department elects not to amend its ratios, at a minimum, the Department should explain how the ratios were developed and whether each ratio is the most reasonable and appropriate to protect public health, safety, and welfare.

The staffing ratios in proposed subsection (e) would require that "one-third of all required physician time shall be provided by a physician" and "time provided by other licensed certified health care professionals may not exceed two-thirds of the required physician time." These proposed regulations would exceed the regulations of advance practice nurses and physician assistants. The Department should explain how the ratios were developed and whether each ratio is the most reasonable and appropriate ratio for the protection of public health, safety, and welfare.

Response

The Department has developed the ratios in subsections (d) and (e) through extensive research. The Department recognizes that physician time is costly but finds the arguments for maintaining the current ratio persuasive. Accordingly, it prefers to maintain the requirement of 1 hour per week of on-site physician time for every 10 patients, as proposed. This guideline for physician coverage was established by the Federal government in 1990. Methadone treatment is a medically directed service. Many patients who are currently enrolled in narcotic treatment programs exhibit complex and multiple medical disorders, both physically and emotionally. Patients are concurrently taking medication for TB, HIV, hepatitis B and hepatitis C, all of which interact with methadone and require ongoing physician monitoring. Further, the nature of methadone treatment requires physician presence for supervision of patient care to maintain the credibility of methadone treatment in the medical and clinical community.

In response to cost concerns, the Department has reduced physician involvement by permitting the use of physician assistants and certified registered nurse practitioners in the ratio. Only one-third of the time must be physician time. In response to the comment that other states impose no physician-patient ratios, the Department agrees that it is true that some states impose no requirements. However, several states do require physician hours and several other states are considering re-adoption of the requirements for physician hours due to problems experienced as a result of insufficient physician coverage. The Department is allowing for up to two-thirds of physician time to be met

through the use of physician assistants or certified registered nurse practitioners. Accordingly, the Department has not changed the regulation.

Comment

Proposed subsection (f), which provides that "two hours of physician assistant or certified registered nurse practitioner time shall be equivalent to one hour of physician time," is both unnecessary and restrictive. One hour of service from these licensed health care providers should be fully considered as it is in physician offices, emergency rooms and other medical facilities. The Department should explain how the ratios were developed and whether each ratio is the most reasonable and appropriate to protect public health, safety, and welfare.

Response

The Department has reconsidered this requirement and agrees. The revisions in subsection (e) render subsection (f) unnecessary and it has been deleted.

Section 715.7. Dispensing or administering staffing. This section provides the requirements of both automatic dispensing systems and manual dispensing systems.

Comment

The requirement of one-full time licensed nurse or other person authorized to dispense controlled substances for every 200 patients for automated dispensing systems in

proposed subsection (a)(1) should be increased to 300 patients because lesser ratios do not result in full utilization of staff and are a waste of resources.

Response

The Department proposed the 1/200 ratio based on findings from on-site inspections. The Department found that 90% of all the facilities within the Commonwealth utilize an automated dispensing system. Automated dispensing systems provide efficiency in dispensing controlled substances and the Department believes that the dispensing or administering staff ratio of 1 to every 200 patients is essential to meet the need of the patients. The Department has not revised the proposed regulation in response to this comment.

Comment

Proposed subsection (a)(2), requiring a 1 to 100 ratio for manual dispensing systems, does not result in full utilization of staff, and would be a waste of resources. The ratio for dispensing or administering staff in a manual dispensing systems should be increased to 1 to 150 patients.

Response

The Department agrees with the recommendation. The ratio has been amended to provide for one full-time nurse or other person authorized to administer or dispense a controlled substance for every 150 patients in an manual or non-automated dispensing system.

Comment

The phrase "timely and orderly manner" contained in proposed subsection (b) is vague. The Department should amend the regulation to provide clarity on what constitutes a timely and orderly manner for the dispensing of medication.

Response

The Department agrees that the phrase "timely and orderly manner" is vague. The Department has revised the entire provision to state: "Dispensing time shall be prorated for patient census. There shall be sufficient dispensing staff to ensure that all patients are medicated within fifteen minutes of arrival at the dispensing area." The original rationale for including the phrase "timely and orderly manner" was to provide for the safety of patients during the dispensing process and has been moved to section 715.17 (relating to medication control).

Section 715.8. Psychosocial staffing. This section requires narcotic treatment programs to comply with staffing ratios in Chapter 704 (relating to staffing requirements for drug and alcohol treatment activities).

Comment

This proposed section simply references the staffing ratios in Chapter 704, but does not specify which ratios are applicable to psychosocial staffing, the counselor or primary care

staff ratios. The Department should reference the specific staffing ratio that applies to psychosocial staffing.

Response

The Department agrees. The Department has revised this section to incorporate the staffing ratios from § 704.12 (relating to full-time equivalent (FTE) maximum client/staff and client/counselor ratios). In subsection (a) (relating to general requirements) narcotic treatment programs are required to comply with the client/staff and client/counselor ratios in paragraphs (1)-(6) during primary care hours. These ratios refer to the total number of clients being treated, including clients with diagnoses other than drug and alcohol addiction served in other facets of the project. Family units may be counted as one client. For inpatient non-hospital detoxification (residential detoxification), 1 full time equivalent (FTE) primary care staff person is required for every 7 clients during primary care hours and a physician is to be on-call at all times. For inpatient hospital detoxification, 1 FTE primary care staff person is required for every 5 clients during primary care hours. For inpatient non-hospital treatment and rehabilitation (residential treatment and rehabilitation), serving adult clients, 1 FTE counselor is required for every 8 clients. In projects for adolescent clients, 1 FTE counselor is required for every 6 six clients. For inpatient hospital treatment and rehabilitation (general, psychiatric or specialty hospital) serving adult clients, 1 FTE counselor is required for every 5 clients. For partial hospitalization, 1 FTE counselor is required for every 10 clients. For outpatients, FTE counselor caseload for counseling in outpatient narcotic treatment programs may not exceed 35 active clients. In subsection (b) (relating to counselor assistants), counselor

assistants may be included in determining FTE ratios when the counselor assistant is eligible for a caseload.

Section 715.9. Intake. This section requires screening of narcotic treatment program applicants prior to admission.

Comment

Under proposed subsection (a)(1), a program is required to "verify that the individual has reached the age of majority." To avoid confusion, the Department should replace "age of majority" with the more specific "age of 18."

Response

The Department notes that in Pennsylvania, for most purposes, the age of majority is 21. In this case, however, the Department adopts the recommendation and replaces "the age of majority" with the phrase "the age of 18."

Comment

Proposed subsection (a)(4) should be clarified. The subsection states that before a narcotic treatment physician prescribes methadone there must be "a determination by the physician that the individual is currently physiologically dependent." The most appropriate care and diagnosis is achieved through an initial face-to-face determination between a physician and patient; however, "determination" is not clearly defined. A third party consultation between a physician assistant, nurse practitioner, or other health care

person and the physician without the physician ever physically seeing the patient could be construed as sufficient for "determination" of dependency. The term "determination" should be further clarified to ensure correct diagnosis and appropriate care.

Response

The Department agrees. Proposed subsection (a)(4) has been revised to require that a narcotic treatment physician make a face-to-face determination of whether an individual is currently physiologically dependent upon a narcotic drug and has been psysiologically dependent for at least 1 year prior to admission for maintenance treatment.

Comment

The proposed language of subsection (b)(3) does not satisfactorily address readmission of persons formerly in treatment. Regardless of voluntary versus involuntary detoxification or number of years out of treatment, readmission should be left entirely to the discretion of the narcotic treatment program as long as current dependence is demonstrated.

Response

The Department agrees in part with the recommendation regarding voluntary versus involuntary detoxification, specifically that consideration be given to any person who has been detoxified, whether voluntarily or involuntarily. The distinction is eliminated. Patients who have been either voluntarily or involuntarily detoxified from comprehensive maintenance treatment may be readmitted to maintenance treatment, without evidence to support findings of current physiologic dependence, up to two years after discharge.

Readmission is conditioned upon the program being able to document prior narcotic drug comprehensive maintenance treatment of six months or more, and the admitting program physician, exercising reasonable clinical judgment, finding readmission to comprehensive maintenance treatment to be medically justified.

Section 715.10. Pregnant patients. This section establishes requirements for the admission and treatment of pregnant patients. This section is included because of the increasing rate of heroin addiction among pregnant women.

Comment

This proposed section does not reference the Federal regulation, which states that a pregnant woman is to be informed of the risks of continued illicit drug use to her and her unborn child. The Department should cross-reference 21 CFR 291.505 (d)(1)(iii)(B)(5).

Response

The Department has added subsection 715.10 (f) to address this comment.

Other Changes

Subsection (e) has been removed. It merely stated the general standard of practice in treatment and it is not necessary to state it as part of the regulation here.

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.

Comments

The phrase "within the provisions of State and Federal confidentiality regulations" contained in this section of the proposed regulation is a vague reference which does not afford notice of the specific requirements which must be satisfied under State and Federal regulations.

Response

The Department agrees. The specific citations 42 CFR 2.22 (relating to notice to patients of Federal confidentiality requirements) and 28 Pa. Code § 709.28 (relating to confidentiality) are referenced in the final regulation.

Section 715.12. Informed patient consent. This section requires the program to secure an informed, voluntary consent from the patient prior to the administering of an agent for detoxification or maintenance treatment.

Comment

This proposed section requires that a narcotic treatment program obtain an "informed, voluntary consent" before an agent can be administered to a patient. The proposed

regulation does not clearly state the specific information that the narcotic treatment program must provide to the patient and whether the consent must be written.

Response

The Department has amended the regulation to require a written consent and to require a list of specific items that must appear in writing on the consent. The following information must be included in the consent: (1) that methadone and LAAM are narcotic drugs which can be harmful if taken without medical supervision; (2) that methadone and LAAM are addictive medications and may, like other drugs used in medical practices, produce adverse results; (3) that alternative methods of treatment exist; (4) that the possible risks and complications of treatment have been explained to the patient; and (5) that methadone is transmitted to the unborn child and will cause physical dependence.

Section 715.13. Patient identification. This section requires a narcotic treatment program to develop a system for patient identification to ensure that the drug is being administered to the appropriate patient and for security and patient care reasons.

Comment

In proposed subsection (a), the term "develop" should be replaced with the term "use."

Response

The Department agrees and has substituted the term "use" in place of "develop."

Section 715.14. Urine testing. This section updates the urine testing procedures to conform with Federal standards and current practices. It requires testing for certain specific substances.

Comment

Neither this proposed section, nor proposed § 715.21 (relating to patient termination), identify the consequence of failing a urine test for a patient in the narcotic treatment program. The Department should explain the consequences when a patient's urine test detects and continues to detect any of the drugs in proposed subsection (a) of this regulation.

Response

The Department believes that if a patient's urine test detects and continues to detect any of the drugs identified in subsection (a), it would indicate the need for an intervention from the facility that could include an increase in dose, an increase in counseling services offered, a change in type of counseling services offered, or eventual discharge from the program. Accordingly, it is not appropriate for the Department to regulate consequences. The testing must be performed. What the facility does with the results will vary on a case by case basis, according to each individuals treatment needs and in conjunction with facility policy. The Department has made no change to the regulation based on this comment.

Comment

Proposed subsection (a) reduces the testing requirement to monthly for all tested substances. The existing regulation requires weekly urine testing for opiates and synthetic narcotics and monthly testing for other controlled substances. Urine testing for the first two years of narcotic addiction treatment should be conducted at a minimum of once per week because these patients need to be monitored more closely for relapse. The current requirement of weekly urine testing should be retained for more stable patients. The Department should explain its rationale behind requiring only monthly testing for all patients.

Response

The Department does not believe that requiring weekly urinalysis is appropriate for the patients that are treated in methadone treatment facilities. The testing is very costly, and is unnecessary for every patient. Further, facilities can require weekly testing for specific clients, if necessary.

Comment

Proposed subsection (b) requires the program "to ensure that urine collected from patients is unadulterated" and "that a random observation ... be conducted professionally, ethically and in a manner that protects patient privacy." The proposed language does not specify whether the observer is required to be a licensed health care professional. Also, the proposed language does not specify the methods to be used to ensure the sample is

unadulterated and that the observation be conducted in a manner that protects patient privacy.

Response

The Department has not changed the proposed regulation. The Department is not requiring the observer of the urinalysis testing to be a licensed health care professional. The Department is requiring that the program establish procedures to ensure that the urine sample is unadulterated and the investigation is conducted in a manner which respects patient privacy. These procedures are left to the discretion of the program.

Comment

Proposed subsection (c) requires a narcotic treatment program to implement policies and procedures addressing the chain of custody of a urine specimen to ensure that the specimen can be traced to the donor. "Chain of custody" is different from ordinary procedures to safeguard identifications of urine screens. It implies a specific set of procedures intended to meet forensic standards. This requirement is unnecessary, expensive and unduly burdensome. Implementing "chain of custody" procedures would increase testing costs by about 400% (or $25,000 per year). The Department should explain the need for a chain of custody and how the benefits outweigh the costs. Additionally, the Department should consider replacing the phrase "traced to the person whom it belongs" with the phrase "traced to the donor."

Response

The Department agrees with the recommendations and adopts the following revision: "A narcotic treatment program shall develop and implement policies and procedures to minimize misidentifications of urine specimens and to ensure that the tested specimens can be traced to the donor."

Section 715.15. Medication dosage. This section requires narcotic treatment programs to meet various Federal standards relating to narcotic treatment medication dosage.

Comment

The phrase "a narcotic treatment program may not administer an agent" in proposed subsections (a), (e) and (f) is inconsistent with the language of proposed subsection (c), which allows methadone to be "administered or dispensed." For clarity, the Department should add the term "dispense" to proposed subsections (a), (e) and (f). Also, the wording of the language of proposed subsection (c) which states "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" is not grammatically correct. An appropriate construct of the phrase would state "or other formulations may be distributed to the program ... ." The program receives the medications and then dispenses them to its patients. Further, the language "tablets, syrup concentrate or" should be omitted from the regulation if narcotic treatment programs do not dispense such formulations.

Response

The Department accepts this recommendation in part. The Department has added the term "dispense" to the phrase "administer or dispense" in subsections (a) and (e), to provide consistency throughout the section. In concert with Federal regulations, the Department will substitute the following language for proposed subsection (c): "Methadone shall be administered or dispensed only in oral form and shall be formulated in such a way as to reduce its potential for parenteral abuse." Subsection (f) has been combined with subsection (e) and modified to be consistent with subsection (c). In addition, subsection (a) was rewritten for clarification.

Section 715.16. Take-home privileges. This section establishes eligibility requirements for patients who may take medication out of the facility and self-administer outside the supervision of the program.

Comment

The current standard for giving patients take-home privileges does not respond to trends toward "medical maintenance." Programs should respond to the changes by permitting "senior patients," those patients who have substantial "clean time" with 5 or more years in treatment, to remain in programs and be able to receive up to a 30-day supply of medication. The proposed regulations seem to grant an exception for such patients, permitting them to attend a clinic twice a month where they receive a 2-week supply of medication. There is no clear procedure for how the requests for exception in this section will be approved and by whom. Also, the language of subsection (a) includes a sentence

which states: "The physician shall make this determination after consultation with appropriate staff." It is unclear who are "appropriate staff within the program" with whom the physician must consult. The Department should expand the regulation to specifically state who are "appropriate staff."

Response

The Department agrees in part. The Department agrees that the phrase "appropriate staff" needs clarity. Therefore, the Department has revised proposed subsection (a) to state that "the narcotic treatment physician shall make this determination after a consultations with staff involved in the patient's care." Medical maintenance as a treatment modality has not been tested effectively, and thus far has only been approved under Federal research pilot studies. The Department, therefore, declines to include medical maintenance in its regulation. The Department wishes to ensure that all take home methadone medication is utilized responsibly with minimal opportunities for diversion. The Department will continue to examine take-home privileges for longer than 6 days on a request for exception basis. Patient specific exceptions may be requested under § 715.29 (relating to exceptions).

Comment

The phrase "exceptional circumstance" in proposed subsection (d)(3) should be amended to make specific reference to the fact that "travel" is considered to be an "exceptional circumstance" under this regulation.

Response

The Department agrees that the phrase "exceptional circumstance" needs refinement. It has revised the regulation to provide that a patient has an exceptional circumstance if the patient confronts circumstances such as illness, personal or family crisis or travel that interfere with the ability to conform to the applicable mandatory attendance schedules.

Section 715.17. Medication control. This section provides that programs develop and implement policies and procedures relating to pharmaceutical services, verbal medication orders and medications.

Comment

Proposed subsection (c)(1)(iii) permits only patients to be present in the dispensing area. If the intent of this regulation is to restrict persons other than employees of the narcotic treatment programs and patients from entering the dispensing area, the subsection should be clarified to reflect that authorized employees are also permitted to enter into the dispensing area.

Response

The Department agrees. The Department's intent is to have subsection (c)(1)(iii) restrict the dispensing area to only patients and authorized staff. Therefore, the Department has revised the subsection to state "only authorized staff and patients who are receiving medication shall be permitted in the dispensing area."

Comment

Proposed subsection (c)(2) states "a narcotic treatment program shall develop and implement written policies and procedures regarding where and how medications are stored ... Agents shall be stored in a locked safe that has been approved by the DEA." However, section 715.26 (relating to security) requires that "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." There is a lack of clarity and consistency throughout the regulation on the requirements for storage areas, specifically, in the storage of a small amount of an agent in a secure area. For clarity, the Department should consider incorporating by reference 21 CFR 1301.72 (relating physical security controls) and 1301.74 (relating to other security controls) in both this section and section 715.26 (relating to security).

Response

The Department agrees that its regulation should be consistent with Federal regulation requirements for storage and security of controlled substances. Accordingly, the Department has specifically referred to 21 CFR 1301.72 and 1301.74 in subsection (c)(2), and in section 715.26.

Comment

The phrase "adequately documented" in proposed subsection (c)(3)(iv) is unclear. The Department should clarify this phrase.

Response

The Department adopts this recommendation. It has deleted the term "adequately" from the regulation, leaving only the requirement of documentation.

Other Changes

Subsection (a) was revised by deleting the phrase "which provide pharmaceutical services." This phrase added nothing to this subsection since compliance is required by all narcotic treatment programs. Subparagraph (c)(1)(vi) has been added to assist in controlling the administering and dispensing of medication.

In addition, various non-substantive changes were made for clarification.

Section 715.18. Rehabilitation services. This section revises the requirements for rehabilitative services accurately reflect current practices of narcotic treatment programs.

Comment

This proposed section requires a narcotic treatment program to provide a full range of rehabilitative services, including legal services, employment services, HIV education services, public health services, adult educational services and behavioral health services. The Federal regulations, specifically 21 CFR 291.505(d)(4)(i)(C), require that each narcotic treatment program provide "medical and rehabilitative services and programs" and "counseling on HIV disease." However, 21 CFR 291.505(d)(4)(iv) requires narcotic treatment programs to "provide opportunities" for vocational rehabilitation, education

and employment. For consistency with Federal regulations, the Department should state that, while programs are required to provide HIV services and public health services, a program shall also provide opportunities for patients to access legal services, employment services, adult educational services and behavioral health services.

Response

The Department agrees and adopts the recommendation which makes the regulation more consistent with Federal regulations.

Section 715.19. Psychotherapy services. This section establishes the requirements for psychotherapy services to be provided to patients.

Comment

The counselor staffing ratios defined in this proposed section need to be refined. There is a demand for a different treatment approach for long-term rehabilitated patients which facilitates deviations from the current client-ratio requirements, required physician hours and rehabilitative and psychotherapy services. To mandate these services would cause unnecessary hardship, time and money on the part of both the client and provider. The Department should amend the regulation to adopt a standard more suitable to meet the needs of the patient at each level of the narcotic treatment program.

Response

The Department agrees in part. Proposed paragraph (1) has been amended to include a requirement that additional psychotherapy shall be provided as dictated by the ongoing assessment of the patient. Proposed paragraph (2) has been revised to require a narcotic treatment program to provide each patient at least 1 hour per month of group or individual psychotherapy during the third and fourth year of treatment. Additional psychotherapy shall also be provided as dictated by the ongoing assessment of the patient. Proposed paragraph (3) has been deleted in its entirety. The Department has substituted the following language:

> After 4 years of treatment, a narcotic treatment program shall provide each patient with at least 1 hour of group or individual psychotherapy every 2 months. Additional psychotherapy shall be provided as dictated by ongoing assessment of the patient.

Section 715.20. Patient transfers. This section requires 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.

Comment

This proposed section requires each narcotic treatment program to develop policies and procedures for transferring patients from one treatment program to another, but makes no mention of whether patient records are to be kept confidential in the event of transfer. Proposed section 715.11 (relating to confidentiality of patient records) sets forth the

importance of the confidentiality of patients records in complying with Federal and State statutes and regulations. The Department should consider cross-referencing section 715.11 in this section to impress upon narcotic treatment programs that patient records will continue to be confidential even if the patient is transferred to another narcotic treatment program.

Response

The Department agrees. The Department has incorporated section 715.11 in this section.

Comment

The 7-day time frame proposed in this section for a narcotic treatment program to transfer patients upon request is without adequate support. The Department should explain how the 7-day time frame was derived, why the time period is necessary and whether the "request" must be submitted by a patient in writing to the narcotic treatment program.

Response

The Department has elected to impose 7-day time period in which a narcotic treatment program must transfer a patient upon request because some programs may wish to retain patients when it would not be appropriate to do so for a variety of reasons. Imposing this specific time requirement will provide efficiency in the transfer because it is a suitable time period for the program to prepare the appropriate paperwork for transfer. Additionally, the Department does not require a patient to submit a request for transfer in

writing because it would likely result in undue delays in the transfer process. The Department has not changed the section in response to the comment.

Section 715.21. Patient termination. This section states that narcotic treatment programs must establish policies regarding termination of clients from the program.

Comment

Proposed paragraph (1) defines in what instances a narcotic treatment program may involuntarily terminate a patient from the program. That list does not include involuntary termination due to nonpayment. "Nonpayment of fees" should be specifically included as a justification for termination. Providers work hard to assist patients to access available funding to support their services and to assist patients, as part of rehabilitation, to work to support themselves. Narcotic treatment programs would not be able to remain in business if they were not able to require payment from those deemed liable for their services.

Response

The Department has not added nonpayment to the list of causes for involuntary termination. The Department believes that the medication these patients are receiving is a life-sustaining medication, as determined by the Department of Public Welfare, and termination because of inability to pay may be detrimental to the health and well being of the patient. Further, a program may conduct a financial intake assessment prior to admission to verify that each individual has the means to pay.

Comment

Proposed paragraph (1)(iii) includes the phrase "excessively absent." This phrase is unclear. The Department should include in this paragraph the standards for determining when absences become excessive.

Response

The Department agrees and has changed the regulation. Subsection (1)(iii) has been revised to include absences of three consecutive days or longer without cause as a cause for termination.

Section 715.22. Patient grievance procedure. This section establishes the procedures for reviewing and resolving patient grievances.

Comment

Proposed subsection (a) requires a narcotic treatment program to develop and utilize a patient grievance procedure. Proposed subsection (b) states "if the grievance is filed against the program director, the review of the case shall be conducted by the governing body." Such an arrangement may not be in the best interests of the patient. A multi-representative group of the narcotic treatment program may be better suited to render judgment in such cases. The Department should consider allowing grievances against the program director to be heard by either a multi-representative group or a subcommittee of

the governing body instituted for the express purposes of grievance adjudication. Additionally, it is unclear whether grievances can be appealed directly to the Department.

Response

The Department accepts this recommendation in part. The Department has revised subsection (b) to permit grievances against the program director to be heard by either a multi-representative group or a subcommittee of the governing body instituted for the express purposes of grievance adjudication. The Department does not wish for grievances to be appealed directly to the Department. Permitting this would add another adjudicative layer and the Department already has a complaint process in existence as a recourse for patient grievances.

Subsection (c) has been revised for clarification.

Section 715.23. Patient records. This section sets out the time period which records must be kept after a patient leaves the program.

Comment

This proposed section contains the phrase "within the provisions of State and Federal confidentiality regulations." This section should provide citations to the specific section of the confidentiality requirements. Further, the Department should consider incorporating a provision by which a patient can authorize a provider to disclose any confidential information as the patient deems in the patient's interest.

Response

The Department agrees in part with this recommendation. The Department has provided citations to 42 CFR 2.16 (relating to security for written records) and 42 CFR 2.22 (relating to notice to patients of Federal confidentiality requirements) to avoid confusion and ambiguity in the interpretation of the regulation. State law does not permit incorporation of a provision permitting a patient to authorize the patient's provider to disclose confidential information as the patient deems in the patient's interest.

Comment

Proposed subsection (b)(15) provides for "psychiatric, psychological or psychosocial evaluations of the patient." The drafting of the language of this subsection implies that psychiatric and psychological evaluations can replace the psychosocial evaluation requirement. This provision should be redrafted to include psychosocial evaluations as a separate and distinct requirement of this subsection.

Response

The Department agrees. Subsection (b)(15) has been revised to allow for psychosocial evaluations as a separate requirement. The Department has added a new subsection (b)(16) which will provide for any psychiatric, psychological or other evaluations if available.

Comment

Proposed subsection (e) requires all patient records, information and documentation to be "maintained on standardized forms." It is unclear from the language of this subsection whether the Department will develop and distribute these forms and whether the Department will permit patient records to be maintained electronically.

Response

The Department does not develop or provide forms to be used for patient records and information. The narcotic treatment programs will develop and utilize these forms. In keeping with current trends in technology, the Department will permit patient records to be maintained electronically.

Section 715.24. Narcotic detoxification. This section requires that minimum procedures for detoxification be developed and implemented by narcotic treatment programs.

Comment

Proposed paragraph (4)(i) requires that take home medication not be dispensed during a 30-day detoxification treatment. Also, narcotic treatment programs are required to observe the patient ingesting the medication 7 days per week. It is suggested that the 7-day-per-week clause be changed to the phrase "daily" to accommodate for a 6 day opening week.

Response

It is medically necessary during the detoxification phase of narcotic treatment programs to observe patients ingesting their medication 7 days per week. The Department has not changed the regulation.

Section 715.25. Prohibition of medication units. This section prohibits medication units from operating in the Commonwealth.

Comment

Because the number of narcotic treatment programs is so few, it is difficult for patients to continue treatment at the program, as well as employment. The Department should explain the rationale behind prohibiting medication units within the Commonwealth. Also, the exact meaning of the term "medication unit" is unclear. In the interest of clarity, the Department should cite the specific Federal regulation which defines medication units.

Response

The Department prohibits medication units within the Commonwealth because these sites can be hundreds of miles from the main narcotic treatment program facility site. Further, only medication is dispensed at these sites. There is no counseling, no support services and no supervision at these medication units. Dispensing medication without clinical or support services is not in the best interests of patients. The Department has not changed the regulation in response to this comment. The Department does agree, however, that

the definition of "medication units" should be included in § 701.1 (relating to general definitions). That definition reads as follows:

> Medication unit – A facility established as part of, but geographically separate from, the narcotic treatment program site, from which a retail pharmacist or a practitioner, who is licensed under state law and registered under federal law to administer or dispense a narcotic drug, may dispense or administer a narcotic drug or collect samples for drug testing or analysis for narcotic drugs.

Section 715.26. Security. This section establishes the requirements for security in narcotic treatment programs and the requirements of narcotic treatment programs to address community concerns.

Comment

This proposed section refers to Federal and State statutes and regulations. This phrase needs to be clarified to reference specific citations to the requirements.

Response

The Department agrees. The Department has provided a citation to 21 CFR 1301.72 and 1301.74 (relating to physical security controls; other security controls). This addition should remove confusion and ambiguity in the interpretation of the regulation.

Section 715.27. Readmission. The Department received no comments on this section, however, it has been revised for clarity.

Section 715.28. Unusual incidents. This section requires a narcotic treatment program to develop a procedure to document and respond to unusual incidents.

Comment

Proposed subsection (c) requires a narcotic treatment program to file "Unusual Incidence Reports." An "unusual incident" under proposed subsection (c)(1) includes "complaints of patient abuse (physical, verbal, sexual, emotional and financial)." The phrase "financial abuse" is unclear. The Department should clarify what constitutes financial abuse. Additionally, there are a number of terms and phrases that are unclear in this proposed section: subsections (a)(1) "inappropriate behavior;" (a)(5) and (c)(2) "unusual circumstances;" (a)(6) and (c)(3) "significant disruption;" and (a)(9) and (b)(1) "unusual incident." The Department should clarify each of the terms indicated.

Response

The Department has deleted the term "financial abuse." The other terms are consistent with established Joint Commission for Accreditation of Health Organizations (JCAHO) Guidelines for Sentinel Events. The narcotic treatment regulations need to be consistent with these commonly accepted industry terms.

Section 715.29. Exceptions. The Department received no comments on this section.

Section 715.30. Applicability. The Department received no comments on this section.

C. FISCAL IMPACT

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

D. PAPERWORK ESTIMATE

There will 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.

E. EFFECTIVE DATE/SUNSET DATE

The regulations will become effective immediately upon publication as final rulemaking. No sunset date is necessary. The Department will monitor the appropriateness of these regulations on a continuing basis.

F. STATUTORY AUTHORITY

The Department was authorized by the General Assembly pursuant to Reorganization Plan No. 2 of 1977 (71 P.S. § 751-25) Reorganization Plan No. 4 of 1981 (71 P.S. § 751-31) and amendments to the Pennsylvania Drug and Alcohol Abuse Control Act (71 P.S. § 1690 et seq.) (Act 63), to assume the function and responsibilities of the Governor's Council on Drug and Alcohol Abuse (Council). The Council's authority to regulate and promulgate rules and regulations was transferred to the Department through those

reorganization plans. See Reorganization Plan No. 2 of 1977 (transferring duties under the Public Welfare Code with regard to regulation, supervision, and licensing of drug and alcohol facilities to the Council), Reorganization Plan No. 4 of 1981 (transferring the functions of the Council to the Department and establishing the Council as an advisory council) and Act 63, as amended by Act of Dec. 20, 1985, P.L. 529, No. 119, (amending Act 63 to reference the Pennsylvania Advisory Council on Drug and Alcohol Abuse). The regulations were promulgated under these provisions and are being rescinded, amended and added pursuant to these provisions. Regulation is also required by Federal regulations, 42 CFR 8.1-8.34.

G. REGULATORY REVIEW

Under Section 5(a) of the Regulatory Review Act, 71 P.S. § 745.5(a) et seq., the Department submitted a copy of the proposed regulations, published at 30 Pa. Bulletin 3795 (July 29, 2000), on July 17, 2000 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 for review and comment. In addition, in compliance with Section 5 (c) and 5.1 (a) of the Act, the Department provided IRRC and the Committees with copies of all comments received.

The Department submitted a copy of the final-form regulation to IRRC and the chairpersons of the Committees on August 20, 2002. In addition, the Department provided IRRC and the Committees with a copy of 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.

In preparing this final-form regulation the Department has considered all comments received from IRRC, the Committees and the public.

This final-form regulations were (deemed) approved by the House Health and Human Services Committee on , 2002 and the Senate Public Health and Welfare Committee on , 2002. IRRC met on , 2002, and approved the regulations in accordance with Section 5.1 (e) of the Regulatory Review Act. The Office of Attorney General approved the regulations on .

H. CONTACT PERSON

Questions regarding these final-form regulations may be submitted to John C. Hair, Director, Bureau of Community Program Licensure and Certification, 132 Kline Plaza, Suite A, Harrisburg, PA 17104, (717) 783-8665. Persons with a disability may also submit questions regarding the final-form regulations by using V/TT (717) 783-6514 for speech and/or hearing impaired persons or the Pennsylvania AT&T Relay Service at (800-654-4984[TT]). Persons with a disability who would like to obtain this document in an alternative format (i.e., large print, audio tape or Braille) may contact Mr. Hair so that necessary arrangements may be made.

I. FINDINGS

The Department finds:

1. Public notice of intention to adopt regulations adopted by this order has been given under sections 201 and 202 of the Act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§ 1201 and 1202), and the regulations thereunder, 1 Pa. Code §§ 7.1 and 7.2.
2. A public comment period was provided as required by law and the comments received were considered.
3. The adoption of the final-form regulations in the manner provided by this order is necessary and appropriate.

J. ORDER

The Department, acting under the authorizing statutes, orders that:

(a) The regulations of the Department, are amended by repealing 4 Pa. Code Chapter 263, amending 28 Pa. Code § 701.1 and adding 28 Pa. Code Chapter 715 (§§ 715.1 – 715.30) as set for in Annex A.

(b) The Secretary of Health shall submit this order and Annex A to the Office of General Counsel and the Office of Attorney General for approval as required by law.

(c) The Secretary of Health shall submit this order, Annex A, and a Regulatory Analysis Form to IRRC, the House Committee on Health and Human Services and the Senate Committee on Public Health and Welfare for their review and action as required by law.

(d) The Secretary of Health shall certify this order and Annex A and deposit them with the Legislative Reference Bureau as required by law.

(e) This order shall take effect upon publication in the *Pennsylvania Bulletin*.

ANNEX A
TITLE 4. ADMINISTRATION
PART XI. GOVERNOR'S COUNCIL ON DRUG AND ALCOHOL ABUSE
***

CHAPTER 263. [METHADONE]

§ 263.1. **[Statement of policy]** **(Reserved).**

[(a) All projects within this Commonwealth which use the drug methadone in the treatment, maintenance or detoxification of persons shall obtain the approval of the Council to operate as such a project. For the purpose of this Part such projects shall be called methadone projects.

(b) Approval of methadone projects shall be contingent upon the compliance of the project with the standards and conditions set forth in this Part.]

§ 263.2. **[Relationship of Federal and State regulations]** **(Reserved).**

All methadone projects shall comply with all Federal regulations concerning the administration, dispensing and storage of methadone.]

§ 263.3. **[Inspection for approval and compliance]** **(Reserved).**

[(a) Methadone projects shall apply to the Council for approval. Requests for approval shall be addressed to the Executive Director of the Council. Within 30 days after request for approval, representatives of the Council will inspect the methadone project and, within 30 days of the inspection, will submit a written report of its findings and recommendations to the Executive Director. A copy of such report will be mailed to the applicant.

(b) Within 30 days after receipt of the report the Executive Director of the Council will rule on the request of the applicant. A decision to disapprove an application will be in writing, and will set forth the reasons therefor. Appeals therefrom will be in accordance with the Administrative Agency Law (71 P.S. §§1710.1—1710.51)(Repealed).

(c) The Executive Director of the Council may grant conditional approval when it is determined:

(1) That the deficiencies of the applicant can be corrected within 60 days.

(2) The deficiencies do not impair the health or safety of the clients or the safety of the public.

(d) The methadone projects currently operating under approval will be inspected within 6 months for compliance with this chapter.

(e) All approved methadone projects will be inspected at least once within a one year period after approval. Inspections will occur without notice to the methadone project and will occur during any regular business hours of the methadone project.

(f) All methadone projects shall, during inspection, make available to the authorized inspection staff of the Council, full and free access to its premises, facilities, records, reports, files and other similar items which may be copied or reproduced for the purpose of the inspection.

(g) All methadone projects which are found in noncompliance with this Chapter may be given reasonable time by the Executive Director of the Council, not to exceed 90 days, to correct such noncompliance provided such continued operation would not endanger the health or safety of the clients or the safety of the public.

(h) A methadone project which desires to contest a finding of noncompliance may request of the Council, in writing, an informal conference with the Executive Director of the Council within 15 days after receipt of notice of noncompliance. The Executive Director will issue a final decision within 15 days thereafter. Appeals therefrom shall be in accordance with §263.4 (relating to revocation or suspension of approval; hearings).]

§ 263.4. **[Revocation or suspension of approval, hearings] (Reserved).**

[Methadone project approval may be suspended or revoked if the methadone project fails to comply with this chapter. Appeals following a suspension or revocation shall be held in accordance with the procedures of the Administrative Agency Law (71 P.S. §§1710.1 – 1710.51) (Repealed).]

§ 263.5. **[Methadone doses] (Reserved).**

[(a) No client shall be administered methadone at doses above 80 milligrams per 24-hour period without prior written approval of the Executive Director of the Council. Dosage levels shall be reviewed at least twice a year for the purpose of determining the optimum dosage level of a client. Such reviews shall be performed by the methadone project physician or his designee with each review occurring no less than 2 months after the last review for the purpose of compliance with this section.

(b) It shall be the decision of the methadone project physician as to the proper dosage level of a client except as otherwise provided in this chapter.]

§ 263.6. **[Urine testing] (Reserved).**

[(a) All methadone projects shall perform a urine test for each client at least weekly and on a random schedule to test for opiates and synthetic narcotics; and at least monthly and on a random schedule to test for amphetamines, barbiturates and any other controlled substances as indicated by the Executive Director of the Council.

(b) Where a methadone project contracts with a laboratory facility for urine testing, such facility shall be approved by the appropriate agencies of both the Federal and State government. The methadone project shall inform the Executive Director of the Council of any change by the facility in the performing of urine testing, immediately upon such change taking place.]

§ 263.7. **[Client case load] (Reserved).**

[The Executive Director of the Council may limit the number of clients that each methadone project shall be permitted to treat at any given time. This client case load figure may be raised or lowered at the request of the project, with the approval of the Executive Director of the Council, or by the Executive Director of the Council at his discretion based upon periodic methadone project inspection

and review. The factors the Executive Director of the Council will consider will include:

(1) Safety.

(2) Physical facility.

(3) Staff size and composition.

(4) Ability to provide required services.]

§ 263.8. [Client records] (Reserved).

[(a) All methadone projects shall maintain client records in conformance with all applicable Federal and State regulations, including the maintenance of a complete file on the premises for each present and former client of the methadone project for a period of at least 4 years after the client has completed treatment or his treatment has been terminated. All client files shall be updated to reflect changes in client status.

(b) Included in each client file shall be the following information:

(1) A complete personal history.

(2) A complete medical history, including the results of an initial intake physical examination and the results of all annual physical examinations given by the methadone project.

(3) All laboratory or other special examinations given by the methadone project.

(4) Documentation or evidence of attempts to document a 2-year history of opiate addiction.

(5) A written justification by the methadone project physician for any client continued in methadone maintenance for a period of more than 2 years.

(6) The current and past methadone dosage level of the client.

(7) Other drugs prescribed by the methadone project physician and the reasons therefor.

(8) All urine testing results.

(9) Counselor notes regarding client progress and status.

(10) Required Federal and State consent forms.

(11) Client attendance record.

(12) All staff conference notes regarding the client.

(13) All psychiatric or psychological evaluations of the client.

(14) All treatment plans for the client.

(15) All drug incidence reports.

(16) All State and Federal exceptions to the regulations granted to the project on behalf of the client.

(17) All referrals to other projects or services.

(18) All take-home privileges granted to the client.

(19) All follow-up regarding the client.

(20) Any additional information required by the Council.

(c) All client file records and information shall be legible, accurate and complete.

(d) In the event the methadone project protocol dictates client information be kept in more than one file or location, it shall be the responsibility of the project to assemble and present such separated information or data as a single client unit to authorized persons conducting methadone monitoring activities at the methadone project upon request.]

§ 263.9. [Dispensing staffing pattern] (Reserved).

[All methadone projects will be staffed as follows:

(1) One hundred clients or less: one full-time licensed nurse, or other person duly authorized by law to dispense controlled substances. Such person shall be known as a dispenser.

(2) More than 100 clients: 20 hours of dispenser time for each additional 50 clients.]

§ 263.10. [Physician staffing pattern] (Reserved).

[One full-time physician shall be available for every 300 clients in treatment. No more than four physicians may combine their time to meet these requirements.]

§ 263.11. [Psychosocial services] (Reserved).

[All methadone projects shall make available a full range of psychosocial services. These services shall include but not be limited to counseling or psychotherapy or both educational counseling and employment services. All methadone projects shall make available the following services either on their premises or within a reasonable distance thereof:

(1) Legal counseling.

(2) Employment services.

(3) Recreational therapy.

(4) Informational services.]

§ 263.12. **[Psychosocial staffing patterns] (Reserved).**

[All methadone projects shall maintain a ratio of at least one full-time counselor/therapist to 40 clients receiving maintenance, detoxification, or drug free treatment. The ratio shall be calculated in the following manner:

(1) A full-time staff person is one who spends 100% of his time counseling clients. A full-time staff person shall spend at least 1/3 of his time providing counseling therapy to be counted as counselor/therapist.

(2) Part-time staff persons will spend at least 15 hours a week in counseling to be counted as 1/3 counselor/therapist.

(3) No full-time staff person spending 100% of their time engaged in administrative, clerical, or custodial activities shall be included in the counselor/therapist ratio.

(4) No part-time staff persons spending less than 15 hours or full-time staff persons spending less than 1/3 of their time as a counselor/therapist shall be included in the ratio.

(5) The provisions of this section shall not preclude the use of supplemental or voluntary service providers but such persons shall not be included in the ratio.

(6) All methadone projects shall designate a chief counselor or supervisor who shall be responsible for the supervision and coordination of the activities of the other counselors/therapists.]

§ 263.13. **[Intake] (Reserved).**

[(a) Prior to methadone administration, all methadone projects shall establish client eligibility, complete an intake physical, collect basic identifying information, including current address, next of kin, emergency contact, phone number, social security number and health insurance information, and complete all applicable State and Federal consent forms. A determination of client eligibility shall be based upon:

(1) A complete 2-year narcotic dependency history by documentation of previous project encounters, or the evaluation of the methadone project physician to support claim of the client of narcotic dependency.

(2) The client having reached the age of majority.

(3) Present dependency on opiates which shall be documented in the record of the client by the physician who shall clearly outline the procedure used to determine such dependency.

(b) All methadone projects shall secure a personal history from the client within the first week of admission which shall be made a part of the record of the client.]

§ 263.14. [Client identification] (Reserved).

[All methadone projects shall provide each client with a clear, unalterable means of identification, which shall include client name, address, photograph, the project name, address and telephone number. All identification cards shall contain both an issuance and expiration date.]

§ 263.15. [Confidentiality of client records] (Reserved).

[All methadone projects shall physically secure all client records and shall not disclose any information from such records unless such disclosure is in accordance with the provisions of Act 63, Act 64 and all applicable Federal and State regulations.]

§ 263.16. **[Transfers] (Reserved).**

[(a) A methadone project shall transfer any client to another methadone project, for continued maintenance, ambulatory detoxification, in-patient detoxification, or another treatment environment upon request of the client and where the methadone project determines that the transfer is in the best interests of the health or safety of the client.

(b) The project shall secure written approval from the receiving project prior to the transfer taking place. The transferring methadone project shall make provisions for continuity of services as specified in this part, detoxification if needed, and transfer of client file materials which shall be compiled at a case termination conference attended by representatives of the medical and psychosocial project staffs involved in the transfer. Client file material to be transferred shall include medical and psychosocial summaries, current status reports, dosage level, urinalysis reports and initial intake information of the client. Any transfer of client information shall be with the written consent of the client. The receiving methadone project shall confirm, in writing, actual receipt of the client file and arrival of the client.

(c) In cases where the client becomes incarcerated or involuntarily confined, the methadone project may transfer the portion of the client file necessary for methadone detoxification.]

§ 263.17. [Client termination] (Reserved).

[(a) All methadone projects may involuntarily terminate a client from the project if it deems that such termination would be in the best interests of the health or safety of the client, or the methadone project finds any of the following conditions to exist or have existed:

(1) The client has committed threats or acts of physical violence in or around the methadone project premises.

(2) The client has sold, distributed or possessed, in or around the methadone project premises, controlled substances without a lawful prescription.

(3) The client has been excessively absent from the methadone project.

(4) The client has been absent for 7 days consecutively without cause.

(5) The client has failed to follow his treatment plan.

(6) The client has had consistently positive urines.

(7) The client has failed to seek employment, training or education.

(b) Any client involuntarily terminated shall be afforded the opportunity to receive methadone detoxification over a period of time not to exceed 21 days, but not less than 7 days.]

§ 263.18. [Client appeal procedures] (Reserved).

[All methadone projects shall develop and utilize a client appeal procedure. Such procedure shall permit aggrieved clients a full and fair opportunity to be heard, to question and confront persons and evidence used against him and have a fair review of his case by the Director of the methadone project. The client appeal procedure shall be in writing, and shall be available for inspection by representatives of the Council.]

§ 263.19. [Readmission] (Reserved).

[(a) If a client requests readmission to a project after voluntary termination from that project, he shall be provided with an evaluation interview and be given priority consideration for readmission.

(b) Where a client has been out of the project for 6 months or less the methadone project shall update the file information of the client and

review the physical state of the client and show current opiate dependency, but need not complete a physical examination. Privileges earned during the previous treatment period may be reinstated at the discretion of the methadone project.

(c) A client who has been out of the methadone project for more than 6 months after voluntary termination shall, upon application for readmission, be treated as a new admission.

(d) Any person who had previously been involuntarily terminated shall be treated as a new admission.]

§ 263.20. [Project file] (Reserved).

[All methadone projects shall:

(1) Maintain on their premises a central methadone project file which will contain but not be limited to the following:

(i) Information and data related to overall client care or services.

(ii) Exceptions to Federal and State regulations.

(iii) Special treatment protocol.

(iv) Any third party agreements for the provision of treatment or rehabilitation services to clients.

(v) Methadone project organizational charts.

(vi) Methadone project policy statements.

(vii) Methadone project goals and objectives.

(viii) Staff role definitions and job descriptions.

(ix) Notices of noncompliance or facsimiles thereof from local, State or Federal monitoring or funding agencies along with a narrative showing attempts to or resolutions of such noncompliance.

(x) A copy of any agreements with local, State or Federal authorities.

(2) Include in their project file any other item or information which the Council may from time-to-time require.]

§ 263.21. [Ambulatory detoxification] <u>(Reserved)</u>.

[Methadone projects may utilize ambulatory detoxification where it has been approved by the Council prior to utilization. Requests should be addressed to the Executive Director of the Council.]

§ 263.22. **[Methadone maintenance in correctional institutions] (Reserved).**

[(a) Methadone maintenance treatment shall not be initiated in any correctional institution unless the Executive Director of the Council determines:

(1) A compelling medical or psychosocial need requires such treatment.

(2) Appropriate arrangements have been made concerning entry into a methadone maintenance project upon release from the institution.

(b) Requests in this regard should be addressed to the Executive Director of the Council, setting forth the reasons therefore.]

§ 263.23. **[FD 1639 drug incidence report] (Reserved).**

[All methadone projects shall send to the Council a copy of a completed Form FD 1639 within ten days after such completion.]

§ 263.24. **[Medication units] (Reserved).**

[Methadone treatment medication units as defined by Federal regulation are prohibited.]

§ 263.25. [Security] (Reserved).

[(a) All methadone projects shall comply with applicable Federal Methadone Security Regulations.

(b) When submitting an application for Council approval to operate a methadone project, all applicants shall enclose a letter from the Bureau of Drug Control, Department of Justice, Commonwealth of Pennsylvania, indicating compliance with this chapter.]

§ 263.26. [Informed client consent forms] (Reserved).

[(a) Before methadone may be administered to a client as treatment, informed voluntary client consent must be obtained. GCDAA From 615, Twenty-One Day Informed Voluntary Consent to Initiation of Methadone Maintenance Treatment, must be completed and retained in the file of the client. Form 615 follows:

(b) Not sooner than 14 days nor later than 21 days from the date of the completion of GCDAA Form 615, if methadone treatment is to continue, informed voluntary client consent must be obtained. GCDAA Form 616, Informed and Voluntary Consent to Continuation of Methadone Maintenance Treatment, must be completed and retained in the file of the client. Form 616 follows:

(c) Before methadone may be administered to a client for the purposes of detoxification, informed voluntary client consent must be obtained. GCDAA Form 617, Informed and Voluntary Consent to Detoxification Utilizing Methadone, must be completed and retained in the file of the client. Form 617 is attached hereto as an exhibit and made a part of these regulations.]

***

[EXHIBIT A]

GCDAA Form 615 (2-76)

FORM 615

Twenty-One Day Informed Voluntary Consent to Initiation of Methadone Maintenance Treatment

Date

Name of Client

Name of Counselor Explaining Procedures

Name of Project Medical Director explaining risks

I hereby authorize and give my voluntary consent *for a period of 21 days only*, to the above named Project Medical Director and/or any appropriately authorized assistants he may select to administer or prescribe the drug methadone as an element in the treatment for my dependence on heroin or other narcotic drugs as defined in AThe Controlled Substance, Drug, Device and Cosmetic Act.≡

IT HAS BEEN EXPLAINED TO ME THAT METHADONE IS A NARCOTIC DRUG WHICH CAN BE HARMFUL. I FURTHER UNDERSTAND THAT METHADONE IS AN ADDICTIVE MEDICATION AND MAY PRODUCE ADVERSE RESULTS.

I **-Procedure** The procedures necessary to treat my condition have been explained to me and I understand the nature of the procedures to be (Revised Treatment Plan) as follows:

II **-Alternative Methods of Treatment** The other methods of treatment have been explained to me and I understand my choice to be from the following:

After considering the other methods, I choose to receive methadone maintenance treatment.

I affirm that I am not enrolled in any other methadone treatment project and I will not attempt to enroll in any other methadone treatment project while enrolled in this project.

I also understand that my treatment may include routine diagnostic procedures and medical treatment and I voluntarily consent and agree.

III **-Risks** The possible risks and complications involved have been explained to me by a medical doctor or his/her designee and I understand that:

Some people on methadone may sweat, become constipated, drowsy or have a decrease in sex drive. Occasionally clients will have an increase in sex drive on methadone. Methadone may depress respiration or slow down the rate of breathing. Clients may experience some initial difficulty sleeping. Most of these problems disappear with time.

I agree that I shall inform any doctor who may treat me for any medical problem that I am enrolled in a methadone treatment project, since the use of other drugs in conjunction with methadone may cause me harm.

I agree that I shall not take any drugs without a physician's advice and prescription. I understand that other drugs combined with methadone may cause me harm.

After considering the possible risks and consequences involved, I desire to receive methadone maintenance treatment.

The goal of methadone maintenance treatment is total rehabilitation of the client. Eventual withdrawal from the use of all drugs, including methadone is an appropriate treatment goal. I realize that for some clients methadone maintenance treatment may continue for relatively long periods of time but that periodic consideration shall be given concerning my complete withdrawal from methadone use.

I UNDERSTAND THAT I MAY WITHDRAW FROM THIS TREATMENT PROJECT AND DISCONTINUE THE USE OF THE DRUG AT ANY TIME AND I SHALL BE AFFORDED DETOXIFICATION UNDER MEDICAL SUPERVISION.

Female Clients of Child-Bearing Age	Clients Under 18 Years of Age
To the best of my knowledge, I [ ] am [ ] am not pregnant at this time. Besides the possible risks involved with the long-term use of methadone, I further understand that, like heroin and other narcotic drugs, information on its effects on pregnant women and on their unborn children is at present inadequate to guarantee that it may not produce significant or serious side effects. It has been explained to me and I understand that methadone is transmitted to the unborn child and will cause physical dependence. Thus, if I am pregnant and suddenly stop taking methadone, I or the unborn child may show sings of withdrawal which may adversely affect my pregnancy or the child. I shall use no other drugs without the Medical Director or his assistants' approval, since these drugs, particularly as they might interact with methadone, may harm me or my unborn child. I shall inform any other doctor who sees me during my present or any future pregnancy or who sees the child after birth, of my current or past participation in a methadone treatment program in order that he may properly care for my child and me. It has been explained to me that after the birth of my child I should not nurse the baby because methadone is transmitted through the milk to the baby and this may cause physical dependence on methadone in the child. I understand that for a brief period following birth, the child may show temporary irritability or other ill effects due to my use of methadone. It is essential for the child=s physician to know of my participation in a methadone treatment program so that he may provide appropriate medical treatment for the child. All the above possible effects of methadone have been fully explained to me and I understand that at present, there have not been enough studies conducted on the longterm use of the drug to assure complete safety to my child. With full knowledge of this, I consent to its use and promise to inform the Medical Director or one of his assistants immediately if I become pregnant in the future.	The client is a minor, ____ years of age, born, _____. The risks of the use of methadone have been explained to [me/us] and [I/we] understand that methadone is a drug on which long-term studies are still being conducted and that information on its effects is incomplete. [I/we] declare that participation in the methadone maintenance treatment program is wholly voluntary on the part of both the [parent(s)/guardian(s)] and the client and that methadone maintenance treatment may be stopped at any time on [my/our] request or that of the client. With full knowledge of the potential benefits and possible risks involved with the use of methadone in the treatment of an adolescent, [I/we] consent to its use upon the minor.

I have explained the contents of this form to the client to the best of my ability:

_____ Physician=s Signature

_____ Date:

I certify that no guarantee or assurance has been made as to the results that may be obtained from methadone maintenance treatment. With full knowledge of the potential benefits and possible risks involved, I consent to methadone treatment.

Signature of Client	Date of Birth	Date:
Signature of Parent(s) or Guardian(s)	Relationship	Date:
Signature of Witness		Date:

[EXHIBIT B]

GCDAA Form 616 (2-76)

FORM 616

Informed and Voluntary Consent to Continuation of Methadone Maintenance Treatment

	Date

Name of Client

Name of Counselor Explaining Procedures

Name of Project Medical Director explaining risks

I hereby authorize and give my voluntary consent to the above named Project Medical Director and/or any appropriately authorized assistants he may select to administer or prescribe the drug methadone as an element in the treatment for my dependence on heroin or other narcotic drugs as defined in AThe Controlled Substance, Drug, Device and Cosmetic Act.≅

IT HAS BEEN EXPLAINED TO ME THAT METHADONE IS A NARCOTIC DRUG WHICH CAN BE HARMFUL. I FURTHER UNDERSTAND THAT METHADONE IS AN ADDICTIVE MEDICATION AND MAY PRODUCE ADVERSE RESULTS.

I -**Procedure** The procedures necessary to treat my condition have been explained to me and I understand the nature of the procedures to be (Revised Treatment Plan) as follows:

II -**Alternative Methods of Treatment** The other methods of treatment have been explained to me and I understand my choice to be from the following:

After considering the other methods, I choose to receive methadone maintenance treatment.

I affirm that I am not enrolled in any other methadone treatment project and I will not attempt to enroll in any other methadone treatment project while enrolled in this project.

I also understand that my treatment may include routine diagnostic procedures and medical treatment and I voluntarily consent and agree.

III **Risks** The possible risks and complications involved have been explained to me by a medical doctor or his/her designee and I understand that:

Some people on methadone may sweat, become constipated, drowsy or have a decrease in sex drive. Occasionally clients will have an increase in sex drive on methadone. Methadone may depress respiration or slow down the rate of breathing. Clients may experience some initial difficulty sleeping Most of these problems disappear with time.

I agree that I shall inform any doctor who may treat me for any medical problem that I am enrolled in a methadone treatment project, since the use of other drugs in conjunction with methadone may cause me harm.

I agree that I shall not take any drugs without a physician=s advice and prescription. I understand that other drugs combined with methadone may cause me harm.

After considering the possible risks and consequences involved, I desire to receive methadone maintenance treatment.

The goal of methadone maintenance treatment is total rehabilitation of the client. Eventual withdrawal from the use of all drugs, including methadone is an appropriate treatment goal. I realize that for some clients methadone maintenance treatment may continue for relatively long periods of time but that periodic consideration shall be given concerning my complete withdrawal from methadone use.

I UNDERSTAND THAT I MAY WITHDRAW FROM THIS TREATMENT PROJECT AND DISCONTINUE THE USE OF THE DRUG AT ANY TIME AND I SHALL BE AFFORDED DETOXIFICATION UNDER MEDICAL SUPERVISION.

Female Clients of Child-Bearing Age	Clients Under 18 Years of Age
To the best of my knowledge, I [ ] am [ ] am not pregnant at this time. Besides the possible risks involved with the long-term use of methadone, I further understand that, like heroin and other narcotic drugs, information on its effects on pregnant women and on their unborn children is at present inadequate to guarantee that it may not produce significant or serious side effects. It has been explained to me and I understand that methadone is transmitted to the unborn child and will cause physical dependence. Thus, if I am pregnant and suddenly stop taking methadone, I or the unborn child may show signs of withdrawal which may adversely affect my pregnancy or the child. I shall use no other drugs without the Medical Director or his assistants= approval, since these drugs, particularly as they might interact with methadone, may harm me or my unborn child. I shall inform any other doctor who sees me during my present or any future pregnancy or who sees the child after birth, of my current or past participation in a methadone treatment program in order that he may properly care for my child and me. It has been explained to me that after the birth of my child I should not nurse the baby because methadone is transmitted through the milk to the baby and this may cause physical dependence on methadone in the child. I understand that for a brief period following birth, the child may show temporary irritability or other ill effects due to my use of methadone. It is essential for the child=s physician to know of my participation in a methadone treatment program so that he may provide appropriate medical treatment for the child. All the above possible effects of methadone have been fully explained to me and I understand that at present, there have not been enough studies conducted on the longterm use of the drug to assure complete safety to my child. With full knowledge of this, I consent to its use and promise to inform the Medical Director or one of his assistants immediately if I become pregnant in the future.	The client is a minor, _____ years of age, born, _____. The risks of the use of methadone have been explained to [me/us] and [I/we] understand that methadone is a drug which long-term studies are still being conducted and that information on its effects is incomplete. [I/we] declare that participation in the methadone maintenance treatment program is wholly voluntary on the part of both the [parent(s)/guardian(s)] and the client and that methadone maintenance treatment may be stopped at any time on [my/our] request or that of the client. With full knowledge of the potential benefits and possible risks involved with the use of methadone in the treatment of an adolescent, [I/we] consent to its use upon the minor.

I have explained the contents of this form to the client to the best of my ability:

_____ Physician=s Signature

_____ Date:

I certify that no guarantee or assurance has been made as to the results that may be obtained from methadone maintenance treatment. With full knowledge of the potential benefits and possible risks involved, I consent to methadone treatment.

Signature of Client	Date of Birth	Date:
Signature of Parent(s) or Guardian(s)	Relationship	Date:
Signature of Witness		Date:

[EXHIBIT C]

GCDAA Form 617 (2-76)

FORM 617

Informed and Voluntary Consent to Detoxification Utilizing Methadone

	Date

Name of Client

Name of Counselor Explaining Procedures

Name of Project Medical Director Explaining Risks

I hereby authorize and give my voluntary consent to the above named Project Medical Director and/or any appropriately authorized assistants he may select to administer or prescribe the drug methadone as an element in the detoxification process from my dependence on heroin or other narcotic drugs as defined in AThe Controlled Substance, Drug, Device and Cosmetic Act.≅

IT HAS BEEN EXPLAINED TO ME THAT METHADONE IS A NARCOTIC DRUG WHICH CAN BE HARMFUL. I FURTHER UNDERSTAND THAT METHADONE IS AN ADDICTIVE MEDICATION AND MAY PRODUCE ADVERSE RESULTS.

I **-Procedure** The procedures necessary to treat my condition have been explained to me and I understand the nature of the procedures to be (Preliminary Detoxification Plan) as follows:

II **-Alternative Methods of Treatment** The other methods of detoxification have been explained to me and I understand my choice to be from the following:

After considering the other methods, I choose to receive detoxification utilizing methadone.

III **-Risks** The possible risks and complications involved have been explained to me by a medical doctor or his/her designee and I understand that:

Some people on methadone may sweat, become constipated, drowsy or have a decrease in sex drive. Occasionally, clients will have an increase in sex drive on methadone. Methadone may depress respiration or slow down the rate of breathing. Clients may experience some initial difficulty sleeping. Most of these problems disappear with time.

I also understand that my detoxification may include routine diagnostic procedures and medical treatment and I voluntarily consent and agree.

I agree that I shall inform any doctor who may treat me for any medical problem that I am undergoing detoxification utilizing methadone, since the use of other drugs in conjunction with methadone may cause me harm.

I agree that I shall not take any drugs without a physician=s advice and prescription. I understand that other drugs combined with methadone may cause me harm.

After considering the possible risks and consequences involved, I desire to receive detoxification utilizing methadone.

[Reverse of Form 617]

Female Clients of Child-Bearing Age	Clients Under 18 Years of Age
To the best of my knowledge, I [ ] am [ ] am not pregnant at this time. Besides the possible risks involved with the long-term use of methadone, I further understand that, like heroin and other narcotic drugs, information on its effects on pregnant women and on their unborn children is at present inadequate to guarantee that it may not produce significant or serious side effects It has been explained to me and I understand that methadone is transmitted to the unborn child and will cause physical dependence. I shall use no other drugs without the Medical Director or his assistants= approval, since these drugs, particularly as they might interact with methadone, may harm me or my unborn child. I shall inform any other doctor who sees me during my present or any future pregnancy or who sees the child after birth, of my current or past participation in a methadone treatment program in order that he may properly care for my child and me. It has been explained to me that after the birth of my child I should not nurse the baby because methadone is transmitted through the milk to the baby and this may cause physical dependence on methadone in the child. I understand that for a brief period following birth, the child may show temporary irritability or other ill effects due to my use of methadone. It is essential for the child=s physician to know of my participation in detoxification utilizing methadone so that he may provide appropriate medical treatment for the child. All the above possible effects of methadone have been fully explained to me and I understand that at present, there have not been enough studies conducted on the longterm use of the drug to assure complete safety to my child. With full knowledge of this, I consent to its use and promise to inform the Medical Director or one of his assistants immediately if I become pregnant in the future.	The client is a minor, _____ years of age, born, _____. The risks of the use of methadone have been explained to [me/us] and [I/we] understand that methadone is a drug which long-term studies are still being conducted and that information on its effects is incomplete. [I/we] declare that participation in detoxification utilizing methadone is wholly voluntary on the part of both the [parent(s)/guardian(s)] and the client. With full knowledge of the potential benefits and possible risks involved with the use of methadone in the detoxification of an adolescent, [I/we] consent to its use upon the minor.

I have explained the contents of this form to the client to the best of my ability:

_____ Physician=s Signature

_____ Date:

I certify that no guarantee or assurance has been made as to the results that may be obtained from detoxification utilizing methadone. With full knowledge of the potential benefits and possible risks involved, I consent to detoxification utilizing methadone.

Signature of Client	Date of Birth	Date:
Signature of Parent(s) or Guardian(s)	Relationship	Date:
Signature of Witness		Date:

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~~ **SUBSTANCE.**

***

Commonwealth approved opioid pharmacotherapy ~~agent~~ **SUBSTANCE** – 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 Pennsylvania Controlled Substance, Drug, Device,

and Cosmetic Act (35 P.S. §§ 780-101 – 780-149) ~~or as added, deleted or rescheduled by regulation~~.

***

CSAT – **CENTER FOR SUBSTANCE ABUSE TREATMENT.**

***

DEA—The Federal Drug Enforcement Administration.

Detoxification of a narcotic dependent person utilizing ~~a Commonwealth approved opioid pharmacotherapy agent~~ **AN AGENT**– Dispensing of ~~a Commonwealth approved opioid pharmacotherapy agent~~ **AN 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.

***

~~*FDA*—The Federal Food and Drug Administration~~

***

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 patient from the maintenance substance is considered as part of maintenance. The ultimate goal of maintenance is to assist the patient 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~~ **AN** 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 **NARCOTIC TREATMENT** physician ~~who meets the qualifying criteria in §715.6(a)(1)(i)—(iii)(relating to physician staffing) and~~ who assumes responsibility 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~~ **AN** agent.

***

MEDICATION UNIT—A FACILITY ESTABLISHED AS PART OF, BUT GEOGRAPHICALLY SEPARATE FROM, THE NARCOTIC TREATMENT PROGRAM SITE, FROM WHICH A RETAIL PHARMACIST OR A PRACTITIONER, WHO IS LICENSED UNDER STATE LAW AND REGISTERED UNDER FEDERAL LAW TO

ADMINISTER OR DISPENSE A NARCOTIC DRUG, MAY DISPENSE OR ADMINISTER A NARCOTIC DRUG OR COLLECT SAMPLES FOR DRUG TESTING OR ANALYSIS FOR NARCOTIC DRUGS.

***

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 **NARCOTIC TREATMENT** 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.

***

PSYCHOTHERAPY—TREATMENT OF PROBLEMS OF AN EMOTIONAL NATURE BY PSYCHOLOGICAL MEANS IN WHICH A TRAINED PERSON DELIBERATELY ESTABLISHES A PROFESSIONAL RELATIONSHIP WITH THE PATIENT WITH THE OBJECTIVE OF REMOVING, MODIFYING OR RETARDING EXISTING SYMPTOMS, MEDIATING DISTURBED PATTERNS OF BEHAVIOR AND PROMOTING POSITIVE PERSONALITY GROWTH AND DEVELOPMENT.

***

Short term detoxification treatment – Detoxification treatment for a period of 30 days or less.

***

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~~ **AN** agent.

***

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~~ MEDICATION 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) **THE DEPARTMENT'S** ~~Approval~~ **APPROVAL** of a narcotic treatment program shall be contingent upon the **NARCOTIC TREATMENT** program's compliance with the standards and conditions set forth 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~~ **SUPPLEMENT** 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 these regulations 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, DEA and ~~the FDA~~ **CSAT** or ~~designee~~ **AN**

ORGANIZATION DESIGNATED BY THE SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION (SAMHSA), UNDER THE AUTHORITY OF 21 U.S.C. § 823, AND 42 U.S.C. §§ 257A, 290AA(D), 290DD-2, 300X-23, 300X-27(A) AND 300Y-11, prior to offering services within the Commonwealth as a narcotic treatment program. Application for approval shall be made simultaneously to the Department, DEA and ~~FDA~~ **CSAT** or **SAMHSA** 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 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~~ **CSAT OR SAMHSA DESIGNEE**.

(b) A narcotic treatment program shall be licensed under the Department's regulations for drug and alcohol facilities set forth in Chapters 157, 704, **705**, 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 pursuant to Chapters 157, 704, **705**, 709, or 711.

(c) The Department will grant approval as a narcotic treatment program after an onsite inspection and review of **NARCOTIC TREATMENT** program policies, procedures and other material, when the Department determines that the requirements for approval have been met.

(d) **THE DEPARTMENT WILL INSPECT A** ~~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 **NARCOTIC TREATMENT** program. The Department may inspect the narcotic treatment program without notice~~, which shall occur~~ during any regular business hours of the **NARCOTIC TREATMENT** program.

(e) **DURING THE INSPECTION PROCESS,** ~~A~~ **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 **OF MATERIALS AS** it deems necessary ~~within~~ **UNDER** the provisions of ~~State and Federal confidentiality regulations~~ **42 CFR 2.53, (RELATING TO AUDIT AND EVALUATION ACTIVITIES), 28 PA. CODE §§ 709.15, 711.15 (RELATING TO RIGHT TO ENTER AND INSPECT; RELATING TO RIGHT TO ENTER AND INSPECT).**

(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 **THE DEPARTMENT DETERMINES** ~~it has been determined~~ that a **NARCOTIC TREATMENT** program satisfies the following:

(1) It has substantially complied with applicable requirements for approval

(2) It is complying with a ~~course~~ **PLAN** of correction approved by the Department **WITH REGARD TO ANY OUTSTANDING DEFICIENCIES.**

(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 **A** ~~plans~~ **PLAN** of ~~corrections~~ **CORRECTION.**

(2) The narcotic treatment program shall complete ~~plans~~ **THE PLAN** of ~~corrections~~ **CORRECTION** and submit ~~them~~ **IT** to the Department within ~~15 working days after the site inspection~~ **21 DAYS AFTER THE LAST DAY OF THE ONSITE INSPECTION.**

(3) The Department will not grant approval ~~of~~ **AS** narcotic treatment program until the Department receives and approves ~~the~~ **A** ~~plans~~ **PLAN** of ~~corrections~~ **CORRECTION.**

§ 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 such actions, shall be the same as procedures in §§ 709.17 , 709.18 , 711.17 and 711.18 **OF THIS PART.**

(b) The Department may recommend to the DEA or ~~the FDA~~ **CSAT** or **SAMHSA's** 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 **NARCOTIC TREATMENT** program in a court of competent jurisdiction.

§ 715.5. **Patient capacity.**

The Department may ~~limit~~ **INCREASE OR DECREASE** 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 **NARCOTIC TREATMENT** program, ~~with the written approval of the Department~~ based upon **THE DEPARTMENT'S** ~~periodic monitoring and~~ review **OF THE NARCOTIC TREATMENT PROGRAM**. The factors the Department will consider include:

(1) Safety. **CONSIDERATIONS INCLUDE DISPENSING TIME, INTERNAL PATIENT FLOW AND EXTERNAL TRAFFIC PATTERNS.**

(2) Physical facility. **CONSIDERATIONS INCLUDE NUMBER AND SIZE OF COUNSELING OFFICES, WAITING AREAS, RESTROOMS, AND DISPENSING AND NURSING WINDOWS.**

(3) Staff size and composition. **CONSIDERATIONS INCLUDE THE NUMBER OF NARCOTIC TREATMENT PHYSICIANS, DISPENSING AND COUNSELING STAFF.**

(4) Ability to provide required services. **CONSIDERATIONS INCLUDE COMPLIANCE WITH LICENSING AND NARCOTIC TREATMENT PROGRAM REGULATIONS AS**

DETERMINED DURING LICENSING, MONITORING AND SPECIAL VISITS TO THE NARCOTIC TREATMENT PROGRAM.

(5) Availability **AND** accessibility of service. **CONSIDERATIONS INCLUDE THE LOCATION OF THE NARCOTIC TREATMENT PROGRAM AND THE HOURS OF OPERATION.**

§ 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 **NARCOTIC TREATMENT** 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 **NARCOTIC TREATMENT** program is unable to hire a medical director who meets the qualifications in paragraph (1), the **NARCOTIC TREATMENT** program may hire an interim medical director. The **NARCOTIC TREATMENT** 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 ~~/~~**AND** 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~~ **36** months of being hired.

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

(i) Supervision of all ~~program~~ **NARCOTIC TREATMENT** physicians.

(ii) Supervision of licensed practical nurses if the **NARCOTIC TREATMENT** 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) **A** ~~Narcotic~~ **NARCOTIC** treatment ~~programs~~ **PROGRAM** 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 **OTHERWISE** available for consultation and verbal medication orders at all times when a **NARCOTIC TREATMENT** program is open and a **NARCOTIC TREATMENT** physician is not present.

(d) A narcotic treatment program shall provide **NARCOTIC TREATMENT** physician services at least 1 hour per week onsite for every ~~ten~~ **10** patients.

(e) **A** ~~Licensed or certified health care professionals~~ **PHYSICIAN ASSISTANT OR CERTIFIED REGISTERED NURSE PRACTITIONER** may perform functions **OF A NARCOTIC TREATMENT PHYSICIAN** in **A** narcotic treatment ~~programs~~ **PROGRAM** if authorized by Federal, State and local laws and regulations, and if these functions are delegated to ~~them~~ **THE PHYSICIAN ASSISTANT OR CERTIFIED REGISTERED NURSE PRACTITIONER** by the medical director, and records are properly countersigned by the medical director or a narcotic treatment physician. However, one-third of all required **NARCOTIC TREATMENT** physician time shall be provided by a **NARCOTIC TREATMENT** physician. Time provided by ~~other licensed or certified health care professionals~~ **A PHYSICIAN ASSISTANT OR CERTIFIED REGISTERED NURSE PRACTITIONER** shall not exceed two-thirds of the required **NARCOTIC TREATMENT** 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 or nonautomatic 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~~ **150** 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~~ **WITHIN 15 MINUTES OF ARRIVAL AT THE DISPENSING AREA.**

§ 715.8. **Psychosocial staffing.**

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

(A) ***GENERAL REQUIREMENTS.*** **A NARCOTIC TREATMENT PROGRAM SHALL COMPLY WITH THE PATIENT/STAFF AND PATIENT/COUNSELOR RATIOS IN PARAGRAPHS (1)-(6) DURING PRIMARY CARE HOURS. THESE RATIOS REFER TO THE TOTAL NUMBER OF PATIENTS BEING TREATED, INCLUDING PATIENTS WITH DIAGNOSES OTHER THAN DRUG AND ALCOHOL ADDICTION SERVED IN OTHER FACETS OF THE PROJECT. FAMILY UNITS MAY BE COUNTED AS ONE PATIENT.**

(1) ***INPATIENT NONHOSPITAL DETOXIFICATION*** **(RESIDENTIAL DETOXIFICATION).**

(I) THERE SHALL BE 1 FULL-TIME EQUIVALENT (FTE) PRIMARY CARE STAFF PERSON AVAILABLE FOR EVERY 7 PATIENTS DURING PRIMARY CARE HOURS.

(II) THERE SHALL BE A NARCOTIC TREATMENT PHYSICIAN ON-CALL AT ALL TIMES.

(2) *INPATIENT HOSPITAL DETOXIFICATION.* THERE SHALL BE 1 FTE PRIMARY CARE STAFF PERSON AVAILABLE FOR EVERY 5 PATIENTS DURING PRIMARY CARE HOURS.

(3) *INPATIENT NONHOSPITAL TREATMENT AND REHABILITATION* (RESIDENTIAL TREATMENT AND REHABILITATION). A NARCOTIC TREATMENT PROGRAM SERVING ADULT PATIENTS SHALL HAVE 1 FTE COUNSELOR FOR EVERY 8 PATIENTS.

(4) *INPATIENT HOSPITAL TREATMENT AND REHABILITATION* (GENERAL, PSYCHIATRIC OR SPECIALTY HOSPITAL). A NARCOTIC TREATMENT PROGRAM SERVING ADULT PATIENTS SHALL HAVE 1 FTE COUNSELOR FOR EVERY 5 PATIENTS.

(5) *PARTIAL HOSPITALIZATION.* A PARTIAL HOSPITALIZATION NARCOTIC TREATMENT PROGRAM SHALL HAVE A

MINIMUM OF 1 FTE COUNSELOR WHO PROVIDES DIRECT COUNSELING SERVICES TO EVERY 10 PATIENTS.

(6) *OUTPATIENTS.* THE COUNSELING CASELOAD FOR 1 FTE COUNSELOR IN AN OUTPATIENT NARCOTIC TREATMENT PROGRAM MAY NOT EXCEED 35 ACTIVE PATIENTS.

(B) *COUNSELOR ASSISTANTS.* A COUNSELOR ASSISTANT ELIGIBLE FOR A COUNSELING CASELOAD MAY BE INCLUDED IN DETERMINING FTE RATIOS.

§ 715.9. **Intake.**

(a) Prior to administration of an agent, **A** narcotic treatment program ~~staff~~ shall screen ~~all~~ **EACH** ~~individuals~~ **INDIVIDUAL** to determine eligibility for admission. The **NARCOTIC TREATMENT** program shall:

(1) Verify that the individual has reached the age of ~~majority~~ **18**.

(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~~. **HAVE A NARCOTIC TREATMENT PHYSICIAN MAKE A FACE-TO-FACE DETERMINATION OF WHETHER AN INDIVIDUAL IS CURRENTLY PHYSIOLOGICALLY DEPENDENT UPON A NARCOTIC DRUG AND HAS BEEN PHYSIOLOGICALLY DEPENDENT FOR AT LEAST 1 YEAR PRIOR TO ADMISSION FOR MAINTENANCE TREATMENT. THE NARCOTIC TREATMENT PHYSICIAN SHALL DOCUMENT IN THE PATIENT'S RECORD THE BASIS FOR THE 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 **NARCOTIC TREATMENT** 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 FOLLOWING CONDITIONS ARE MET:**

(I) ~~the~~ **THE NARCOTIC TREATMENT** program attended is able to document prior narcotic drug comprehensive maintenance treatment of 6 months or more, ~~and~~ .

(II) ~~the~~ **THE** admitting ~~program~~ **NARCOTIC TREATMENT** physician, exercising reasonable clinical judgment, finds readmission to comprehensive maintenance treatment to be medically justified.

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

(d) A **NARCOTIC TREATMENT** 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~~ **PATIENT**.

(e) A narcotic treatment program shall secure a personal history from the patient within the first week of admission ~~which~~. **THE PERSONAL HISTORY** 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~~ **NARCOTIC TREATMENT** 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 **NARCOTIC TREATMENT** ~~program~~ physician before the initial dose is administered to the patient.

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

(c) Counseling records and other appropriate patients records must reflect the nature of prenatal support provided by the **NARCOTIC TREATMENT** program.

(d) Within 3 months after termination of pregnancy, the ~~program~~ **NARCOTIC TREATMENT** 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~~ **TREATMENT** or receive detoxification treatment.

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

~~(f)~~ **(E) A** ~~Patients~~ **PATIENT** who ~~are~~ **IS** or ~~become~~ **BECOMES** pregnant may not be started or continued on LAAM, except by the written order of a **NARCOTIC TREATMENT** 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.

(F) THE NARCOTIC TREATMENT PROGRAM SHALL ENSURE THAT EACH FEMALE PATIENT IS FULLY INFORMED OF THE POSSIBLE RISK TO HER OR HER UNBORN CHILD FROM CONTINUED USE OF ILLICIT DRUGS AND FROM USE OF, OR WITHDRAWAL FROM A NARCOTIC DRUG ADMINISTERED OR DISPENSED BY THE PROGRAM IN COMPREHENSIVE MAINTENANCE OR

DETOXIFICATION TREATMENT.

§ 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~~ 42 CFR 2.22 (RELATING TO NOTICE TO PATIENTS OF FEDERAL CONFIDENTIALITY REQUIREMENTS) AND 21 CFR 291.505 (RELATING TO DRUGS USED FOR TREATMENT OF NARCOTIC ADDICTS) and ~~State statutes and regulations.~~ 28 PA. CODE § 709.28 (RELATING TO CONFIDENTIALITY).

§ 715.12. Informed patient consent.

A ~~Narcotic~~ NARCOTIC treatment ~~programs~~ PROGRAM shall obtain an informed, voluntary, WRITTEN consent before an agent may be administered to the patient for either maintenance or detoxification treatment. THE FOLLOWING MUST APPEAR ON THE PATIENT CONSENT FORM:

(1) **THAT METHADONE AND LAAM ARE NARCOTIC DRUGS WHICH CAN BE HARMFUL IF TAKEN WITHOUT MEDICAL SUPERVISION.**

(2) **THAT METHADONE AND LAAM ARE ADDICTIVE MEDICATIONS AND MAY, LIKE OTHER DRUGS USED IN MEDICAL PRACTICES, PRODUCE ADVERSE RESULTS.**

(3) **THAT ALTERNATIVE METHODS OF TREATMENT EXIST.**

(4) **THAT THE POSSIBLE RISKS AND COMPLICATIONS OF TREATMENT HAVE BEEN EXPLAINED TO THE PATIENT.**

(5) **THAT METHADONE IS TRANSMITTED TO THE UNBORN CHILD AND WILL CAUSE PHYSICAL DEPENDENCE.**

§ 715.13. **Patient identification.**

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

(b) A NARCOTIC TREATMENT ~~Program~~ PROGRAM ~~staff~~ shall maintain onsite a photograph of each patient which includes the patient's name and birth date. The NARCOTIC TREATMENT program shall ~~ensure that the photograph is updated~~ UPDATE THE PHOTOGRAPH 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 drug or drugs have been determined by a program to be abused~~ IF THE NARCOTIC TREATMENT PROGRAM DETERMINES THAT ANY OTHER DRUG OR DRUGS ARE ABUSED in that NARCOTIC TREATMENT program's locality or have been identified in the patient's drug and alcohol history as being a drug of abuse or use, a NARCOTIC TREATMENT 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~~ **TO MINIMIZE MISIDENTIFICATION OF URINE SPECIMENS AND TO ENSURE THAT THE TESTED SPECIMENS CAN BE TRACED TO THE DONOR.**

(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, 263, and 263a notes), and State requirements, specifically the Pennsylvania 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 any 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 at 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.~~ **THE NARCOTIC TREATMENT PHYSICIAN SHALL REVIEW THE DOSAGE LEVELS AT LEAST TWICE A YEAR, WITH EACH REVIEW OCCURING NO LESS THAN 2 MONTHS APART, TO DETERMINE A PATIENT'S THERAPEUTIC DOSAGE.**

(b) The narcotic treatment physician shall determine the proper dosage level for a patient, except as otherwise provided in this section. If the ~~program~~ **NARCOTIC TREATMENT** physician determining the initial dose is not the ~~program~~ **NARCOTIC TREATMENT** physician who conducted the **PATIENT** examination, the ~~program~~ **NARCOTIC TREATMENT** physician shall consult with the **NARCOTIC TREATMENT** 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.~~ **AND SHALL BE FORMULATED IN SUCH A WAY AS TO REDUCE ITS POTENTIAL FOR PARENTERAL ABUSE.**

(d) A narcotic treatment program shall label all take-home medication with the patient's name and the **NARCOTIC TREATMENT** program's name, address and telephone number and shall ~~be packaged~~ **PACKAGE ALL TAKE-HOME MEDICATION** 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~~. **LAAM SHALL BE ADMINISTERED OR DISPENSED ONLY IN ORAL FORM AND SHALL BE FORMULATED IN SUCH A WAY AS TO REDUCE ITS POTENTIAL FOR PARENTERAL ABUSE.**

~~(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)~~**(F)** The **NARCOTIC TREATMENT** 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 **NARCOTIC TREATMENT** program may give take-home medications only to **A** ~~patients~~ **PATIENT** who the **NARCOTIC TREATMENT** physician has determined ~~are~~ **IS** responsible and able to handle narcotic drugs outside the **NARCOTIC TREATMENT** program. The **NARCOTIC TREATMENT** physician shall make this determination after consultations with ~~appropriate staff within the program~~ **STAFF INVOLVED IN THE PATIENT'S CARE.** The ~~program~~ **NARCOTIC TREATMENT** 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 **NARCOTIC TREATMENT** 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~~ **NARCOTIC TREATMENT** 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 **NARCOTIC TREATMENT** program attendance.

(3) Absence of serious behavioral problems at the **NARCOTIC TREATMENT** 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 **NARCOTIC TREATMENT** 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 **NARCOTIC TREATMENT** program may permit a patient to reduce attendance at the **NARCOTIC TREATMENT** program for observation to ~~three~~ **3** times weekly and receive no more than a 2-day take-home supply of medication when, in the reasonable clinical judgment of the ~~program~~ **NARCOTIC TREATMENT** physician, which is documented in the patient record:

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

(i) A patient demonstrates satisfactory adherence to **NARCOTIC TREATMENT** 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 **NARCOTIC TREATMENT** program may permit a patient to reduce attendance at the **NARCOTIC TREATMENT** program for observation to ~~one~~ **1** time weekly and receive no more than a 6-day take-home supply of medication when in the reasonable clinical judgment of the ~~program~~ **NARCOTIC TREATMENT** physician, which is documented in the patient record:

(i) A patient demonstrates satisfactory adherence to **NARCOTIC TREATMENT** 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 any criminal activity within the previous year.

(d) A **NARCOTIC TREATMENT** program may make exceptions to the requirements in subsection (c) relating to the length of time of satisfactory adherence to **NARCOTIC TREATMENT** program rules and number of days of take-home medication when, in the reasonable clinical judgment of the ~~program~~ **NARCOTIC TREATMENT** 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 **SUCH AS ILLNESS, PERSONAL OR FAMILY CRISIS, OR TRAVEL** which interferes with the **PATIENT'S** 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 **NARCOTIC TREATMENT** program **MAY NOT** 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,~~ **WHEN A PATIENT IS PERMANENTLY DISABLED, THAT** ~~each~~ case shall be reviewed at least annually to determine whether the need for the exception ~~continues to exist~~ **STILL EXISTS**.

§ 715.17. **Medication control.**

(a) **A NARCOTIC TREATMENT** ~~Programs~~ **PROGRAM** ~~which provide pharmaceutical services~~ shall comply with all applicable Federal and State statutes and regulations regarding the storing, compounding, administering ~~or~~ **AND** dispensing of medication.

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

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

(1) *Administration of medication.*

(i) A ~~program~~ **NARCOTIC TREATMENT** 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~~ **NARCOTIC TREATMENT** 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 **AUTHORIZED STAFF AND** patients **WHO ARE RECEIVING MEDICATION** shall be permitted in the dispensing area.

(iv) There shall be only one patient permitted at a dispensing station at any given time.

(v) Each patient shall be observed when ingesting the agent.

(VI) ADMINISTERING AND DISPENSING SHALL BE CONDUCTED IN A MANNER THAT PROTECTS THE PATIENT FROM DISRUPTION OR ANNOYANCE FROM OTHER INDIVIDUALS.

(2) *Drug storage areas.* A narcotic treatment program shall develop and implement written policies and procedures regarding ~~where and how~~ **STORAGE OF** 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 **PURSUANT TO 21 CFR 1301.72 AND 1301.74 (RELATING TO PHYSICAL SECURITY CONTROLS; OTHER SECURITY CONTROLS.)**

(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 laws 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 **THE** 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~~ **THE PERSON** administering **THE** 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 **A** 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 any other controlled substances stored.

Each inventory **RECORD** 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~~ **OR** medication ~~errors~~ **ERROR** to a narcotic treatment ~~program~~ physician immediately and initiate corrective action. **THE NARCOTIC TREATMENT PROGRAM SHALL RECORD THE** ~~The~~ reaction or error ~~must be recorded~~ in the drug administration record and the clinical chart, and **SHALL INFORM** ~~all~~ **EACH** ~~persons~~ **PERSON** who ~~are~~ **IS** authorized to administer medication or supervise self-medication ~~must 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.~~ **REHABILITATIVE SERVICES SHALL INCLUDE HIV EDUCATION SERVICES, EMPLOYMENT SERVICES, ADULT EDUCATIONAL SERVICES AND BEHAVIORAL HEALTH SERVICES. A PATIENT SHALL ALSO HAVE THE OPPORTUNITY TO ACCESS LEGAL 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. **ADDITIONAL PSYCHOTHERAPY SHALL BE PROVIDED AS DICTATED BY ONGOING ASSESSMENT OF THE PATIENT.**

(2) A narcotic treatment program shall provide each patient at least 1 hour per month of group or individual psychotherapy ~~after 2 years~~ **DURING THE THIRD AND FOURTH YEAR OF TREATMENT. ADDITIONAL PSYCHOTHERAPY SHALL BE PROVIDED AS DICTATED BY ONGOING ASSESSMENT OF THE PATIENT.**

(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.~~ **AFTER 4 YEARS OF TREATMENT, A NARCOTIC TREATMENT PROGRAM SHALL PROVIDE EACH PATIENT WITH AT LEAST 1 HOUR OF GROUP OR INDIVIDUAL PSYCHOTHERAPY EVERY 2 MONTHS. ADDITIONAL PSYCHOTHERAPY SHALL BE PROVIDED AS DICTATED BY ONGOING ASSESSMENT OF THE PATIENT.**

§ 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 must contain the written consent of the patient. **A NARCOTIC TREATMENT PROGRAM SHALL MAINTAIN THE CONFIDENTIALITY OF PATIENT RECORDS REMAINING IN ITS POSSESSION AFTER THE TRANSFER PURSUANT TO SECTION 715.11 (RELATING TO CONFIDENTIALITY OF PATIENT RECORDS).** 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 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~~ **TO RETAIN** the patient in the program have failed.

(1) A narcotic treatment program may involuntarily terminate a patient from the **NARCOTIC TREATMENT** 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 **NARCOTIC TREATMENT** program premises.

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

(iii) The patient has been ~~excessively~~ absent from the **NARCOTIC TREATMENT** program **FOR 3 CONSECUTIVE DAYS OR LONGER WITHOUT CAUSE.**

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

(2) A patient terminated involuntarily, except ~~patients~~ **A PATIENT** who ~~commit or threaten to commit~~ **COMMITS OR THREATENS 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~~ **GRIEVANCES** 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~~ **EITHER A MULTI-REPRESENTATIVE GROUP OF THE NARCOTIC TREATMENT PROGRAM OR A SUBCOMMITTEE OF THE GOVERNING**

BODY INSTITUTED FOR THE EXPRESS PURPOSES OF GRIEVANCE ADJUDICATION.

(c) Penalties may not be initiated prior to final resolution with the exception ~~of~~ **THAT PENALTIES MAY BE INITIATED AGAINST** patients who have committed acts of physical violence or who have threatened to commit acts of physical violence in or around the **NARCOTIC TREATMENT** program premises.

§ 715.23. **Patient records.**

(a) A narcotic treatment program shall maintain patient records in conformance with ~~all applicable Federal~~ **42 CFR 2.16 (RELATING TO SECURITY FOR WRITTEN RECORDS) AND 42 CFR 2.22 (RELATING TO NOTICE TO PATIENTS OF FEDERAL CONFIDENTIALITY REQUIREMENTS)** and State statutes and regulations. A **NARCOTIC TREATMENT** program shall maintain a complete file on the premises for each present and former patient of the narcotic treatment program for a period of 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; **WHICH SHALL** ~~examination should~~ include an annual reevaluation by the narcotic treatment ~~program~~ physician.

(6) Results of laboratory tests or other special examinations 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~~ **PSYCHOSOCIAL** evaluations of the patient.

(16) ANY PSYCHIATRIC, PSYCHOLOGICAL OR OTHER EVALUATIONS, IF AVAILABLE.

~~(16)~~ **(17)** Treatment plans and applicable periodic treatment plan updates.

~~(17)~~ **(18)** Federal and State exceptions to the regulations granted to the project on behalf of the patient.

~~(18)~~ **(19)** Referrals to other projects or services.

~~(19)~~ **(20)** Take-home privileges granted to the patient.

~~(20)~~ **(21)** Annual evaluation by the counselor.

~~(21)~~ **(22)** Aftercare plan, if applicable.

~~(22)~~ **(23)** Discharge summary.

~~(23)~~ **(24)** Follow-up information regarding the patient.

~~(24)~~ **(25)** 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~~ **AND** 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 **OR ELECTRONICALLY.**

(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 **NARCOTIC** 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 **NARCOTIC** detoxification period may not be included.

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

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

(i) Take-home medication is not allowed during a 30-day **NARCOTIC** 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 **NARCOTIC** detoxification and possible drug-free treatment referral.

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

§ 715.25. **Prohibition of ~~medical~~ MEDICATION 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 **REGULATIONS, INCLUDING 21 CFR 1301.72 AND 1301.74 (RELATING TO PHYSICAL SECURITY CONTROLS; OTHER SECURITY CONTROLS)** 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~~ **DESIGNATE** 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 **NARCOTIC TREATMENT** program, that ~~person~~ **NARCOTIC TREATMENT PROGRAM** shall ~~be provided~~ **PROVIDE THAT PATIENT** with an evaluation interview and ~~be given~~ **SHALL GIVE THAT PATIENT** 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 **THE** premises.

(4) Complaints of patient abuse (physical, verbal, sexual~~,~~ **AND** 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) DRUG RELATED HOSPITALIZATION OF A PATIENT.

~~(9)~~**(10)** 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) A ~~Narcotic~~ **NARCOTIC** treatment ~~programs~~ **PROGRAM** shall file a written Unusual Incident Report with the Department within 48 hours following **AN** unusual ~~incidents~~ **INCIDENT**:

(1) Complaints of patient abuse (physical, verbal, sexual~~;~~ **AND** emotional~~; financial~~).

(2) Death or serious injury due to trauma, suicide, medication error or unusual circumstances.

(3) Significant disruption of services due to **A** disaster such as **A** fire, storm, flood or other occurrence.

(4) 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 **AN** exception from **A** specific ~~regulations~~ **REGULATION.** The request for an exception from a specific regulation shall be in writing, with governing body approval, and shall state how the **NARCOTIC TREATMENT** 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 **OR** 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.

Commonwealth of Pennsylvania

DEPARTMENT OF HEALTH

HARRISBURG

ROBERT S. ZIMMERMAN, JR., MPH
SECRETARY OF HEALTH

August 20, 2002

Mr. Robert E. Nyce
Executive Director
Independent Regulatory Review Commission
14th Floor, 333 Market Street
Harrisburg, PA 17101

Re: Department of Health – Final Regulations No. 10-159
Standards for Approval of Narcotic Treatment Programs

Dear Mr. Nyce:

Enclosed are final-form regulations for review by the Commission in accordance with the Regulatory Review Act (71 P.S. §§745.1-745.15). These regulations revise and update standards for the approval of narcotic treatment programs in the Commonwealth.

Section 5.1(a) of the Regulatory Review Act, 71 P.S.§745.5a(a), provides that upon completion of the agency's review of comments following proposed rulemaking, the agency is to submit to the Commission a copy of the agency's response to comments received, the names and addresses of the commentators who have requested additional information relating to the final-form regulations, and the text of the final-form regulations which the agency intends to adopt.

A list of the names and addresses of the commentators who requested a copy of the final-form regulations is enclosed. Their comments were previously forwarded to the Commission by the Department.

Section 5.1(e) of the Regulatory Review Act, 71 P.S. §745.5a(e), provides that within 10 days following the expiration of the Standing Committee review period, or at its next regularly scheduled meeting, whichever is later, the Commission shall approve or disapprove the final-form regulations.

The Department will provide the Commission with any assistance it requires to facilitate a thorough review of the regulations. If you have any questions, please contact Deborah Griffiths, Director of the Office of Legislative Affairs, at (717) 783-3985.

Sincerely,

Robert S. Zimmerman, Jr.
Secretary of Health

Enclosures

COMMENTATORS FOR REGULATION 10-159
WHO REQUESTED A COPY OF THE FINAL FORM REGULATIONS

Lynn Cooper
Senior Policy Specialist
Pennsylvania Community Providers Association
2400 Park Drive
Harrisburg, Pennsylvania 17110-9303

David L. Piccolli, II
Vice President
Discovery House
66 Pavilion Avenue
Providence, Rhode Island 02905

Glen J. Cooper
Executive Director
New Direction Treatment Services
1810 Steelstone Road, Suite 101
Allentown, Pennsylvania 18109

George J. Vogel, Jr.
Executive Director
Council on Chemical Abuse
Berks County Services Center
633 Court Street, Floor 12
Reading, Pennsylvania 19601

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D NUMBER:	10-159
SUBJECT:	Standards for approval of narcotic treatment programs
AGENCY	Department of Health

TYPE OF REGULATION

Proposed Regulation

X Final Regulation

Final Regulation with Notice of Proposed Rulemaking Omitted

120-day Emergency Certification of the Attorney General

120-day Emergency Certification of the Governor

Delivery of Tolled Regulation
a. With Revisions b. Without Revisions

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
8/20/02	J. d. Chan	HOUSE COMMITTEE ON HEALTH & HUMAN SERVICES
8/20/02		SENATE COMMITTEE ON PUBLIC HEALTH & WELFARE
8/20		
8/20/02		INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL
		LEGISLATIVE REFERENCE BUREAU

August 9, 2002