Regulatory Analysis Form

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IRRC Number: 2134

(1) Agency

Department of Health

(2) I.D. Number (Governor's Office Use)

10-159

(3) Short Title

Standards for Approval of Narcotic Treatment Programs

(4) PA Code Cite

28 PA Code
Chapter 715

(5) Agency Contacts & Telephone Numbers

Primary Contact: John C. Hair, Director
Bureau of Community Program
Licensure and Certification
(717) 783-8665

Secondary Contact:

(6) Type of Rulemaking (Check One)

√ Proposed Rulemaking

___ Final Order Adopting Regulation

___ Final Order, Proposed Rulemaking Omitted

(7) Is a 120-Day Emergency Certification Attached?

√ No

___ Yes: By the Attorney General

___ Yes: By the Governor

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

The Department of Health, by these proposed regulations, amends the regulations which govern the approval and monitoring of narcotic treatment programs in the Commonwealth of Pennsylvania. The original regulations, 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 April, 1994, 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, 21 C.F.R. §291.505.

(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.

21 C.F.R. §291.505 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 Food and Drug Administration and the State Authority and receive approval of both. 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 proposing to amend 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 1970's, 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; i.e., LAAM. 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 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 allow for a maximum dose of 100 mg. while the current state regulations allow for a maximum dose of 80 mg.,

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

(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 address these differences 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; i.e., in allowing for a maximum methadone dose of 100 mg. versus the current 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; i.e., 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.

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(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, 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 6000 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.

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(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 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 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 will result in cost reduction for physician time.

(4) Amended regulations allow for the use of physician assistants, in lieu of licensed physicians, for routine medical functions. Again, this 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 governments 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 and 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.

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(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	$	$	$	$	$	$
Local Government	$	$	$	$	$	$
State Government	$	$	$	$	$	$
Total Savings	$	$	$	$	$	$
COSTS:						
Regulated Community	$	$	$	$	$	$
Local Government	$	$	$	$	$	$
State Government	$	$	$	$	$	$
Total Costs	$	$	$	$	$	$
REVENUE LOSSES:						
Regulated Community	$	$	$	$	$	$
Local Government	$	$	$	$	$	$
State Government	$	$	$	$	$	$
Total Revenue Losses						

(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)	$			

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(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. No.
(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.

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(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 stakeholderes from providers, law enforcement and government. These regulations are a culmination of that process. No further meetings or hearings are contemplated unless deemed appropriate as a result of comments received during the public comment period.

(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 approval and publication as final. 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

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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
JUN 22 2000 DATE OF APPROVAL	DOCUMENT/FISCAL NOTE NO. 10-159	May 24 2000 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.

PROPOSED 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

CONTINUATION SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU
(Pursuant to Commonwealth Documents Law)

Notice is hereby given that the Department of Health (Department) proposes to amend narcotic addiction treatment standards for the approval of narcotic addiction treatment programs under the powers and duties contained in Articles IX and X of the Public Welfare Code (62 P.S. §§901-922, 1001-1031 and 1051-1059) and the Pennsylvania Drug and Alcohol Abuse Control Act (P.L. 221 No. 63) (71 P.S. §§1690.101 et seq.).

The Department proposes to replace narcotic addiction treatment standards by adding 28 Pa. Code Chapter 715, amending 28 Pa. Code §701.1 and repealing 4 Pa. Code Chapter 263, as set forth in Annex A hereto.

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PURPOSE OF THE RULEMAKING

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

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

Chapter 715 is being created to replace current narcotic addiction treatment regulations in 4 Pa. Code Chapter 263. Existing regulations as applied are not consistent

with current health practices or Federal requirements. They are more burdensome than Federal regulations.

REQUIREMENTS OF THE REGULATIONS

A. Definitions

§701.1. General definitions.

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

§715.1. General provisions.

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

§715.2. Relationship of Federal and state regulations.

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

§715.3. Approval of narcotic treatment programs.

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

This section also addresses Department coordination with Federal agencies.

§715.4. Denial, revocation or suspension of approval.

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

§715.5. **Patient capacity.**

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

§715.6. **Physician staffing.**

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

§715.7. **Dispensing or administering staffing.**

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

§715.8. Psychosocial staffing.

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

§715.9. Intake.

This section would require screening of all narcotic treatment program applicants prior to admission. The criteria for acceptance of an applicant would be included. There would be the following three exceptions to the eligibility criteria: a one year history of physiologic dependency would not be required for detoxification or pregnant addicts, a physical examination and lab tests would not be required for a re-admitted patient who was out of treatment for less than six months after a voluntary termination, and evidence of physiologic dependency would not be required for re-admission of patients previously admitted and voluntarily detoxified within the past two years.

§715.10. Pregnant patients.

This section would establish requirements for the admission and treatment of pregnant patients. This is subject matter that is not addressed in the regulations the Department is proposing for repeal. This would be included because of the increasing rate of heroin addiction among pregnant women. These programs are designed to take into account the special circumstances surrounding pregnant opiate addicts and to promote the

health and safety of the babies. In addition, there are special restrictions for the use of LAAM with regard to pregnant patients. These restrictions and requirements would be identified here.

§715.11. Confidentiality of patient records.

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

§715.12. Informed patient consent.

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

§715.13. Patient identification.

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

§715.14. Urine testing.

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

§715.15. Medication dosage.

This section would require narcotic treatment programs to meet various Federal standards relating to narcotic treatment medication dosage. The current state regulations requires projects to obtain Department approval prior to increasing dosage above 80 mg. The process of obtaining waivers from the Department is time consuming, and inefficient. This process would be eliminated. The new regulation would permit the physician to make reduction changes and t hose in excess of the Federal requirement would require the physician to document in the patient's chart the rationale for dosages above the Federal requirements.

§715.16. Take-home privileges.

This section would establish requirements for patients to be eligible to take medication out of the program and self administer outside the supervision of the program. A minimal time period of adherence to program rules, policies and procedures is established.

Exceptions are provided for special circumstances that are determined on a case-by-case basis.

§715.17. Medication control.

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

§715.18. Rehabilitative services.

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

§715.19. Psychotherapy services.

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

§715.20. Patient transfers.

This section would require each narcotic treatment program to develop policies regarding the transfer of patients to another narcotic treatment program or another treatment environment upon the request of the patient. The concern has been that once a patient requests a transfer, for whatever reason, facilities often attempt to keep the patient longer

than the patient wishes or to talk to the patient out of transferring. This causes adverse environment for both the facility and the patient.

§715.21. Patient termination.

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

§715.22. Patient grievance procedures.

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

§715.23. Patient records.

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

§715.24. Narcotic detoxification.

This section would establish minimum procedures for detoxification services provided by narcotic treatment programs. Minimum standards will be established, but

programs are permitted to implement additional procedures, provided they are not in conflict with the minimum standards.

§715.25. Prohibition of medication units.

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

§715.26. Security.

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

§715.27. Readmission.

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

§715.28. Unusual incidents.

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

§715.29. Exceptions.

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

§715.30. Applicability.

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

AFFECTED PERSONS

All staff and clients of licensed and approved narcotic treatment programs would be affected. Over 6000 individuals benefit from the provisions of these amended regulations.

FISCAL IMPACT

It is anticipated that the amendments to the narcotics addiction treatment program regulations would have no fiscal impact. In fact, it is anticipated that facilities, once in

compliance, will experience savings as a result of these amendments. There would be no measurable costs imposed upon local or state government.

PAPERWORK REQUIREMENTS

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

EFFECTIVE DATE

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

SUNSET DATE

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

STATUTORY AUTHORITY

Articles IX and X of the Public Welfare Code (62 P.S. §§901-1059) (relating to the licensure of facilities) as transferred to the Department of Health by Reorganization Plan Number 2 of 1977, (71 P.S. §751-25) (relating to the transfer of drug and alcohol facility

licensure authority from the Department of Public Welfare to the Governor's Council on Drug and Alcohol Abuse), and Reorganization Plan under 4 of 1981 (71 P.S. §751-31) (relating to the transfer of the powers and duties of the Governor's Council on Drug and Alcohol Abuse to the Department of Health) and the Pennsylvania Drug and Alcohol Abuse Control Act, 1972-63. as amended (71 P.S. §§1690.01 et seq.) (relating to the control, prevention, treatment and rehabilitation aspects of drug and alcohol abuse problems).

REGULATORY REVIEW

Under Section 5(a) of the Regulatory Review Act, 71 P.S. §745.1 et seq., the Department submitted a copy of the proposed regulations on July 18, 2000 to the Independent Regulatory Review Commission and to the Chairpersons of the House Committee on Health and Human Services and the Senate Committee on Public Health and Welfare. In addition to submitting the proposed regulations, the Department has provided the Commission and the Committees with a copy of a detailed Regulatory Analysis Form prepared by the Department in compliance with Executive Order 1996-1, "Regulatory Review and Promulgation." A copy of this material is available to the public upon request.

If the Commission has any objections to any portion of the proposed regulations, it will notify the Department by September 29, 2000 [ten days after expiration of the review period granted to the Standing Committees]. Such notification shall specify the regulatory review criteria which have not been met by that portion. The Act specifies detailed

procedures for review, prior to final publication of the regulation, by the Department, the General Assembly and the Governor, of objections raised.

CONTACT PERSON

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

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.] (Reserved).

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 "The 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 "The 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 "The 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.

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.

***

Agent – Commonwealth approved opioid pharmacotherapy agent.

***

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

***

Controlled substance – A drug, substance, or an immediate precursor included in schedules I through V of the Pennsylvania Controlled Substance, Drug, Device, and Cosmetic Act, 35 P.S. 780-101 et seq., or as added, deleted or rescheduled by regulation.

***

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

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

***

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

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

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

***

Medical director – A physician who meets the qualifying criteria in §715.6(a)(1)(i-iii)(relating to physician staffing) and who assumes responsibility for the administration of all medical services performed in the narcotic treatment program, including ensuring that the program is in compliance with all federal, state, and local laws and regulations regarding the medical treatment of narcotic addiction with a Commonwealth approved opioid pharmacotherapy agent.

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

Narcotic treatment physician – A physician who meets the qualifying criteria in §715.6(a)(1)(i-iii)(relating to physician staffing) 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 pharmacotherpay agents under a physician's order either for detoxification purposes or for maintenance and when appropriate or necessary provides a comprehensive range of medical and rehabilitative services.

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Physician – An individual who has a currently registered license to practice medicine or osteopathic medicine in the Commonwealth.

***

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 pharmacotherpay agent.

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CHAPTER 715. STANDARDS FOR APPROVAL OF NARCOTIC TREATMENT PROGRAM

§715.1. General provisions.

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

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

§715.2. Relationship of federal and state regulations.

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

(b) These regulations are intended to complement the Federal regulations governing narcotic treatment programs set forth in 21 C.F.R. §291.505 and

21 C.F.R. § Part 1300 to end. Where 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, the Federal Drug Enforcement Administration (DEA) and the Federal Food and Drug Administration (FDA) or designee 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 or designee. The Department will forward a recommendation for approval to the Federal officials after a review of policies and procedures and an on-site inspection by an authorized representative of the Department and 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 C.F.R. §291.505 and 21 C.F.R. §Part 1300 or other Federal statutes shall constitute the final determination on the application for approval by DEA and FDA.

(b) A narcotic treatment program shall be licensed pursuant to the Department's regulations for drug and alcohol facilities set forth in Chapters 157 (Drug and alcohol services general provisions), 704 (Staffing requirements for drug and alcohol treatment activities), 709 (Standards for license of freestanding treatment activities), or 711 (Standards for certification of treatment activities which are a part of a health care facility) of this Title. 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, 709, or 711.

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

(d) A narcotic treatment program shall be inspected at least annually to determine compliance with State narcotic treatment program regulations. This inspection shall consist of an on-site visit and shall include an examination of patient records, reports, files, policies and procedures, and

other similar items to enable the Department to make an evaluation of the approval status of the program. The Department may inspect the narcotic treatment program without notice, which shall occur during any regular business hours of the program.

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

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

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

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

(2) It is complying with a course of correction approved by the Department.

(3) Its existing deficiencies will not adversely alter the health, welfare or safety of the facility's patients.

(h) Notification of deficiencies

(1) The authorized Department representative will provide the narcotic treatment program director with a record of deficiencies with instructions to submit plans of corrections.

(2) The narcotic treatment program shall complete plans of corrections and submit them to the Department within 15 working days after the site inspection.

(3) The Department will not grant approval of a narcotic treatment program until the Department receives and approves the plans of corrections.

§715.4. Denial, revocation or suspension of approval.

(a) The Department shall 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 Section 709.17 (relating to refusal or revocation of license), 709.18 (relating to hearings), 711.17 (relating to refusal or revocation of license), and 711.18 (relating to hearings).

(b) The Department may, at any time, recommend to the DEA or the FDA or designee to initiate proceedings to revoke or deny Federal approval pursuant to 21 C.F.R. 291.505(h).

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

§715.5. Patient capacity.

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

(1) safety;

(2) physical facility;

(3) staff size and composition;

(4) ability to provide required services; and,

(5) availability/accessibility of service.

§715.6. Physician staffing.

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

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

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

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

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

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

(3) The medical director's responsibilities include but are not limited to the following:

(i) Supervision of all program physicians; and

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

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

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

(d) A narcotic treatment program shall provide physician services at least one hour per week on-site for every ten patients.

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

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

§715.7. Dispensing or administering staffing.

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

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

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

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

§715.8. Psychosocial staffing.

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

§715.9. Intake.

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

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

(2) Verify the individuals 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; and

(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 one year before admission for maintenance treatment. Documentation shall include the basis for the physician's determination of current dependency and evidence of a one year history of addiction.

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

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

(2) Upon readmitting a patient who has been out of a program for six 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 two years after discharge, if the program attended is able to document prior narcotic drug comprehensive maintenance treatment of six months or more, and the admitting program physician, exercising reasonable clinical judgment, finds readmission to comprehensive maintenance treatment to be medically justified.

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

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

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

§715.10. Pregnant patients.

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

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

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

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

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

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

§715.11. Confidentiality of patient records.

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

§715.12. Informed patient consent.

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

§715.13. Patient identification.

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

(b) Program staff shall maintain on site a photograph of each patient which includes the patient's name and birth date. The program shall ensure that the photograph is updated every three 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 in that program's locality or have been identified in the patient's drug and alcohol history as being a drug of abuse or use, a program may conduct a test or analysis for any of those drugs as well.

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

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

(d) A narcotic treatment program shall ensure that a laboratory that performs the testing required under this section shall be in compliance with all applicable federal requirements, specifically the Clinical Laboratory Improvement Amendments, and state requirements, specifically the Pennsylvania Clinical Laboratory Act, and its regulations.

§715.15. Medication dosage.

(a) A narcotic treatment program shall 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 patient's dose above the Federal limit, the program physician shall examine the patient and this examination shall be documented in the patient chart. Dosage levels shall be reviewed as least twice a year for the purpose of determining a patient's optimum dosage. These reviews shall be performed by the program's physician with each review occurring no less than two months apart.

(b) The narcotic treatment physician shall determine the proper dosage level for a patient, except as otherwise provided in this section. If the program physician determining the initial dose is not the program physician who conducted the examination, the program physician must consult with the physician who performed the examination before determining the patient's initial dose and schedule.

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

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

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

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

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

§715.16. Take-home privileges.

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

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

(1) Absence of recent abuse of drugs (narcotic or non-narcotic), including alcohol.

(2) Regular program attendance.

(3) Absence of serious behavioral problems at the program.

(4) Absence of known recent criminal activity.

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

(6) Length of time in comprehensive maintenance treatment.

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

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

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

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

[a] a patient demonstrates satisfactory adherence to program rules for at least three months;

[b] a patient demonstrates substantial progress in rehabilitation;

[c] a patient demonstrates responsibility in handling narcotic drugs; and

[d] a patient demonstrates that rehabilitation progress would improve by decreasing the frequency of attendance for observation.

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

[a] a patient demonstrates satisfactory adherence to program rules for at least two years;

[b] a patient demonstrates substantial progress in rehabilitation;

[c] a patient demonstrates responsibility in handling narcotic drugs; and

[d] a patient demonstrates that rehabilitation progress would improve by decreasing the frequency of attendance for observation.

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

[a] a patient demonstrates satisfactory adherence to program rules for at least three years;

[b] a patient demonstrates substantial progress in rehabilitation;

[c] a patient demonstrates responsibility in handling narcotic drugs;

[d] a patient demonstrates that rehabilitation progress would improve by decreasing the frequency of attendance for observation;

[e] a patient demonstrates no major behavioral problems;

[f] a patient is employed, is actively seeking employment, attends school, is a homemaker or is considered unemployable for mental or physical reasons.

[g] a patient is not know to have abused alcohol or other drugs within the previous year. and

[h] a patient is not known to have engaged in any criminal activity within the previous year.

(d) A program may make exceptions to the requirements in subsection (c) relating to the length of time of satisfactory adherence to program rules and number of days of take-home medication when, in the reasonable clinical judgment of the program physician, which is documented in the patient record:

(1) a patient has a permanent physical disability,

(2) a patient has a temporary disability, or

(3) a patient has an exceptional circumstance which interferes with the ability to conform to the applicable mandatory attendance schedules. In all cases, the patient must demonstrate an ability to responsibly handle narcotic drugs.

(e) With any exception granted pursuant to subsection (d), in no case shall a program permit a patient to receive more than a two-week take-home supply of medication.

(f) Any exception granted pursuant to subsection (d) shall continue only for as long as the temporary disability or exceptional circumstance exists. In the case of a permanent disability, each case shall be reviewed at least annually to determine whether the need for the exception continues to exist.

§715.17. Medication control.

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

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

(1) Administration of medication.

(i) A program physician shall determine the patient's initial and subsequent dose and schedule. The physician shall communicate the initial and subsequent dose and schedule to the person responsible for the administration of medication. Each medication order and/or dosage change shall be written and signed by the program physician.

(ii) An agent shall be administered or dispensed only by a practitioner licensed under the appropriate Federal and State laws to dispense agents to patients.

(iii) Only patients shall be permitted in the dispensing area.

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

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

(2) Drug storage areas.

A narcotic treatment program shall develop and implement written policies and procedures regarding where and how medications are stored and who has access to the medication storage area. All agents shall be stored in a locked safe that has been approved by the DEA.

(3) Inspection of storage areas.

A narcotic treatment program shall inspect all drug storage areas and the dispensing station at least quarterly to ensure that the areas are maintained in compliance with Federal, State and local 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 must 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; and

(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. Any agent or other drug prescribed and/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) name of medication;

(ii) date prescribed;

(iii) dosage;

(iv) frequency;

(v) route of administration;

(vi) date and time administered;

(vii) name of staff administering medication; and

(viii) 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 any other controlled substance as well as a plan of action if loss, theft or misuse does occur. In the event of loss, theft or misuse, all Federal and State laws 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 shall include:

(i) the date the inventory was conducted;

(ii) time of day it was conducted;

(iii) name and amount of each product on hand at the time of the inventory; and

(iv) the name of the individual conducting the inventory.

(7) Drug reactions and medication errors.

A narcotic treatment program shall report any adverse drug reaction and medication errors to a narcotic treatment program physician immediately and initiate corrective action. The reaction or error must be recorded in the drug administration record and the clinical chart, and all persons who are 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 on site or through referral agreements, a full range of rehabilitative services, which shall include legal services, employment services, HIV education services, public health services, adult educational services, and behavioral health services.

§715.19. Psychotherapy services.

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

(a) A narcotic treatment program shall provide each patient an average of 2.5 hours of psychotherapy per month during their first two years, one hour of which shall be individual psychotherapy.

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

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

§715.20. Patient transfers.

A narcotic treatment program shall develop written transfer policies and procedures which shall require that the narcotic treatment program transfer any patient to another narcotic treatment program for continued maintenance, detoxification, or another treatment activity within seven 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. 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 the patient in the program have failed.

(a) A narcotic treatment program may involuntarily terminate a patient from the program if it deems that such termination would be in the best interests

of the health or safety of the patient and/or others, or the program finds any of the following conditions to exist.

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

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

(3) the patient has been excessively absent from the program.

(4) the patient has failed to follow his treatment plan objectives.

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

§715.22. Patient grievance procedures.

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

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

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

§715.23. Patient records.

(a) A narcotic treatment program shall maintain patient records in conformance with all applicable Federal and State laws and regulations. A 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 four years after the patient has completed treatment or treatment has been terminated. Files shall be updated regularly so that all information contained herein 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 examination given by the narcotic treatment program; examination should include an annual re-evaluation by the narcotic treatment program physician.

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

(7) documentation of a one-year history of narcotic dependency, if applicable.

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

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

(10) urine testing results.

(11) counselor notes regarding patient progress and status.

(12) applicable consent forms.

(13) patient record of services.

(14) case consultation notes regarding the patient.

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

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

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

(18) referrals to other projects or services.

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

(20) annual evaluation by the counselor.

(21) aftercare plan, if applicable.

(22) discharge summary.

(23) follow-up information regarding the patient.

(24) documentation of patient grievances.

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

(1) employment, education or training.

(2) legal standing.

(3) substance abuse.

(4) financial management abilities.

(5) physical and emotional health.

(6) fulfillment of treatment objectives.

(7) family and community supports.

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

standards for certification of treatment activities which are a part of a health care facility.

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

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

§715.24. Narcotic detoxification.

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

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

(b) For calculating the one-year narcotic dependency history required for admission to maintenance treatment, the detoxification period shall not be included.

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

(d) Minimum requirements for short-term detoxification treatment.

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

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

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

(4) No narcotic treatment program may provide short-term detoxification treatment to any individual until at least seven days

after the conclusion of any previous short-term detoxification treatment.

(e) Minimum requirements for long-term detoxification treatment.

(1) A narcotic treatment program shall administer medication in such a manner 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.

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

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

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

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

§715.25. Prohibition of medical units.

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

§715.26. Security.

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

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

§715.27. **Readmission.**

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

§715.28. **Unusual incidents.**

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

(1) Physical assault by a patient.

(2) Inappropriate behavior by a patient causing disruption to the narcotic treatment program.

(3) Selling of drugs on premises.

(4) Complaints of patient abuse (physical, verbal, sexual, emotional, financial).

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

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

(7) Incident with potential for negative community reaction or which the facility director believes may lead to community concern.

(8) Theft, burglary, break-in or similar incident at the facility.

(9) Any other unusual incident 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, where indicated.

(4) Ongoing monitoring of the corrective action plan.

(c) Narcotic treatment programs shall file a written Unusual Incident Report with the Department within 48 hours following unusual incidents:

(1) Complaints of patient abuse (physical, verbal, sexual, emotional, financial).

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

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

(4) Incident with potential for negative community reaction or which the facility director believes may lead to community concern.

(5) Drug related hospitalization of a patient.

§715.29. Exceptions.

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

These regulations apply to the use of any agent which may be approved by the Department for use in narcotic/opioid dependency medication therapy. These regulations apply 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

July 17, 2000

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

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

Dear Mr. Nyce:

Attached are proposed regulations for review by the Commission in accordance with the Regulatory Review Act, (71 P.S. §§745.1-745.15). The proposed regulations will replace narcotic addiction treatment standards by adding 28 Pa. Code Chapter 715, amending 28 Pa. Code §701.1 and repealing 4 Pa. Code Chapter 263. The purpose of the amendment is to revise and update current narcotic addiction treatment standards for the approval of narcotic addiction treatment programs to conform with updated Federal regulations.

Section 5(g) of the Regulatory Review Act, 71 P.S. §745.5(g), provides that the Commission shall, within 10 days after the expiration of the Standing Committee review period, notify the proposing agency of any objections to the proposed regulations. The regulations are expected to be published July 29, 2000. A 30-day comment period is provided.

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, the agency shall submit to the Commission a copy of the agency's response to the comments received and the text of the final form regulations which the agency intends to adopt.

The Department will provide the Commission within 5 days of receipt, a copy of any comment received pertaining to the proposed regulations. The Department will also provide the Commission with any assistance it requires to facilitate a thorough review of the proposed

regulations. If you have any questions, please contact John C. Hair, Director, Bureau of Community Program Licensure and Certification, 132 Kline Plaza, Suite A, Harrisburg, PA 17104, (717) 783-8665.

Sincerely,

Robert S. Zimmerman, Jr.
Secretary of Health

Enclosures

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER: 10-159

SUBJECT: Governor's Council on Drug and Alcohol Abuse and Drug and Alcohol Facilities Services

AGENCY: DEPARTMENT OF HEALTH

TYPE OF REGULATION

X Proposed Regulation

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
7/19/00	Lisa J. Burris	HOUSE COMMITTEE ON HEALTH & HUMAN SERVICES
7-19-00		
7/19/00		SENATE COMMITTEE ON PUBLIC HEALTH & WELFARE
7-19-00	Debbie K. Eaton	
7-19-00	J. Vaillancourt	INDEPENDENT REGULATORY REVIEW COMMISSION
_____	_____	ATTORNEY GENERAL
07/19/00		LEGISLATIVE REFERENCE BUREAU

June 26, 2000