Comments of the Independent Regulatory Review Commission

Department of Drug and Alcohol Programs Regulation #74-1 (IRRC #3049)

Standards for Licensure of Freestanding Treatment Facilities

May 7, 2014

We submit for your consideration the following comments on the proposed rulemaking published in the March 8, 2014 *Pennsylvania Bulletin*. Our comments are based on criteria in Section 5.2 of the Regulatory Review Act (RRA) (71 P.S. § 745.5b). Section 5.1(a) of the RRA (71 P.S. § 745.5a(a)) directs the Department of Drug and Alcohol Programs (DDAP) to respond to all comments received from us or any other source.

1. Conforms to the intention of the General Assembly; Determining whether the regulation is in the public interest; Clarity and lack of ambiguity; Implementation procedures.

Act 50 of 2010 (Act 50) created DDAP, and Section 13 of Act 50 transferred all regulations related to drug or alcohol abuse from the Department of Health to DDAP. This proposed regulation is DDAP's first modification of the regulations formerly under the Department of Health.

In the first sentence of the Preamble, DDAP identifies itself as the "Department." A reader is likely to assume that any reference to *Department* in the proposed regulation is a reference to DDAP. In reviewing existing Chapter 701, we find that *Department* is defined as "The Department of Health of the Commonwealth." The proposed regulation does not include definitions. Terms such as *program* and *project* which are used in the proposed regulation are already defined in Chapter 701 (relating to general provisions).

Given this most basic issue regarding which department is being referred to in the proposed regulation, we have grave concerns regarding the clarity of the regulation as proposed, and whether the regulation as proposed conforms to the intention of the General Assembly. Given that the General Assembly carved out drug and alcohol abuse programs from the Department of Health and transferred authority to DDAP, DDAP should follow through on the powers and duties authorized under Act 50. We strongly recommend that DDAP take appropriate action to modify, repeal or supersede existing regulations as necessary to ensure clarity within this proposed regulation and any future proposed regulations.

In furtherance of the intention of the General Assembly and as an additional point of clarity, we recommend that DDAP seek to change the title of Part V to "Department of Drug and Alcohol

Programs" to avoid confusion and to more clearly distinguish DDAP's regulations from those of Department of Health.

2. Determining whether the regulation is in the public interest; Economic or fiscal impacts; Compliance with the Regulatory Review Act.

Section 5.2 of the RRA directs this Commission to determine whether a regulation is in the public interest. When making this determination, the Commission considers criteria such as economic or fiscal impact and reasonableness. To make that determination, the Commission must analyze the text of the Preamble and proposed regulation, as well as the reasons for the new or amended language. The Commission also considers the information a promulgating agency is required to provide under Section 5 of the RRA in the Regulatory Analysis Form (RAF) (71. P.S. § 745.5(a)).

The explanation of the regulation in the Preamble and RAF is not sufficient to allow this Commission to determine if the regulation is in the public interest. DDAP did not provide the rationale for the proposed amendments. For example, DDAP did not explain why:

- Requirements related to project goals and objectives are being removed from Section 709.23;
- Requirements for written agreements for 24-hour emergency psychiatric and medical coverage are being removed from Section 709.24; or
- Nearly all references to personnel policies, procedures, records and rights are being removed from Section 709.26.

In the Preamble and RAF submitted with the final-form regulation, DDAP should provide a description of the amendments proposed for each section of the regulation and explain in detail why the amendments are needed.

Similarly, the information contained in the RAF is not sufficient to allow the Commission to determine if the regulation is in the public interest. For example:

- Why is the regulation needed? (#10) DDAP's statement that the amended regulation "is needed to streamline DDAP's review of drug and alcohol facilities" is insufficient given the volume of proposed deletions and additions to the regulation.
- What type of and how many small businesses will be affected? (#15) DDAP should include a citation to the relevant provisions of the federal definition of small business that were reviewed in the development of the rulemaking and an analysis of their applicability/inapplicability to the regulation.
- Who are the persons, groups or entities, including small businesses, that will be required to comply with the regulation? (#16) DDAP should include an approximate number that will be required to comply.
- Why does DDAP believe that the information requested under #23 and #23a is not applicable to this regulation? We ask for complete responses to these questions.

We ask DDAP to provide more detailed information in the RAF and Preamble submitted with the final-form regulation as required under Section 745.5(a) of the RRA.

3. Section 709.26. Personnel management. – Clarity and lack of ambiguity; Implementation procedures.

DDAP proposes to amend Subsection (a) to require that personnel policies and procedures are in compliance with State and Federal employment laws. DDAP's amended language states: "These laws include, but are not limited to: (1) Utilization of volunteers. (2) Rules of conduct. (3) Supervision of staff. (4) Orientation of new employees." Is it DDAP's intent to state that the laws include these four items? We ask DDAP to revise and clarify the intent of this subsection.

4. Section 709.31. Data Collection System. – Clarity and lack of ambiguity; Implementation procedures.

DDAP proposes to amend Subsection (b) to state, "Verbal orders for medication can be given only by a physician or other medical professional authorized by State and Federal law to prescribe medication and verbal orders may be received only by another physician, pharmacist or nurse, or medical professional authorized by State and Federal law to receive verbal orders." The Pennsylvania Society of Physician Assistants (PSPA) states that in its experience, regulations that do not specifically list physician assistants are frequently misinterpreted and challenged for a physician assistant's ability to perform a particular task or procedure. PSPA requests that physician assistants specifically be named in the regulation. We agree that the proposed language relating to giving and receiving verbal orders to prescribe medication is vague and recommend that DDAP revise this language to specify which medical professionals are permitted to give and receive verbal orders for medication.

5. Miscellaneous clarity.

The *Pennsylvania Code & Bulletin Style Manual* (Fifth Edition) requires in Section 6.16 that agencies avoid the phrase "includes, but is not limited to" and use "includes" instead. The phrase "includes, but is not limited to" or a variation thereof appears frequently throughout the proposed regulation. DDAP should revise the final-form regulation in accordance with the style requirements of the *Pennsylvania Code & Bulletin Style Manual.*