RULES AND REGULATIONS

Title 4—ADMINISTRATION
Title 28—HEALTH AND SAFETY

DEPARTMENT OF HEALTH
[4 PA. CODE CH. 263]
[28 PA. CODE CHS. 701 AND 715]
Drug and Alcohol Facilities and Services

The Department of Health (Department) amends the standards for approval of narcotic treatment programs by deleting 4 Pa. Code Chapter 263 (relating to methadone), amending 28 Pa. Code Chapter 701 (relating to general provisions) and adding 28 Pa. Code Chapter 715 (relating to standards for approval of narcotic treatment programs) to read as set forth in Annex A.

A. *Purpose of the Final-Form Rulemaking*

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

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

Chapter 715 replaces the deleted methadone treatment regulations in 4 Pa. Code Chapter 263. Those regulations, as applied, were not consistent with current health practices or Federal requirements. They were more burdensome than Federal regulations.

B. *Comments*

Chapter 701. General Provisions

Subchapter A. Definitions

Section 701.1. General definitions.

This section defines terms used in Part V (relating to drug and alcohol facilities and services).

Comment

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

Response

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

Comment

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

Response

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

Comment

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

Response

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

Comment

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

Response

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

Other Changes

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

The Department has added the words "narcotic treatment" before the words "physician" and "program" for clarity and consistency throughout the regulations. The Department has also added a definition for "psychotherapy" since that term has been added in § 715.19 (relating to psychotherapy services). The Department has also deleted the definition of and reference to "Federal Food and Drug Administration (FDA)" and added a definition for the "Center For Substance Abuse Treatment

(CSAT)" since the functions previously performed by the FDA are now performed by CSAT.

Chapter 715. Standards for Approval of Narcotic Treatment Program

Section 715.1. General provisions.

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

Section 715.2. Relationship of Federal and State regulations.

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

Comment

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

Response

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

Section 715.3. Approval of narcotic treatment programs.

This section sets forth the process by which a narcotic treatment program shall obtain and maintain licensure and approval for operation within this Commonwealth.

Comment

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

Response

The Department agrees. The term "designee" has been replaced by the phrase "an organization designated by the Substance Abuse and Mental Health Services Administration under the authority of 21 U.S.C.A. § 823; 42 U.S.C.A. §§ 257a, 290aa(d), 290dd-2, 300x-23, 300x-27(a) and 300y-11."

Comment

Proposed subsection (d) provides that the Department may inspect the narcotic treatment program without notice whereas the existing regulation at 4 Pa. Code § 263.3(e) states that "inspections will occur without notice to the methadone project." The Department should explain the rationale behind removing mandatory notice inspections from the regulation. Subsection (d) does not articulate what standards will be used by the Department to determine which narcotic treatment programs will be inspected without notice and with notice.

Response

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

Comment

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

Response

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

Comment

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

Response

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

Comment

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

Response

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

Other Changes

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

Section 715.4. Denial, revocation or suspension of approval.

This section outlines when approval will be denied, revoked or suspended due to noncompliance by an applicant or a program.

Comment

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

Response

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

Section 715.5. Patient capacity.

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

Comment

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

Response

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

The following criteria will be used by the Department in evaluating the factors in paragraphs (1)—(5): (1) Safety—considerations include dispensing time, internal patient flow and external traffic patterns; (2) Physical facility—considerations include number and size of counseling office, waiting area, restrooms, and dispensing and nursing windows; (3) Staff size and composition—considerations include the number of physician, dispensing and counseling staff; (4) Ability to provide required services—considerations include compliance with licensing and narcotic treatment program regulations as determined during licensing, monitoring and special visits to the program; and (5) Availability and accessibility of service—considerations include the location of the narcotic treatment program and the hours of operation. These criteria are reflected in the final amendments.

Section 715.6. Physician staffing.

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

Comment

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

Response

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

Comment

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

Response

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

Comments

Proposed subsections (d) and (e) contain the staffing ratios for physicians and other licensed and certified health care professionals providing treatment to patients in narcotic treatment programs. The 1:10 physician-hour per week per patient ratio in subsection (d) is excessive, unnecessary, costly and unreasonable. The economics of narcotics addiction treatment for smaller clinics simply does not allow for a large and unnecessary allocation to

physician services. Further, other states impose no physician-patient requirements on narcotic treatment programs. The Department should consider amending the ratio to a maximum of 1:25 or a minimum of 1:15. If the Department elects not to amend its ratios, at a minimum, the Department should explain how the ratios were developed and whether each ratio is the most reasonable and appropriate to protect public health, safety and welfare.

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

Response

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

In response to cost concerns, the Department has reduced physician involvement by permitting the use of physician assistants and certified registered nurse practitioners in the ratio. Only 1/3 of the time must be physician time. In response to the comment that other states impose no physician-patient ratios, the Department agrees that it is true that some states impose no requirements. However, several states do require physician hours and several other states are considering readoption of the requirements for physician hours due to problems experienced as a result of insufficient physician coverage. The Department is allowing for up to 2/3 of physician time to be met through the use of physician assistants or certified registered nurse practitioners. Accordingly, the Department has not changed the section.

Comment

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

Response

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

Section 715.7. Dispensing or administering staffing.

This section provides the requirements of both automatic dispensing systems and manual dispensing systems.

Comment

The requirement of one full-time licensed nurse or other person authorized to dispense controlled substances for every 200 patients for automated dispensing systems in proposed subsection (a)(1) should be increased to 300 patients because lesser ratios do not result in full utilization of staff and are a waste of resources.

Response

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

Comment

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

Response

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

Comment

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

Response

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

Section 715.8. Psychosocial staffing.

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

Comment

This proposed section simply references the staffing ratios in Chapter 704, but does not specify which ratios are applicable to psychosocial staffing, the counselor or primary care staff ratios. The Department should reference the specific staffing ratio that applies to psychosocial staffing.

Response

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

Section 715.9. Intake.

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

Comment

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

Response

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

Comment

Proposed subsection (a)(4) should be clarified. The subsection states that before a narcotic treatment physician prescribes methadone there must be "a determination by the physician that the individual is currently physiologically dependent." The most appropriate care and diagnosis is achieved through an initial face-to-face determination between a physician and patient; however, "determination" is not clearly defined. A third party consultation between a physician assistant, nurse practitioner or other health care person and the physician without the physician ever physically seeing the patient could be construed as sufficient for "determination" of dependency. The term "determination" should be further clarified to ensure correct diagnosis and appropriate care.

Response

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

Comment

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

Response

The Department agrees in part with the recommendation regarding voluntary versus involuntary detoxification, specifically that consideration be given to any person who has been detoxified, whether voluntarily or involuntarily. The distinction is eliminated. Patients who have been either voluntarily or involuntarily detoxified from comprehensive maintenance treatment may be readmitted to maintenance treatment, without evidence to support findings of current physiologic dependence, up to 2 years after discharge. Readmission is conditioned upon the program being able to document prior narcotic drug comprehensive maintenance treatment of 6 months or more, and the admitting program physician, exercising reasonable clinical judgment, finding readmission to comprehensive maintenance treatment to be medically justified.

Section 715.10. Pregnant patients.

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

Comment

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

Response

The Department has added § 715.10(f) (relating to pregnant patients) to address this comment.

Other Changes

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

Section 715.11. Confidentiality of patient records.

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

Comments

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

Response

The Department agrees. The specific citations 42 CFR 2.22 (relating to notice to patients of Federal confidentiality requirements) and § 709.28 (relating to confidentiality) are referenced in the final-form rulemaking.

Section 715.12. Informed patient consent.

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

Comment

This proposed section requires that a narcotic treatment program obtain an "informed, voluntary consent" before an agent can be administered to a patient. The proposed rulemaking does not clearly state the specific information that the narcotic treatment program must provide to the patient and whether the consent must be written.

Response

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

Section 715.13. Patient identification.

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

Comment

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

Response

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

Section 715.14. Urine testing.

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

Comment

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

Response

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

Comment

Proposed subsection (a) reduces the testing requirement to monthly for all tested substances. The existing regulation requires weekly urine testing for opiates and synthetic narcotics and monthly testing for other controlled substances. Urine testing for the first 2 years of narcotic addiction treatment should be conducted at a minimum of once per week because these patients need to be monitored more closely for relapse. The current requirement of weekly urine testing should be retained for more stable patients. The Department should explain its rationale behind requiring only monthly testing for all patients.

Response

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

Comment

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

Response

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

Comment

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

chain of custody and how the benefits outweigh the costs. Additionally, the Department should consider replacing the phrase "traced to the person whom it belongs" with the phrase "traced to the donor."

Response

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

Section 715.15. Medication dosage.

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

Comment

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

Response

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

Section 715.16. Take-home privileges.

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

Comment

The current standard for giving patients take-home privileges does not respond to trends toward "medical maintenance." Programs should respond to the changes by permitting "senior patients," those patients who have substantial "clean time" with 5 or more years in treatment, to remain in programs and be able to receive up to a 30-day supply of medication. The proposed regulations seem to grant an exception for these patients, permitting them to attend a clinic twice a month where they receive a 2-week supply of medication. There is no clear procedure for how the requests for exception in this section will be approved and by whom. Also, the language of subsection (a) includes a sentence which states: "The physician shall make this determination after consultation with appropriate staff." It is unclear who are "appropriate staff within the program" with whom the physician must consult. The Department should expand the regulation to specifically state who are "appropriate staff."

Response

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

Comment

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

Response

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

Section 715.17. Medication control.

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

Comment

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

Response

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

Comment

Proposed subsection (c)(2) states "a narcotic treatment program shall develop and implement written policies and procedures regarding where and how medications are stored . . . . Agents shall be stored in a locked safe that has been approved by the DEA." However, § 715.26 (relating to security) requires that "a narcotic treatment program shall meet the security standards for the distribution and storage of controlled substances as required by Federal and State statutes and regulations." There is a

lack of clarity and consistency throughout the regulation on the requirements for storage areas, specifically, in the storage of a small amount of an agent in a secure area. For clarity, the Department should consider incorporating by reference 21 CFR 1301.72 and 1301.74 (relating physical security controls; and other security controls) in both this section and § 715.26.

Response

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

Comment

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

Response

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

Other Changes

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

In addition, various nonsubstantive changes were made for clarification.

Section 715.18. Rehabilitation services.

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

Comment

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

Response

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

Section 715.19. Psychotherapy services.

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

Comment

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

Response

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

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

Section 715.20. Patient transfers.

This section requires each narcotic treatment program to develop policies regarding the transfer of patients to another narcotic treatment program or another treatment environment upon the request of the patient.

Comment

This proposed section requires each narcotic treatment program to develop policies and procedures for transferring patients from one treatment program to another, but makes no mention of whether patient records are to be kept confidential in the event of transfer. Proposed § 715.11 (relating to confidentiality of patient records) sets forth the importance of the confidentiality of patients records in complying with Federal and State statutes and regulations. The Department should consider cross-referencing § 715.11 in this section to impress upon narcotic treatment programs that patient records will continue to be confidential even if the patient is transferred to another narcotic treatment program.

Response

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

Comment

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

Response

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

program to prepare the appropriate paperwork for transfer. Additionally, the Department does not require a patient to submit a request for transfer in writing because it would likely result in undue delays in the transfer process. The Department has not changed the section in response to the comment.

Section 715.21. Patient termination.

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

Comment

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

Response

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

Comment

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

Response

The Department agrees and has changed the regulation. Paragraph (1)(iii) has been revised to include absences of 3 consecutive days or longer without cause as a cause for termination.

Section 715.22. Patient grievance procedures.

This section establishes the procedures for reviewing and resolving patient grievances.

Comment

Proposed subsection (a) requires a narcotic treatment program to develop and utilize a patient grievance procedure. Proposed subsection (b) states "if the grievance is filed against the program director, the review of the case shall be conducted by the governing body." The arrangement may not be in the best interests of the patient. A multi-representative group of the narcotic treatment program may be better suited to render judgment in these cases. The Department should consider allowing grievances against the program director to be heard by either a multi-representative group or a subcommittee of the governing body instituted for the express purposes of grievance adjudication. Additionally, it is unclear whether grievances can be appealed directly to the Department.

Response

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

Subsection (c) has been revised for clarification.

Section 715.23. Patient records.

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

Comment

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

Response

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

Comment

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

Response

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

Comment

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

Response

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

Section 715.24. Narcotic detoxification.

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

Comment

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

Response

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

Section 715.25. Prohibition of medication units.

This section prohibits medication units from operating in this Commonwealth.

Comment

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

Response

The Department prohibits medication units within this Commonwealth because these sites can be hundreds of miles from the main narcotic treatment program facility site. Further, only medication is dispensed at these sites. There is no counseling, no support services and no supervision at these medication units. Dispensing medication without clinical or support services is not in the best interests of patients. The Department has not changed the regulation in response to this comment. The Department does agree, however, that the definition of "medication units" should be included in § 701.1. That definition reads as follows:

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

Section 715.26. Security.

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

Comment

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

Response

The Department agrees. The Department has provided a citation to 21 CFR 1301.72 and 1301.74. This addition should remove confusion and ambiguity in the interpretation of the regulation.

Section 715.27. Readmission.

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

Section 715.28. Unusual incidents.

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

Comment

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

Response

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

Section 715.29. Exceptions.

The Department received no comments on this section.

Section 715.30. Applicability.

The Department received no comments on this section.

C. *Fiscal Impact*

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

D. *Paperwork Estimate*

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

E. *Effective Date/Sunset Date*

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

F. *Statutory Authority*

The Department was authorized by the General Assembly under Reorganization Plan No. 2 of 1977 (71 P. S. § 751-25); Reorganization Plan No. 4 of 1981 (71 P. S. § 751-31); and the Pennsylvania Drug and Alcohol Abuse Control Act (71 P. S. §§ 1690.101—1690.114) (Act 63), to assume the function and responsibilities of the Governor's Council on Drug and Alcohol Abuse (Council). The Council's authority to regulate and promulgate rules and regulations was transferred to the Department through those reorganization plans. See Reorganization Plan No. 2

of 1977 (transferring duties under the Public Welfare Code with regard to regulation, supervision and licensing of drug and alcohol facilities to the Council), Reorganization Plan No. 4 of 1981 (transferring the functions of the Council to the Department and establishing the Council as an advisory council) and Act 63, as amended by the act of December 20, 1985 (P. L. 529, No. 119), (amending Act 63 to reference the Pennsylvania Advisory Council on Drug and Alcohol Abuse). This final-form rulemaking was promulgated under these provisions and is being deleted, amended and added under these provisions. This final-form rulemaking is also required by Federal regulations, 42 CFR 8.1—8.34 (relating to certification of opioid treatment programs).

G. *Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on July 17, 2000, the Department submitted a copy of the proposed rulemaking, published at 30 Pa.B. 3795 (July 29, 2000), to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the House Committee on Health and Human Services and the Senate Committee on Public Health and Welfare for review and comment. In addition, in compliance with section 5(c) of the Regulatory Review Act, the Department provided IRRC and the Committees with copies of the comments received.

The Department submitted a copy of the final-form rulemaking to IRRC and the Chairpersons of the House Health and Human Services Committee and the Senate Public Health and Welfare Committees on August 26, 2002. In addition, the Department provided IRRC and the Committees with a copy of a Regulatory Analysis Form prepared by the Department in compliance with Executive Order 1996-1, "Regulatory Review and Promulgation." A copy of this material is available to the public upon request.

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

Under section 5.1(d) of the Regulatory Review Act (71 P. S. § 745.5a(d)), this final-form rulemaking was deemed approved by the House and Senate Committees on September 16, 2002. IRRC met on September 26, 2002, and approved the final-form rulemaking in accordance with section 5.1 (e) of the Regulatory Review Act. The Office of Attorney General approved the regulations on October 28, 2002.

H. *Contact Person*

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

Findings

The Department finds that:

(1) Public notice of intention to adopt regulations adopted by this order has been given under sections 201 and 202 of the act of July 31, 1968 (P. L. 769, No. 240) (45 P. S. §§ 1201 and 1202), and the regulations thereunder, 1 Pa. Code §§ 7.1 and 7.2.

(2) A public comment period was provided as required by law and the comments received were considered.

(3) The adoption of the final-form rulemaking in the manner provided by this order is necessary and appropriate.

Order

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

(a) The regulations of the Department, 4 Pa. Code Chapter 263, are amended by deleting §§ 263.1—263.26; 28 Pa. Code Chapters 701 and 705, are amended by amending § 701.1 and by adding §§ 715.1—715.30 to read as set forth in Annex A, with ellipses referring to the existing text of the regulations.

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

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

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

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

ROBERT S. ZIMMERMAN, Jr.,
Secretary

(*Editor's Note*: For the text of the order of the Independent Regulatory Review Commission, relating to this document, see 32 Pa.B. 5145 (October 12, 2002).)

Fiscal Note: Fiscal Note 10-159 remains valid for the final adoption of the subject regulations.

Annex A

TITLE 4. ADMINISTRATION

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

CHAPTER 263. (Reserved)

§§ 263.1—263.26. (Reserved).

TITLE 28. HEALTH AND SAFETY

PART V. DRUG AND ALCOHOL FACILITIES AND SERVICES

CHAPTER 701. GENERAL PROVISIONS

Subchapter A. DEFINITIONS

§ 701.1. General definitions.

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

* * * * *

Agent—A Commonwealth approved opioid pharmacotherapy substance.

CSAT—Center for substance abuse treatment.

* * * * *

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

Controlled substance—A drug, substance or an immediate precursor included in Schedules I through V of the Pennsylvania Controlled Substance, Drug, Device, and Cosmetic Act (35 P. S. §§ 780-101—780-149).

* * * * *

DEA—The Federal Drug Enforcement Administration.

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

* * * * *

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

Long-term residential facilities—Facilities where the average length of stay exceeds 90 days.

MH/MR administrator—The person appointed by the local authority to carry out duties, as provided in the Mental Health and Mental Retardation Act of 1966 (50 P. S. §§ 4101—4704), within a county MH/MR program.

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

Medical director—A narcotic treatment physician who 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 an agent.

Medication—A prescription drug ordered by a licensed physician.

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

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

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

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

* * * * *

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

* * * * *

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

* * * * *

Short-term detoxification treatment—Detoxification treatment for 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 an agent.

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CHAPTER 715. STANDARDS FOR APPROVAL OF NARCOTIC TREATMENT PROGRAM

Sec.
715.1. General provisions.
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§ 715.1. General provisions.

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

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

§ 715.2. Relationship of Federal and State regulations.

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

(b) This chapter is intended to supplement the Federal regulations governing narcotic treatment programs in 21

CFR Chapter II, 1300—1399 (relating to Drug Enforcement Administration, Department of Justice).

§ 715.3. Approval of narcotic treatment programs.

(a) An entity shall apply for and receive approval as required from the Department, DEA and CSAT or an organization designated by the Substance Abuse and Mental Health Services Administration (SAMHSA), under the authority of section 303 of the Controlled Substances Act (21 U.S.C.A. § 823) and sections 501(d), 509(a), 543, 1923, 1927(a) and 1976 of the Public Health Service Act (42 U.S.C.A. §§ 290aa(d), 290bb-2(a), 290dd-2, 300x-23, 300x-27(a) and 300y-11), prior to offering services within this Commonwealth as a narcotic treatment program. Application for approval shall be made simultaneously to the Department, DEA and CSAT or SAMHSA designee.

(1) The Department will forward a recommendation for approval to the Federal officials after a review of policies and procedures and an onsite inspection by an authorized representative of the Department and after a determination has been made that the requirements for approval under this chapter have been met.

(2) The decision of the Federal officials set forth in 21 CFR Chapter II (relating to Drug Enforcement Administration, Department of Justice) or other Federal statutes shall constitute the final determination on the application for approval by DEA and CSAT or SAMHSA designee.

(b) A narcotic treatment program shall be licensed under the Department's regulations for drug and alcohol facilities in Chapter 157, 704, 705, 709 or 711. When a licensee applies to operate a narcotic treatment program, the history component of the application of the licensee shall include the licensee's record of operation of any facility regulated by any State or Federal entity. A narcotic treatment program may not be recommended for approval unless licensure has been obtained under Chapters 157, 704, 705, 709 or 711.

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

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

(e) During the inspection process, a narcotic treatment program shall make available to the authorized staff of the Department full and free access to its premises, facilities, records, reports, files and other similar items necessary for a full and complete evaluation. The Department may make copies of materials it deems necessary under 42 CFR 2.53 (relating to audit and evaluation activities) and §§ 709.15 and 711.15 (relating to right to enter and inspect; and right to enter and inspect).

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

(g) The Department may grant approval as a narcotic treatment program after an onsite inspection when the Department determines that a narcotic treatment program satisfies the following:

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

(2) It is complying with a plan of correction approved by the Department with regard to any outstanding deficiencies.

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

(h) Notification of deficiencies involves the following:

(1) The authorized Department representative will provide the program director with a record of deficiencies with instructions to submit a plan of correction.

(2) The narcotic treatment program shall complete the plan of correction and submit it to the Department within 21 days after the last day of the onsite inspection.

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

§ 715.4. Denial, revocation or suspension of approval.

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

(b) The Department may recommend to the DEA or CSAT or SAMHSA's designee to initiate proceedings to revoke or deny Federal approval.

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

§ 715.5. Patient capacity.

The Department may increase or decrease the number of patients a narcotic treatment program may treat. The Department may raise the patient capacity, upon the written request of the narcotic treatment program, based upon the Department's review of the narcotic treatment program. The factors the Department will consider include:

(1) *Safety.* Considerations include dispensing time, internal patient flow and external traffic patterns.

(2) *Physical facility.* Considerations include the number and size of counseling offices, waiting areas, restrooms, and dispensing and nursing windows.

(3) *Staff size and composition.* Considerations include the number of narcotic treatment physicians, dispensing and counseling staff.

(4) *Ability to provide required services.* Considerations include compliance with licensing and narcotic treatment program regulations as determined during licensing, monitoring and special visits to the narcotic treatment program.

(5) *Availability and accessibility of service.* Considerations include the location of the narcotic treatment program and the hours of operation.

§ 715.6. Physician staffing.

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

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

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

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

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

(2) When a narcotic treatment program is unable to hire a medical director who meets the qualifications in paragraph (1), the narcotic treatment program may hire an interim medical director. The narcotic treatment program shall develop and submit to the Department for approval a training plan for the interim medical director, addressing the measures to be taken for the interim medical director to achieve minimal competencies and proficiencies until the interim medical director meets qualifications identified in paragraph (1)(i), (ii) or (iii). The interim medical director shall meet the qualifications within 36 months of being hired.

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

(i) Supervision of narcotic treatment physicians.

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

(b) A narcotic treatment program may employ narcotic treatment physicians to assist the medical director. A narcotic treatment physician's responsibilities include:

(1) Performing a medical history and physical exam.

(2) Determining diagnosis and determining narcotic dependence.

(3) Reviewing treatment plans.

(4) Determining dosage and all changes in doses.

(5) Ordering take-home privileges.

(6) Discussing cases with the treatment team.

(7) Issuing verbal orders pertaining to patient care.

(8) Assessing coexisting medical and psychiatric disorders.

(9) Treating or making appropriate referrals for treatment of these disorders.

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

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

(e) A physician assistant or certified registered nurse practitioner may perform functions of a narcotic treatment physician in a narcotic treatment program if authorized by Federal, State and local laws and regulations, and if these functions are delegated to the physician assistant or certified registered nurse practitioner by the medical director, and records are properly countersigned by the medical director or a narcotic treatment physician. One-third of all required narcotic treatment physician time shall be provided by a narcotic treatment physician. Time provided by a physician assistant or certified registered nurse practitioner may not exceed two-thirds of the required narcotic treatment 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 nurse or other person authorized by law to administer or dispense a controlled substance shall be available for every 200 patients.

(2) If it operates a manual or nonautomatic dispensing system, one full-time nurse or other person authorized by law to administer or dispense a controlled substance shall be available for every 150 patients.

(b) Dispensing time shall be prorated for patient census. There shall be sufficient dispensing staff to ensure that all patients are medicated within 15 minutes of arrival at the dispensing area.

§ 715.8. Psychosocial staffing.

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

(1) *General requirements.* A narcotic treatment program shall comply with the patient/staff and patient/counselor ratios in subparagraphs (i)—(vi) during primary care hours. These ratios refer to the total number of patients being treated, including patients with diagnoses other than drug and alcohol addiction served in other facets of the project. Family units may be counted as one patient.

(i) *Inpatient nonhospital detoxification (residential detoxification).*

(A) There shall be one full-time equivalent (FTE) primary care staff person available for every seven patients during primary care hours.

(B) There shall be a narcotic treatment physician on-call at all times.

(ii) *Inpatient hospital detoxification.* There shall be one FTE primary care staff person available for every five patients during primary care hours.

(iii) *Inpatient nonhospital treatment and rehabilitation (residential treatment and rehabilitation).* A narcotic treatment program serving adult patients shall have one FTE counselor for every eight patients.

(iv) *Inpatient hospital treatment and rehabilitation (general, psychiatric or specialty hospital).* A narcotic treatment program serving adult patients shall have one FTE counselor for every five patients.

(v) *Partial hospitalization.* A partial hospitalization narcotic treatment program shall have a minimum of one FTE counselor who provides direct counseling services to every ten patients.

(vi) *Outpatients.* The counseling caseload for one FTE counselor in an outpatient narcotic treatment program may not exceed 35 active patients.

(2) *Counselor assistants.* A counselor assistant eligible for a counseling caseload may be included in determining FTE ratios.

§ 715.9. Intake.

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

(1) Verify that the individual has reached 18 years of age.

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

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

(4) Have a narcotic treatment physician make a face-to-face determination of whether an individual is currently physiologically dependent upon a narcotic drug and has been physiologically dependent for at least 1 year prior to admission for maintenance treatment. The narcotic treatment physician shall document in the patient's record the basis for the determination of current dependency and evidence of a 1 year history of addiction.

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

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

(2) Upon readmitting a patient who has been out of a narcotic treatment program for 6 months or less after a voluntary termination, the narcotic treatment program shall update the information in and review the patient's file to show current opiate narcotic dependency, but need not conduct a physical examination and applicable laboratory tests. Privileges earned during the previous treatment may be reinstated at the discretion of the narcotic treatment physician.

(3) A patient who has been treated and later detoxified from comprehensive maintenance treatment may be readmitted to maintenance treatment, without evidence to support findings of current physiologic dependence, up to 2 years after discharge, if the following conditions are met:

(i) The narcotic treatment program attended is able to document prior narcotic drug comprehensive maintenance treatment of 6 months or more.

(ii) The admitting narcotic treatment physician, exercising reasonable clinical judgment, finds readmission to comprehensive maintenance treatment to be medically justified.

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

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

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

§ 715.10. Pregnant patients.

(a) A narcotic treatment program may place a pregnant patient, regardless of age, who has had a documented narcotic dependency in the past and who may return to narcotic dependency, on a comprehensive maintenance regime.

(1) For these patients, evidence of current physiological dependence on narcotic drugs is not needed if a narcotic treatment physician certifies the pregnancy and, exercising reasonable clinical judgment, finds treatment to be medically justified.

(2) Evidence of all findings and the criteria used to determine the findings shall be recorded in the patient's record by the admitting narcotic treatment physician before the initial dose is administered to the patient.

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

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

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

(e) A patient who is or becomes pregnant may not be started or continued on LAAM, except by the written order of a narcotic treatment physician who determines that LAAM is the best therapy for that patient.

(1) An initial pregnancy test shall be performed for each prospective female patient of childbearing potential before admission to LAAM comprehensive maintenance treatment.

(2) A monthly pregnancy test shall be performed thereafter on female patients on LAAM.

(f) The narcotic treatment program shall ensure that each female patient is fully informed of the possible risk to her or her unborn child from continued use of illicit drugs and from use of, or withdrawal from a narcotic drug administered or dispensed by the program in comprehensive maintenance or detoxification treatment.

§ 715.11. Confidentiality of patient records.

A narcotic treatment program shall physically secure and maintain the confidentiality of all patient records in accordance with 42 CFR 2.22 (relating to notice to patients of Federal confidentiality requirements) and § 709.28 (relating to confidentiality).

§ 715.12. Informed patient consent.

A narcotic treatment program shall obtain an informed, voluntary, written consent before an agent may be administered to the patient for either maintenance or detoxification treatment. The following shall appear on the patient consent form:

(1) That methadone and LAAM are narcotic drugs which can be harmful if taken without medical supervision.

(2) That methadone and LAAM are addictive medications and may, like other drugs used in medical practices, produce adverse results.

(3) That alternative methods of treatment exist.

(4) That the possible risks and complications of treatment have been explained to the patient.

(5) That methadone is transmitted to the unborn child and will cause physical dependence.

§ 715.13. Patient identification.

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

(b) A narcotic treatment program shall maintain onsite a photograph of each patient which includes the patient's name and birth date. The narcotic treatment program shall update the photograph every 3 years.

§ 715.14. Urine testing.

(a) A narcotic treatment program shall complete an initial drug-screening urinalysis for each prospective patient and a random urinalysis at least monthly thereafter.

(1) Each test shall be for opiates, methadone, amphetamines, barbiturates, cocaine and benzodiazepines.

(2) If the narcotic treatment program determines that other drugs are abused in that narcotic treatment program's locality or have been identified in the patient's drug and alcohol history as being a drug of abuse or use, a narcotic treatment program may conduct a test or analysis for other drugs as well.

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

(c) A narcotic treatment program shall develop and implement policies and procedures to minimize misidentification of urine specimens and to ensure that the tested specimens can be traced to the donor.

(d) A narcotic treatment program shall ensure that a laboratory that performs the testing required under this section shall be in compliance with applicable Federal requirements, specifically the Clinical Laboratory Improvement Amendments of 1998 (42 U.S.C.A. §§ 201 note, 263 and 263a notes), and State requirements, specifically the Pennsylvania Clinical Laboratory Act (35 P. S. §§ 2151—2165) and Chapter 5 (relating to clinical laboratories).

§ 715.15. Medication dosage.

(a) The narcotic treatment physician shall review the dosage levels at least twice a year, with each review occurring at least 2 months apart, to determine a patient's therapeutic dosage.

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

(c) Methadone shall be administered or dispensed only in oral form and shall be formulated to reduce its potential for parenteral abuse.

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

(e) LAAM shall be administered or dispensed only in oral form and shall be formulated to reduce its potential for parenteral abuse.

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

§ 715.16. Take-home privileges.

(a) A narcotic treatment program shall determine whether a patient may be provided take-home medications.

(1) A narcotic treatment program may give take-home medications only to a patient who the narcotic treatment physician has determined is responsible and able to handle narcotic drugs outside the narcotic treatment program.

(2) The narcotic treatment physician shall make this determination after consultations with staff involved in the patient's care.

(3) The narcotic treatment physician shall document in the patient record the rationale for permitting take-home medication.

(4) A narcotic treatment physician may rescind take-home medication privileges.

(5) A narcotic treatment program shall develop written policies and procedures relating to granting and rescinding take-home medication privileges.

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

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

(2) Regular narcotic treatment program attendance.

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

(4) Absence of known recent criminal activity.

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

(6) Length of time in comprehensive maintenance treatment.

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

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

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

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

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

(ii) A patient demonstrates substantial progress in rehabilitation.

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

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

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

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

(ii) A patient demonstrates substantial progress in rehabilitation.

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

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

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

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

(ii) A patient demonstrates substantial progress in rehabilitation.

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

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

(v) A patient demonstrates no major behavioral problems.

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

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

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

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

(1) A patient has a permanent physical disability.

(2) A patient has a temporary disability.

(3) A patient has an exceptional circumstance such as illness, personal or family crisis, or travel which interferes with the patient's ability to conform to the applicable mandatory attendance schedules. In all cases, the patient shall demonstrate an ability to responsibly handle narcotic drugs.

(e) With an exception granted under subsection (d), a narcotic treatment program may not permit a patient to receive more than a 2-week take-home supply of medication.

(f) An exception granted under subsection (d) shall continue only for as long as the temporary disability or exceptional circumstance exists. When a patient is permanently disabled, that case shall be reviewed at least annually to determine whether the need for the exception still exists.

§ 715.17. Medication control.

(a) A narcotic treatment program shall comply with applicable Federal and State statutes and regulations regarding the storing, compounding, administering and dispensing of medication.

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

(c) A narcotic treatment program shall develop and implement written policies and procedures regarding the medications used by patients which shall include, at a minimum:

(1) *Administration of medication.*

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

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

(iii) Only authorized staff and patients who are receiving medication shall be permitted in the dispensing area.

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

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

(vi) Administering and dispensing shall be conducted in a manner that protects the patient from disruption or annoyance from other individuals.

(2) *Drug storage areas.* A narcotic treatment program shall develop and implement written policies and procedures regarding storage of medications and access to the medication storage area. Agents shall be stored in a locked safe that has been approved by the DEA under 21 CFR 1301.72 and 1301.74 (relating to physical security controls; and other security controls).

(3) *Inspection of storage areas.* A narcotic treatment program shall inspect all drug storage areas and the dispensing station at least quarterly to ensure that the areas are maintained in compliance with Federal, State and local laws and regulations. A narcotic treatment program shall develop and implement written policies and procedures regarding who performs the inspections, how often, and in what manner the inspections are to be documented. The policies and procedures shall include the following:

(i) Disinfectants and drugs for external use shall be stored separately from oral and injectable drugs.

(ii) Drugs requiring special conditions for storage to insure stability shall be properly stored.

(iii) Outdated and contaminated drugs shall be removed and destroyed according to Federal and State regulations.

(iv) Administration of controlled substances shall be documented.

(v) Controlled substances and other abusable drugs shall be stored in accordance with Federal and State regulations.

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

(i) The name of the medication.

(ii) The date prescribed.

(iii) The dosage.

(iv) The frequency.

(v) The route of administration.

(vi) The date and time administered.

(vii) The name of the person administering the medication.

(viii) The take-home schedule, if applicable.

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

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

(i) The date the inventory was conducted.

(ii) The time of day it was conducted.

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

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

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

§ 715.18. Rehabilitative services.

(a) A narcotic treatment program shall provide, either onsite or through referral agreements, a full range of rehabilitative services. Rehabilitative services shall include:

(1) HIV education services.

(2) Employment services.

(3) Adult educational services.

(4) Behavioral health services.

(b) A patient shall also have the opportunity to access legal services.

§ 715.19. Psychotherapy services.

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

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

(2) A narcotic treatment program shall provide each patient at least 1 hour per month of group or individual psychotherapy during the third and fourth year of treatment. Additional psychotherapy shall be provided as dictated by ongoing assessment of the patient.

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

§ 715.20. Patient transfers.

A narcotic treatment program shall develop written transfer policies and procedures which shall require that the narcotic treatment program transfer a patient to another narcotic treatment program for continued maintenance, detoxification or another treatment activity within 7 days of the request of the patient.

(1) The transferring narcotic treatment program shall transfer patient files which include admission date, medical and psychosocial summaries, dosage level, urinalysis reports or summary, exception requests, and current status of the patient, and shall contain the written consent of the patient.

(2) A narcotic treatment program shall maintain the confidentiality of patient records remaining in its possession after the transfer under § 715.11 (relating to confidentiality of patient records).

(3) The transferring narcotic treatment program shall document what materials were sent to the receiving narcotic treatment program.

(4) The receiving narcotic treatment program shall document in writing that it notified the transferring narcotic treatment program of the admission of the patient and the date of the initial dose given to the patient by the receiving narcotic treatment program.

§ 715.21. Patient termination.

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

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

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

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

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

(iii) The patient has been absent from the narcotic treatment program for 3 consecutive days or longer without cause.

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

(2) A patient terminated involuntarily, except a patient who commits or threatens to commit acts of physical violence, shall be afforded the opportunity to receive detoxification of at least 7 days. The detoxification may take place at the facility or the patient may be referred to another narcotic treatment program or hospital licensed and approved by the Department for detoxification.

§ 715.22. Patient grievance procedures.

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

(b) The procedure shall permit aggrieved patients a full and fair opportunity to be heard, to question and confront persons and evidence used against them and to have a fair review of their grievances by the narcotic treatment program director. If the grievance is filed against the narcotic treatment program director, the review of the case shall be conducted by either a multi-representative group of the narcotic treatment program or a subcommittee of the governing body instituted for the express purposes of grievance adjudication.

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

§ 715.23. Patient records.

(a) A narcotic treatment program shall maintain patient records in conformance with 42 CFR 2.16 and 2.22 (relating to security for written records; and notice to patients of Federal confidentiality requirements) and State statutes and regulations. A narcotic treatment program shall maintain a complete file on the premises for each present and former patient of the narcotic treatment program for at least 4 years after the patient has completed treatment or treatment has been terminated. Files shall be updated regularly so that the information is current.

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

(1) A complete personal history.

(2) A complete drug and alcohol history.

(3) A complete medical history.

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

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

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

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

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

(9) Other drugs prescribed by the narcotic treatment 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) Psychosocial evaluations of the patient.

(16) Any psychiatric, psychological or other evaluations, if available.

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

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

(19) Referrals to other projects or services.

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

(21) Annual evaluation by the counselor.

(22) Aftercare plan, if applicable.

(23) Discharge summary.

(24) Follow-up information regarding the patient.

(25) Documentation of patient grievances.

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

(1) Employment, education and training.

(2) Legal standing.

(3) Substance abuse.

(4) Financial management abilities.

(5) Physical and emotional health.

(6) Fulfillment of treatment objectives.

(7) Family and community supports.

(d) A narcotic treatment program shall prepare a treatment plan that outlines realistic short and long-term treatment goals which are mutually acceptable to the patient and the narcotic treatment program.

(1) The treatment plan shall identify the behavioral tasks a patient shall perform to complete each short-term goal.

(2) The narcotic treatment physician or the patient's counselor shall review, reevaluate, modify and update each patient's treatment plan as required by Chapters 157, 709 and 711 (relating to drug and alcohol services general provisions; standards for licensure of freestanding treatment activities; and standards for certification of treatment activities which are a part of a health care facility).

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

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

§ 715.24. Narcotic detoxification.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

§ 715.25. Prohibition of medication units.

Narcotic treatment medication units are prohibited.

§ 715.26. Security.

(a) A narcotic treatment program shall meet the security standards for the distribution and storage of controlled substances as required by Federal regulations, including 21 CFR 1301.72 and 1301.74 (relating to physical security controls; and other security controls) and State statutes and regulations.

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

§ 715.27. Readmission.

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

§ 715.28. Unusual incidents.

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

(1) Physical assault by a patient.

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

(3) Selling of drugs on the premises.

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

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

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

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

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

(9) Drug related hospitalization of a patient.

(10) Other unusual incidents the narcotic treatment program believes should be documented.

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

(1) Documentation of the unusual incident.

(2) Prompt review and investigation.

(3) Implementation of a timely and appropriate corrective action plan, when indicated.

(4) Ongoing monitoring of the corrective action plan.

(c) A narcotic treatment program shall file a written Unusual Incident Report with the Department within 48 hours following an unusual incident including the following:

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

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

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

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

(5) Drug related hospitalization of a patient.

§ 715.29. Exceptions.

A narcotic treatment program is permitted, at the time of application or any time thereafter, to request an exception from a specific regulation.

(1) The request for an exception from a specific regulation shall be in writing, with governing body approval, and shall state how the narcotic treatment program will meet the intent of the regulation.

(2) The Department may withhold the granting of an exception and may require a narcotic treatment program to be in actual operation to assess if the exception is appropriate.

(3) The Department will reserve the right to revoke any exception previously granted.

(4) The narcotic treatment program shall maintain documentation of the Department's approval of an exception.

(5) If the exception relates to a specific patient, the narcotic treatment program shall maintain documentation of the exception in the patient's record.

§ 715.30. Applicability.

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

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Title 40—LIQUOR

LIQUOR CONTROL BOARD

[40 PA. CODE CH. 9]

[Correction]

Transporters-for-Hire

An error occurred in the preamble to the final rulemaking which appeared at 32 Pa.B. 5512 (November 9, 2002). The correct version of the second paragraph is as follows:

The amendments are necessary in order to aid entities licensed by the Board as transporters-for-hire. Transporters-for hire are authorized to engage in the commercial transportation of liquor, malt or brewed beverages or alcohol to or from points located in this Commonwealth. The regulations currently require transporters-for-hire to own or lease their vehicles and employ the drivers of these vehicles. This regulatory change would permit these licensees to contract with unlicensed haulers for transportation services using the unlicensed transporters' vehicles and drivers. Such a regulatory change would enable transporters-for-hire to adjust to fluctuations in business volume without having to commit to large expenditures in vehicles and personnel. Moreover, persons who have contracted with and are performing transportation services for a transporter-for-hire would be considered agents of the licensee thus making the transporter-for-hire's license liable for any violation that may result. Additionally, the regulations required that transporters-for-hire notify the Board of vehicles that are no longer in service. The Board has not required this notification by its licensees as a matter of practice for numerous years; therefore, this requirement is being deleted.

[Pa.B. Doc. No. 02-1998. Filed for public inspection November 8, 2002, 9:00 a.m.]

Title 58—RECREATION

FISH AND BOAT COMMISSION

[58 PA. CODE CHS. 61 AND 63]

Fishing

The Fish and Boat Commission (Commission) by this order amends Chapters 61 and 63 (relating to seasons, sizes and creel limits; and general fishing regulations). The Commission is publishing this rulemaking under the authority of 30 Pa.C.S. (relating to the Fish and Boat Code) (code).

A. *Effective Date*

This rulemaking will go into effect upon publication of an order adopting the amendments in the *Pennsylvania Bulletin*.

B. *Contact Person*

For further information on the amendments, contact Laurie E. Shepler, Assistant Counsel, (717) 705-7815, P. O. Box 67000, Harrisburg, PA 17106-7000. This final-form rulemaking is available electronically through the Commission's website (http://www.fish.state.pa.us).

C. *Statutory Authority*

The amendments to §§ 61.1 and 63.3 (relating to Commonwealth inland waters; and fishing in approved trout waters) are published under the statutory authority of section 2102 of the code (relating to rules and regulations). The amendment to § 63.20 (relating to permits for the protection and management of trout and salmon) is published under the statutory authority of section 2904 of the code (relating to permits for protection and management of particular fish).

D. *Purpose and Background*

This rulemaking is designed to update, modify and improve the Commission's regulations pertaining to fishing. The specific purpose of this rulemaking is described in more detail under the summary of changes.

E. *Summary of Changes*

(1) *Section 61.1.* According to this section, the extended trout season applies to "all approved trout waters streams plus lakes and ponds." The "Summary of Fishing Regulations and Laws" (Summary Book), on the other hand, provides that the extended trout season applies to "all approved trout streams and their downstream areas and all lakes and ponds." Because the current wording of

§ 61.1 is a bit awkward and does not include the downstream areas, the Commission amended this section as proposed.

(2) *Sections 63.3 and 63.20.* The allocation of stocked trout is a dynamic process, which has recently resulted in some changes, with some waters that were previously not to be stocked by the Commission this year having been added back to the stocking program. Under §§ 63.3 and 63.20 and § 65.26 (relating to extended trout seasons), the term "approved trout waters" has regulatory significance.

(a) Approved trout waters are closed to all fishing from March 1 to opening day. With the exception of the select trout lakes and several special cases, this means that it is illegal to fish for anything in these waters during the "closed season." For waters not listed, fishing is permitted and a person does not commit a violation as long as the individual does not take, catch, kill or possess trout. (A fish returned immediately unharmed to the waters from which taken is not considered a violation.)

(b) The extended trout season (day after Labor Day until the last day of February of following year) applies to approved trout waters with a creel limit of three per day.

(c) An angler needs a trout stamp to fish in approved trout waters from opening day until the first Saturday in May regardless of what the angler says he is fishing for.

The Commission's regulations are currently worded in a way that seems to limit the Commission's ability to add waters back to the approved trout waters list. Currently, the list is defined as the list in the Summary Book, which does not give the Commission much flexibility. Accordingly, the Commission amended §§ 63.3 and 63.20 as proposed.

F. *Paperwork*

This rulemaking will not increase paperwork and will create no new paperwork requirements.

G. *Fiscal Impact*

This rulemaking will have no adverse fiscal impact on the Commonwealth or its political subdivisions. This rulemaking will impose no new costs on the private sector or the general public.

H. *Public Involvement*

A notice of proposed rulemaking was published at 32 Pa.B. 3493 (July 20, 2002). The Commission did not receive any public comments regarding the proposals.

Findings

The Commission finds that:

(1) Public notice of intention to adopt the amendments adopted by this order has been given under sections 201 and 202 of the act of July 31, 1968 (P. L. 769, No. 240) (45 P. S. §§ 1201 and 1202) and the regulations promulgated thereunder, 1 Pa. Code §§ 7.1 and 7.2.

(2) A public comment period was provided, and no comments were received.

(3) The adoption of the final-form rulemaking by the Commission in the manner provided in this order is necessary and appropriate for administration and enforcement of the authorizing statutes.

Order

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

(a) The regulations of the Commission, 58 Pa. Code Chapters 61 and 63, are amended by amending §§ 61.1, 63.3 and 63.20 to read as set forth at 32 Pa.B. 3493.

(b) The Executive Director will submit this order and 32 Pa.B. 3493 to the Office of Attorney General for approval as to legality as required by law.

(c) The Executive Director shall certify this order and 32 Pa.B. 3493 and deposit them with the Legislative Reference Bureau as required by law.

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

PETER A. COLANGELO,
Executive Director

Fiscal Note: Fiscal Note 48A-129 remains valid for the final adoption of the subject regulations.

[Pa.B. Doc. No. 02-2053. Filed for public inspection November 15, 2002, 9:00 a.m.]

FISH AND BOAT COMMISSION
[58 PA. CODE CHS. 101, 109, 111 AND 115]
Boating

The Fish and Boat Commission (Commission) by this order amends Chapters 101, 109, 111 and 115. The Commission is publishing this final-form rulemaking under the authority of 30 Pa.C.S. (relating to the Fish and Boat Code) (code). The final-form rulemaking relates to boating.

A. *Effective Date*

With the exception of the amendment to § 111.2 (relating to Allegheny County), the final-form rulemaking will go into effect on January 1, 2003. The amendment to § 111.2 will go into effect on May 1, 2003, not January 1, 2003, as proposed.

B. *Contact Person*

For further information on the final-form rulemaking, contact Laurie E. Shepler, Assistant Counsel, P. O. Box 67000, Harrisburg, PA 17106-7000, (717) 705-7815. This final-form rulemaking is available electronically through the Commission's website (http://www.fish.state.pa.us).

C. *Statutory Authority*

The amendments to §§ 101.2 and 109.3 (relating to reportable boating accidents; and personal watercraft) are published under the statutory authority of section 5123 of the code (relating to general boating regulations). The amendment to § 111.2 is published under the statutory authority of section 5124 of the code (relating to particular areas of water). The amendments to §§ 115.4, 115.8 and 115.9 (relating to annual safety inspections; personnel requirements of passenger carrying boats; and licenses for operators) are published under the statutory authority of section 5122 of the code (relating to registrations, licenses, permits, plates and statistics).

D. *Purpose and Background*

The final-form rulemaking is designed to update, modify and improve the Commission's regulations pertaining to boating. The specific purpose of the final-form rulemaking is described in more detail under the summary of changes. The Commission's Boating Advisory Board considered all of the amendments prior to the

Commission's consideration of them on final-form rulemaking and recommended that the Commission adopt them as set forth in the notice of proposed rulemaking except as described in this Preamble.

E. *Summary of Changes*

(1) *Section 101.2.* The United States Coast Guard has raised the threshold of property damage for reportable accidents involving recreational vessels. Prior to this change, the Coast Guard's regulations, like the Commission's, required a boating accident to be reported when damage to the vessel and other property totaled more than $500 or there was a complete loss of the vessel. The National Association of State Boating Law Administrators (NASBLA) successfully persuaded the Coast Guard to increase the amount of damage to $2,000.

Adoption of this final-form rulemaking will result in less paperwork being required by the public to report a loss. It also will reduce the amount of recordkeeping by the Bureau of Law Enforcement and the Bureau of Boating and Education. In 2001, 90 recreational boating accidents were reported to the Commission. If the Commission had been using the new criteria of $2,000 or more, there would have been 16 fewer or 74 reportable accidents, a reduction of 18%. In 2000, the change would have been less dramatic. There were 90 accidents reported. With the new criteria, there would have been eight fewer reportable accidents, a reduction of 9%. The Commission adopted this amendment as proposed.

(2) *Section 109.3.* NASBLA has a model act for personal watercraft that includes a definition of the term "personal watercraft." The definition is very similar to the definition in the Commission's regulations and to those enacted by other states. The Commission's definition, however, was vague when it refers to the position of the operator (rather than in the conventional manner of boat operation). The NASBLA model act is clearer and does not change the "spirit" or the intent of the existing Commission regulation. In addition, recent developments in boat design continue to make clarification necessary so that boat operators and the Commission's officers clearly understand the legal requirements for all boats. The Commission amended the definition of "personal watercraft" as proposed.

(3) *Section 111.2.* On February 15, 2002, the Commission received a petition from "Boaters are Voters," Pittsburgh. The petition requested an extension of the existing slow, minimum height swell speed zone currently in place at the "Point" in Pittsburgh to encompass the area between the Fort Duquesne and Sixth Street Bridges, a distance of about 1,500 feet. The petition was accompanied by letters of support from six organizations and petition sheets with 291 signatures.

The Commission published a notice of proposed rulemaking in the *Pennsylvania Bulletin* and held a public meeting in the Pittsburgh area to give the public additional opportunity to comment. Essentially, boaters are in two camps—those that want a "slow no wake" zone along the entire developing Pittsburgh waterfront and those that do not want further restrictions. In between these extremes are boaters who see a need for some restrictions during certain specified time periods. The Commission has reviewed the comments in the context of the site and has concluded that additional restrictions are warranted. Arguments for extending the zone to encompass the waterside development of the David E. Lawrence Convention Center are also persuasive. Accordingly, the Commission, on final-form rulemaking, amended § 111.2(c) to extend the slow, no wake zone on the Allegheny River to the Fort Wayne (Norfolk Southern) Bridge, instead of the Sixth Street Bridge as proposed. This extension will add an additional 2,000 feet to the zone and will encompass the waterside development in the vicinity of the David E. Lawrence Convention Center. This final-form rulemaking will go into effect on May 1, 2003.

The Commission also approved the publication of a new notice of proposed rulemaking to extend the slow, no wake zone on the Monongahela River from the Fort Pitt Bridge to the Smithfield Bridge and to change the time that the zones are in effect to 7-days-a-week, 24-hours-a-day between May 1 and October 1. Having the zone in effect 7-days-a-week, 24-hours-a-day, between May 1 and October 1 will enhance the boaters' understanding of the regulation and make education, notification (signage) and enforcement easier to implement. If adopted on final-form rulemaking, this amendment also would go into effect on May 1, 2003. The amendments, if promulgated in toto, would address the concerns expressed by the City of Pittsburgh and others and would encompass the river areas currently under active development.

(4) *Sections 115.4, 115.8 and 115.9.* A recent review of Chapter 115 (relating to boats carrying passengers for hire) revealed that minor changes were needed to correct some of the problems and concerns that occur for owners and operators of passenger carrying vessels and the inspectors that inspect these vessels. In § 115.4(a) and (d), the Commission adopted amendments to make it clear that when the inspector arrives on the agreed date of inspection, the vessel must be completely ready for inspection and a current certificate of insurance must be presented to the inspector. Too often, vessels are not ready for inspection and certificates of insurance are late or never forwarded by the insurance companies.

The Commission also amended § 115.8 to provide accommodations for persons with physical limitations. Recently, the owner of a passenger carrying vessel requested certification as a passenger for hire operator. A doctor had certified that the individual is physically qualified to operate a passenger carrying vessel in accordance with the Commission's current standards. The individual's physical limitations, however, would prohibit him from handling mooring lines, associated equipment and certain emergencies without assistance. These limitations would not interfere with the actual operation of the vessel.

The fee requirement in § 115.9(a) was redundant because § 115.9(c) already requires that the applicable fee be attached to the application. Thus, the Commission deleted the fee requirement in § 115.9(a). The Commission also amended § 115.9(d) to be more specific concerning examination requirements for the oral and practical test. Prior regulations required a Boating Safety Education Certificate for crewmembers but not the operator. Accordingly, the Commission amended these sections as proposed.

F. *Paperwork*

The final-form rulemaking will not increase paperwork and will create no new paperwork requirements.

G. *Fiscal Impact*

The final-form rulemaking will have no adverse fiscal impact on the Commonwealth or its political subdivisions. The final-form rulemaking will impose no new costs on the private sector or the general public.

H. *Public Involvement*

A notice of proposed rulemaking was published at 32 Pa.B. 3490 (July 20, 2002). The Commission also sent copies of the proposed amendments to Chapter 115 to all operators of "passengers for hire" boats.

The Commission did not receive any public comments regarding the proposals except for the amendment to § 111.2. During the formal public comment period, the Commission received a total of 86 comments, including a form letter submitted by 63 individuals opposing the amendment to § 111.2. The Commission also received public comments before and after the formal period for accepting comments. Copies of all public comments have been provided to the Commissioners. In addition, the Commission held a public meeting on August 1, 2002, in Monroeville to give the public an additional opportunity to comment. About 40 people attended the meeting and expressed a wide divergence of views.

Findings

The Commission finds that:

(1) Public notice of intention to adopt the amendments adopted by this order has been given under sections 201 and 202 of the act of July 31, 1968 (P. L. 769, No. 240) (45 P. S. §§ 1201 and 1202) and the regulations promulgated thereunder (1 Pa. Code §§ 7.1 and 7.2).

(2) A public comment period was provided, and the comments that were received were considered.

(3) The adoption of the final-form rulemaking of the Commission in the manner provided in this order is necessary and appropriate for administration and enforcement of the authorizing statutes.

Order

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

(a) The regulations of the Commission, 58 Pa. Code Chapters 101, 109, 111 and 115, are amended by amending §§ 101.2, 109.3, 115.4, 115.8 and 115.9 to read as set forth at 32 Pa.B. 3490 and by amending § 111.2 to read as set forth in Annex A.

(b) The Executive Director will submit this order, 32 Pa.B. 3490 and Annex A to the Office of Attorney General for approval as to legality as required by law.

(c) The Executive Director shall certify this order, 32 Pa.B. 3490 and Annex A and deposit them with the Legislative Reference Bureau as required by law.

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

PETER A. COLANGELO,
Executive Director

Fiscal Note: Fiscal Note 48A-128 remains valid for the final adoption of the subject regulations.

Annex A

TITLE 58. RECREATION

PART II. FISH AND BOAT COMMISSION

Subpart C. BOATING

CHAPTER 111. SPECIAL REGULATIONS COUNTIES

§ 111.2. Allegheny County.

(a) *Allegheny River.* The following special regulations apply to the Allegheny River:

(1) Boats are limited to slow, minimum height swell speed from Miles 12.8 to Lock and Dam Number 2 at Mile 14.5 in the back channel of Twelve and Fourteen Mile Islands.

(2) The area behind Nine Mile Island, Mile 10.0 to Mile 10.4 is a designated ski zone. Boats not actively engaged in towing water skiers are limited to slow, minimum height swell speed.

(b) *Monongahela River.* Water skiing is prohibited from the Glassport Bridge (Mile 19.4) to the Union Railroad Bridge (Mile 21.1) at Clairton.

(c) *Allegheny, Monongahela and Ohio Rivers (City of Pittsburgh).* Boats are limited to slow, minimum height swell speed from the Fort Pitt Bridge over the Monongahela River and the Fort Wayne (Norfolk Southern) Bridge over the Allegheny River to the West End Bridge over the Ohio River. This zone shall be in effect on weekends from May 1 to October 1 from 3 p.m. Friday until midnight Sunday and from 3 p.m. on the day preceding Memorial Day, July 4 and Labor Day until midnight of the holiday.

(d) *Youghiogheny River.* Boats are limited to slow, minimum height swell speed from the mouth of the Youghiogheny River to the McKeesport Access Area, a distance of about 200 yards.

[Pa.B. Doc. No. 02-2054. Filed for public inspection November 15, 2002, 9:00 a.m.]

FISH AND BOAT COMMISSION

[58 PA. CODE CH. 111]

Boating; Horsepower Limits

The Fish and Boat Commission (Commission) by this orders amends Chapter 111 (relating to special regulations counties). The Commission is publishing this final-form rulemaking under the authority of 30 Pa.C.S. (relating to the Fish and Boat Code) (code). This final-form rulemaking relates to horsepower limits at six State park lakes.

A. *Effective Date*

This final-form rulemaking will go into effect upon publication of this order adopting the amendments in the *Pennsylvania Bulletin.*

B. *Contact Person*

For further information on this final-form rulemaking, contact Laurie E. Shepler, Assistant Counsel, (717) 705-7815, P. O. Box 67000, Harrisburg, PA 17106-7000. This final-form rulemaking is available electronically through the Commission's website (http://www.fish.state.pa.us).

C. *Statutory Authority*

The amendments to §§ 111.9, 111.10, 111.11, 111.32, 111.43 and 111.67 are published under the statutory authority of section 5124 of the code (relating to particular areas of water).

D. *Purpose and Background*

This final-form rulemaking is designed to update, modify and improve the Commission's regulations pertaining to boating. The specific purpose of the final-form rulemaking described in more detail under the summary of changes. The Commission's Boating Advisory Board considered the amendments prior to the Commission's

consideration of them on final-form rulemaking and recommended that the Commission adopt them as set forth in the notice of proposed rulemaking.

E. *Summary of Proposal*

The Department of Conservation and Natural Resources (DCNR) announced on March 14, 2002, that boating horsepower limits at six State park lakes have been changed in a pilot program seeking better enforcement and the best protection of the environment. Under the pilot program, outboard motor limits have been increased from 10 horsepower to 18 horsepower at the following lakes: Lake Marburg, Codorus State Park, York County; Lake Wilhelm, Maurice K. Goddard State Park, Mercer County; Lake Arthur, Moraine State Park, Butler County; Lake Nockamixon, Nockamixon State Park, Bucks County; Glendale Lake, Prince Gallitzin State Park, Cambria County; and Yellow Creek Lake, Yellow Creek State Park, Indiana County. The pilot program went into effect immediately.

At DCNR's request, the Commission has, in the past, adopted special boating regulations for State park lakes. These regulations maintained unlimited horsepower at seven State park lakes; motors not larger than 10 horsepower at seven State park lakes (including the six where the test program has been implemented); and electric motors only at 35 State parks lakes.

With regard to the lakes included in the pilot program, the Commission believed that its special regulations governing them should be deleted until a time as the DCNR has made a final determination as to horsepower limits. On final-form rulemaking, the Commission adopted the amendments deleting the special regulations, as proposed. The Commission also adopted an amendment to § 111.11(a) (relating to Cambria County) to add text that previously was inadvertently omitted.

F. *Paperwork*

This final-form rulemaking will not increase paperwork and will create no new paperwork requirements.

G. *Fiscal Impact*

This final-form rulemaking will have no adverse fiscal impact on the Commonwealth or its political subdivisions. This final-form rulemaking will impose no new costs on the private sector or the general public.

H. *Public Involvement*

A notice of proposed rulemaking was published at 32 Pa.B. 3951 (August 10, 2002). The Commission did not receive any public comments regarding the proposal to remove the horsepower restrictions on the pilot program lakes. However, the Commission received comments, which it forwarded to the DCNR, regarding increasing the horsepower restrictions at these lakes.

Findings

The Commission finds that:

(1) Public notice of intention to adopt the amendments adopted by this order has been given under sections 201 and 202 of the act of July 31, 1968 (P. L. 769, No. 240) (45 P. S. §§ 1201 and 1202) and the regulations promulgated thereunder, 1 Pa. Code §§ 7.1 and 7.2.

(2) A public comment period was provided, and no comments were received.

(3) The adoption of this final-form rulemaking by the Commission in the manner provided in this order is necessary and appropriate for administration and enforcement of the authorizing statutes.

Order

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

(a) The regulations of the Commission, 58 Pa. Code Chapter 111, are amended by amending §§ 111.9—111.11, 111.32, 111.43 and 111.67 to read as set forth at 32 Pa.B. 3951.

(b) The Executive Director will submit this order and 32 Pa.B. 3951 to the Office of Attorney General for approval as to legality as required by law.

(c) The Executive Director shall certify this order and 32 Pa.B. 3951 and deposit them with the Legislative Reference Bureau as required by law.

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

PETER A. COLANGELO,
Executive Director

Fiscal Note: Fiscal Note 48A-127 remains valid for the final adoption of the subject regulations.

[Pa.B. Doc. No. 02-2055. Filed for public inspection November 15, 2002, 9:00 a.m.]

FISH AND BOAT COMMISSION
[58 PA. CODE CH. 111]
Boating; Pike County

The Fish and Boat Commission (Commission) by this orders amends Chapter 111 (relating to special regulations counties). The Commission is publishing this amendment under the authority of 30 Pa.C.S. (relating to the Fish and Boat Code) (code).

A. *Effective Date*

The amendment will go into effect upon publication of an order adopting the amendment in the *Pennsylvania Bulletin*.

B. *Contact Person*

For further information on this final-form rulemaking, contact Laurie E. Shepler, Assistant Counsel, (717) 705-7815, P. O. Box 67000, Harrisburg, PA 17106-7000. This final-form rulemaking is available electronically through the Commission's website (http://www.fish.state.pa.us).

C. *Statutory Authority*

The amendment to § 111.52 (relating to Pike County) is published under the statutory authority of section 5124 of the code (relating to particular areas of water).

D. *Purpose and Background*

This final-form rulemaking is designed to update, modify and improve the Commission's regulations pertaining to boating. The specific purpose of this final-form rulemaking is described in more detail under the summary of changes.

E. *Summary of Changes*

Under § 111.52(c)(5), floating docks and mooring buoys shall be removed from Lake Wallenpaupack, Pike County, prior to December 1 of the year. Commission staff believe that the Commission adopted this regulation in the early 1970s at the request of PP&L, which wanted to make the lake safer for snowmobiles. From a boating safety perspective, the regulation did not serve any purpose. In

addition, the Department of Environmental Protection, Bureau of Watershed Management, has prepared a draft general permit specific to Lake Wallenpaupack for docks, access paths and ramps, boat launching ramps and shoreline stabilization and protection projects at the lake. One of the permit conditions will be that floating docks must be removed from the water by December 1 of each year. Therefore, the special boating regulation is no longer necessary, and the Commission removed it, as proposed.

F. *Paperwork*

This final-form rulemaking will not increase paperwork and will create no new paperwork requirements.

G. *Fiscal Impact*

This final-form rulemaking will have no adverse fiscal impact on the Commonwealth or its political subdivisions. This final-form rulemaking will impose no new costs on the private sector or the general public.

H. *Public Involvement*

A notice of proposed rulemaking was published at 32 Pa.B. 3492 (July 20, 2002). The Commission did not receive any public comments regarding the proposal.

Findings

The Commission finds that:

(1) Public notice of intention to adopt the amendment adopted by this order has been given under sections 201 and 202 of the act of July 31, 1968 (P. L. 769, No. 240) (45 P. S. §§ 1201 and 1202) and the regulations promulgated thereunder, 1 Pa. Code §§ 7.1 and 7.2.

(2) A public comment period was provided, and no comments were received.

(3) The adoption of the final-form rulemaking by the Commission in the manner provided in this order is necessary and appropriate for administration and enforcement of the authorizing statutes.

Order

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

(a) The regulations of the Commission, 58 Pa. Code Chapter 111, are amended by amending § 111.52 to read as set forth in 32 Pa.B. 3492.

(b) The Executive Director will submit this order and 32 Pa.B. 3492 to the Office of Attorney General for approval as to legality as required by law.

(c) The Executive Director shall certify this order and 32 Pa.B. 3492 and deposit them with the Legislative Reference Bureau as required by law.

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

PETER A. COLANGELO,
Executive Director

Fiscal Note: Fiscal Note 48A-130 remains valid for the final adoption of the subject regulation.

[Pa.B. Doc. No. 02-2056. Filed for public inspection November 15, 2002, 9:00 a.m.]