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INDEPENDENT REGULATORY REVIEW COMMISSION

333 MARKET STREET, 14TH FLOOR, HARRISBURG, PA 17101

September 28, 2000

Honorable Robert Zimmerman, Jr., Secretary
Department of Health
802 Health and Welfare Building
Harrisburg, PA 17108

Re: Regulation #10-159 (IRRC #2134)
Department of Health
Drug and Alcohol Facilities and Services

Dear Secretary Zimmerman:

Enclosed are our Comments. They are also available on our website at www.irrc.state.pa.us.

Our Comments list objections and suggestions for consideration when you prepare the final version of this regulation. We have also specified the regulatory criteria which have not been met. These Comments are not a formal approval or disapproval of the proposed version of this regulation.

If you would like to discuss these Comments, please contact my office at 783-5417.

Sincerely,

Robert E. Nyce
Executive Director
wbg
Enclosure

cc: Honorable Dennis M. O'Brien, Majority Chairman, House Health and Human Services Committee
Honorable Frank L. Oliver, Democratic Chairman, House Health and Human Services Committee
Honorable Harold F. Mowery, Chairman, Senate Public Health and Welfare Committee
Honorable Vincent J. Hughes, Minority Chairman, Senate Public Health and Welfare Committee
John C. Hair
Stanley Mitchell
Nia Wilson

Comments of the Independent Regulatory Review Commission

on

Department of Health Regulation No. 10-159

Drug and Alcohol Facilities and Services

September 28, 2000

We submit for your consideration the following objections and recommendations regarding this regulation. Each objection or recommendation includes a reference to the criteria in the Regulatory Review Act (71 P.S. § 745.5a(h) and (i)) which has not been met. The Department of Health (Department) must respond to these Comments when it submits the final-form regulation. If the final-form regulation is not delivered by August 28, 2002, the regulation will be deemed withdrawn.

1. General. - Economic impact; Protection of the public health, safety and welfare; Reasonableness; Clarity.

Applicable federal and state laws and regulations

Sections 715.3(e), 715.11, 715.17, 715.23(a) and 715.26(a) contain the phrases "within the provisions of State and Federal confidentiality regulations," "in accordance with applicable Federal and State statutes and regulations" or "required by Federal State statutes and regulations." These vague references do not afford notice as to the specific requirements which must be satisfied. Therefore, the Department should provide citations to the specific sections of the CFR or Pa. Code with which compliance is expected.

Staffing ratios

The Department uses ratios to establish minimum requirements for staffing and availability of services. Commentators believe the ratios in Sections 715.6(d), 715.6(e), 715.6(f), 715.7(a), 715.8 and 715.19 require more staffing than is necessary, particularly for long-term maintenance patients. These sections contain ratios for physician staffing, dispensing staffing, psychosocial staffing and psychotherapy services. How did the Department develop these ratios? Is each ratio the most reasonable and appropriate to protect public health, safety and welfare? What data supports this determination?

Appeals

Section 715.3, relating to approval of narcotic treatment programs, requires Department approval to operate a program. Section 715.4, relating to patient capacity, requires Department approval to raise the permitted patient capacity of a program. If the Department does not grant approval of either request, what recourse does the applicant have? The Department should clearly

establish appeal procedures in the final-form regulation, or cross-reference provisions where appeal procedures are delineated.

2. Section 701.1. Definitions. - Consistency with statute and federal regulations; Clarity.

Agent

This term is defined as a "Commonwealth approved opioid pharmacotherapy *agent*." (Emphasis added.) Definitions should not use the word that is being defined. The Department should replace the word "agent" with an appropriate term such as "controlled substance."

Controlled substance

This term is defined as "a drug, substance, or an immediate precursor included in schedules I through V of The Controlled Substance, Drug, Device, and Cosmetic Act, *or as added, deleted or rescheduled by regulation*." (Emphasis added.) The phrase "or as added, deleted or rescheduled by regulation" makes the definition inconsistent with the statutory definition. Further, the phrase is not needed and should be deleted from the final-form regulation.

Detoxification of a narcotic dependent person utilizing a Commonwealth approved opioid pharmacotherapy agent

It is not clear why the Department is not using the defined term "agent" in this term and in the definition. The lengthy term and definition would be clearer if the phrase "Commonwealth approved opioid pharmacotherapy agent" was replaced with the defined term "agent."

This comment also applies to the definitions of "maintenance treatment," "medical director," "narcotic treatment program" and "state authority." We suggest that the Department replace the phrase "Commonwealth approved opioid pharmacotherapy agent" with the defined term "agent" in the text of these four definitions.

Maintenance treatment

The definition of this term is not consistent with the definition of the term found in 21 CFR 291.505(a)(2). The proposed definition does not include the other two types of treatment, i.e. comprehensive maintenance treatment and interim maintenance treatment. The Department should adopt the CFR definition by reference or explain why the definition of the term in this regulation should not be consistent with the federal definition.

3. Section 715.2. Relationship of federal and state regulations. - Clarity.

We have two concerns with Subsection (b). First, the regulation states, "When there is a conflict between this chapter and the Federal regulations, the stricter standard shall apply." No notice is offered indicating the compliance standard. Therefore, this sentence should be deleted. If the Department is or becomes aware of conflicts with federal requirements, the Department should amend its regulations to address the conflicts.

Second, Subsection (b) states this "chapter is intended to *complement* the Federal regulations...." (Emphasis added.) The term "complement" is not clear. The Department should replace the term "complement" with the term "supplement" or "supercede" to more clearly convey the Department's intent.

4. Section 715.3. Approval of narcotic treatment programs. - Clarity.

Subsection (a) establishes that "an entity shall apply for and receive approval as required from the Department, the DEA and the FDA *or designee*...." (Emphasis added.) It is not clear what the Department intends by the term "designee." The Department should either define "designee" or delete the reference from the final-form regulation.

Subsection (d) states, "The Department *may* inspect the narcotic treatment program without notice...." (Emphasis added.) Senator Vincent Hughes, Minority Chair of the Public Health and Welfare Committee, asked in his comments of September 13, 2000, why the Department has changed the existing notice requirement from "*will* inspect" without notice to "*may* inspect." (Emphasis added.) The Department should advise us of their response to this question.

Subsection (g) does not contain a time limit for narcotic treatment programs to correct deficiencies. Senator Hughes notes in his comments of September 13, 2000, that the existing language in 4 Pa. Code Section 263.3(c) provides a conditional approval if cited deficiencies can be corrected within 60 days. The Department should explain why the proposed regulation does not have a maximum time limit for programs to correct deficiencies.

In Subsection (h)(2), it is not clear when the Department would require the submittal of plans of correction. Would the Department require the plans within 15 working days after the site inspection, or within 15 working days after the program receives the results of the site inspection? Additionally, it is not clear whether "working" days are calendar or business days. The Department should clarify this subsection to address these questions in the final-form regulation.

5. Section 715.5. Patient capacity. - Need; Reasonableness; Clarity.

This section begins with the broad statement, "The Department *may limit* the number of patients a narcotic treatment program may treat at a given time." (Emphasis added.) However, the remainder of this provision relates to criteria the Department will consider when a program requests an increase in the permitted patient capacity. Does the Department intend to use Section 715.5 for any other purpose, such as lowering the permitted patient capacity of a program? Can Section 715.5 supercede the staffing ratios in Section 715.7? The Department should explain the intent of Section 715.5 and amend or delete the first sentence accordingly.

This section also requires written approval of the Department to be "based upon *periodic* monitoring and review." (Emphasis added.) It is not clear what time frame is intended by "periodic." This should be clarified in the final-form regulation.

Additionally, it is not clear what criteria are to be used to evaluate the factors listed in Subsections (1) through (5). The Department should list these criteria or reference the applicable citations where appropriate.

6. Section 715.6. Physician staffing. - Need; Reasonableness; Clarity.

Subsection (a)(2) allows a program to hire an interim medical director; requires the program to "develop and submit to the Department for approval a training program for the interim medical director;" and requires an interim medical director to meet medical director qualifications within 24 months of being hired. Commentators believe the 24-month limit is unreasonable. They state that certification by the American Society of Addiction Medicine can take up to three years. They suggest allowing 36 months for an interim medical director to attain these qualifications. Since the Department must approve the training program, why is the 24-month limit needed?

Subsection (a)(3)(i) requires a medical director to supervise "program physicians." Subsection (b) states that programs may employ "narcotic treatment physicians to assist the medical director." The terms "program physicians" and "narcotic treatment physicians" are not defined. It is not clear if there is a distinction in function between the two positions or if the terms are interchangeable. Whichever term or terms are used in the final-form rulemaking, the Department should use them consistently and define the term or terms in Section 701.1.

7. Section 715.8. Psychosocial staffing. - Clarity.

This section does not specify the ratio in Chapter 704 that psychosocial staffing must meet. Section 704.12 contains ratios that vary, depending on whether the position is considered "counselor" or "primary care staff." As defined in Section 701.1, the terms "counselor" and "primary care staff" both include counseling. As a result, it is not clear which ratio applies to psychosocial staffing. The Department should reference the specific staffing ratio that applies to psychosocial staffing in Section 704.12.

8. Section 715.9. Intake. - Clarity.

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

9. Section 715.10. Pregnant patients. - Protection of the public health, safety and welfare.

Under 21 CFR 291.505(d)(1)(iii)(B)(5), the program sponsor must "ensure that each female patient is fully informed of the possible risks to her or her unborn child from continued use of illicit drugs and from the use of, or withdrawal from, a narcotic drug administered or dispensed by the program in comprehensive maintenance or detoxification treatment." Why is this requirement not included in Section 715.10?

10. Section 715.12. Informed patient consent. - Clarity.

This section requires "an informed, voluntary consent" before an agent can be administered to a patient. It is not clear what information must be provided to the patient and whether the consent must be written. The Department should clarify the requirement for "informed, voluntary consent."

11. Section 715.13. Patient identification. - Clarity.

In Subsection (a) the term "develop" should be replaced with the term "use."

12. Section 715.14. Urine testing. - Need; Reasonableness; Economic impact; Clarity.

Failure of a urine test

This section and Section 715.21 (relating to patient termination) do not directly mention the consequence of failing a urine test. The Department should explain what happens if a patient's urine test detects and continues to detect any of the drugs in Subsection (a).

Subsection (a)

This subsection requires a random urinalysis at least monthly. Commentators believe that a patient, in the first two years of treatment, needs a urinalysis a minimum of once per week. Why is the Department requiring only monthly testing?

Subsection (b)

This subsection requires the program "to ensure that urine collected from patients is unadulterated." This subsection also requires random observation "to be conducted professionally, ethically and in a manner that protects patient privacy."

We have two questions. First, is the observer required to be a licensed healthcare professional? Second, how can a program both ensure the sample is unadulterated and conduct an observation "in a manner that protects patient privacy"?

Subsection (c)

Commentators believe establishing a "chain of custody" for urine specimens is costly and unnecessary. The Department should explain the need for a chain of custody and how the benefits outweigh the costs.

For clarity, the Department should consider replacing the phrase "...traced to the person to whom it belongs" with the phrase "...traced to the donor."

13. Section 715.15. Medication dosage. - Clarity.

Subsection (a) states, "A narcotic treatment program may not administer an agent..." Subsection (c) allows methadone, an agent, to be "administered or dispensed." For clarity, the Department should add the term "dispense" to Subsection (a) in the final-form regulation.

14. Section 715.16. Take-home privileges. - Clarity.

Subsection (a) includes the sentence "The physician shall make this determination after consultations with *appropriate staff within the program*." (Emphasis added.) The phrase "appropriate staff within the program" is unclear. The Department should amend this section to state with which staff the physician must consult.

15. Section 715.17. Medication control. - Clarity.

This section includes requirements for narcotic treatment programs to store, compound, administer and dispense medication. We have three issues with this section.

First, Subsection (c)(1)(iii) states, "Only patients shall be permitted in the dispensing area." We understand the intent is to restrict persons other than employees of the narcotic treatment program and the patient from entering the dispensing area. For clarity, this subsection should be amended to reflect that authorized employees are also allowed to enter the dispensing area.

Second, 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." Section 715.26, relating to security, requires that "A narcotic treatment program shall meet the security standards for the distribution and storage of controlled substances as required by Federal and State statutes and regulations." The requirements for storage are unclear, specifically in dealing with a narcotic treatment program that stores a small amount of an agent in a secure area.

Specifically, 21 CFR 1301.72 and 1301.74 cover the requirements for the storage and security of controlled substances in general. For greater clarity, the Department should consider incorporating by reference 21 CFR 1301.72 and 1301.74 in both this section and Section 715.26, relating to security.

Finally, the phrase "adequately documented" in Subsection (c)(3)(iv) is unclear. The Department should clarify this phrase in the final-form regulation.

16. Section 715.18. Rehabilitative services. - Consistency with federal regulations; Clarity.

This section requires a narcotic treatment program to "provide ...a full range of rehabilitative services, which shall include legal services, employment services, HIV education services, public health services, adult educational services and behavioral health services." Federal regulations, specifically 21 CFR 291.505(d)(4) and (d)(4)(i)(C) require each narcotic treatment program to provide "medical and rehabilitative services and programs" and "counseling on HIV disease," respectively. However, 21 CFR 291.505(d)(4)(iv) requires narcotic treatment programs to "provide opportunities" for vocational rehabilitation, education and employment. For consistency with the federal regulations, the Department should clearly 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.

17. Section 715.20. Patient transfers. - Need and Clarity.

This section requires narcotic treatment programs to develop policies and procedures for transferring patients from one narcotic treatment program to another. There is nothing in Section 715.20 that indicates the patient's records are confidential. The Department should consider cross-referencing Section 715.11, relating to the confidentiality of patient records, in this section to clarify that patient records will continue to be confidential even if transferred to another narcotic treatment program.

Section 715.20 also requires a narcotic treatment program to transfer patients within seven days of their request. We have two concerns. First, the Department should explain how this seven-day time frame was arrived at, and why it is necessary. Second, is a "request" required to be in writing?

18. Section 715.21. Patient termination. - Clarity.

This section outlines the policies and procedures for a patient's involuntary termination from a program. We have two issues regarding this section. First, commentators have suggested including "nonpayment" as a cause for involuntary termination from a program. The Department should add "nonpayment" to the list or explain why it should not be included.

Second, Paragraph (1)(iii) includes the phrase "excessively absent." This phrase is unclear. For clarity, the Department should include in this paragraph the standards for determining when absences become excessive.

19. Section 715.22. Patient grievance procedures. - Reasonableness; Clarity.

Subsection (a) requires a narcotic treatment program to develop and utilize a patient grievance procedure. Subsection (b) states "...if the grievance is filed against the narcotic treatment program director, the review of the case shall be conducted by the governing body."

Commentators have noted that such an arrangement may not be in the best interests of the patient. A multi-representative group of the narcotic treatment program may be better suited to render judgment in such cases. The Department should consider allowing grievances against the program director to be heard by either a multi-representative group or a sub-committee of the governing body instituted for the express purposes of grievance adjudication.

Additionally, the final-form regulations should clarify that grievances can be appealed to the Department.

20. Section 715.23. Patient records. - Clarity.

Subsection (e) requires all patient records, information and documentation be "maintained on standardized forms." Will these forms be developed and provided by the Department? Also, will the Department allow records to be maintained electronically? If so, the Department should include the phrase "provided by the Department" in Subsection (e) of the final-form regulation, and clarify whether files can be maintained electronically.

21. Section 715.25. Prohibition of medical units. - Clarity.

Section 715.25 prohibits medical units from operating within the Commonwealth. We have two concerns with this section. First, commentators have argued that, because the number of narcotic treatment facilities is so few, it is difficult for patients to continue treatment at the program, as well as employment. Given the limited number of treatment facilities, the Department should explain its rationale for prohibiting medical units in Pennsylvania.

Second, the exact meaning of the term "medical unit" is unclear. For clarity, the Department should consider citing the specific federal regulation that defines medical units in this section.

22. Section 715.28 Unusual incidents. - Need and Clarity.

Subsection (c) requires narcotic treatment programs to file "Unusual Incidence Reports." An "unusual incident" under Subsection (c)(1) includes "Complaints of patient abuse (physical, verbal, sexual, emotional, financial)." The phrase "financial abuse" is unclear. The Department should clarify what constitutes financial abuse in the final-form regulation.

Additionally, there are a number of terms and phrases that are unclear in Section 715.28. These include:

- "inappropriate behavior" in Subsection (a)(1);
- "unusual circumstances" in the section title and Subsections (a)(5) and (c)(2);
- "significant disruption" in Subsections (a)(6) and (c)(3);
- "unusual incident" in Subsections (a)(9) and (b)(1); and
- "timely and appropriate" in Subsection (b)(3).

The Department should provide specific criteria for determining these standards or delete them in the final-form regulation.