

RULES AND REGULATIONS

DEPARTMENT OF DRUG AND ALCOHOL PROGRAMS

[28 PA. CODE CH. 709]

Standards for Licensure of Freestanding Treatment Facilities

[44 Pa.B. 6660]

[Saturday, October 18, 2014]

The Department of Drug and Alcohol Programs (Department) amends §§ 709.21—709.26 and 709.28—709.32 and adds § 709.34 (relating to reporting of unusual incidents) to read as set forth in Annex A.

This final-form rulemaking reduces redundant and outdated requirements and maintains the elements regarding quality and safety. With the addition of § 709.34, the Department is requiring that all drug and alcohol facilities develop and implement policies and procedures to respond to and report specific unusual incidents. Some facilities are currently required by § 715.28 (relating to unusual incidents) to report unusual incidents and most other facilities are also providing these reports on a voluntary basis.

The preliminary proposed regulation was presented and discussed with the Department's stakeholders at a meeting on June 28, 2013, which was followed by a 30-day comment period. The proposed rulemaking was a result of comments and suggestions made at the stakeholder meeting and the comment period. Further revisions were made in the final-form rulemaking in response to comments by the Independent Regulatory Review Commission (IRRC) and the Pennsylvania Society of Physician Assistants (PSPA).

A. *Effective Date*

The final-form rulemaking will be effective upon publication in the *Pennsylvania Bulletin*.

B. *Contact Persons*

For further information concerning the final-form rulemaking, contact Ronald G. Young, Director, Division of Program Licensure, 132 Kline Plaza, Harrisburg, PA 17104, (717) 783-8675; or Tawny K. Mummah, Deputy General Counsel, Counsel to the Department of Drug and Alcohol Programs, 333 Market Street, 17th Floor, Harrisburg, PA 17101, (717) 783-6563. The final-form rulemaking is available on the Department's web site at www.ddap.pa.gov.

C. Statutory Authority

This final-form rulemaking is authorized under the act of July 9, 2010 (P. L. 348, No. 50) (Act 50), which created the Department. Specifically, Act 50 added section 2301-A of The Administrative Code of 1929 (71 P. S. § 613.1) and provided the Department with the power to promulgate rules and regulations necessary to carry out the provisions in paragraph (9) of this section.

D. Background and Purpose

Act 50 transferred the powers, duties and functions of the Department of Health concerning drug or alcohol abuse to the Department. The goal of this final-form rulemaking is to eliminate redundant or outdated requirements and maintain or strengthen the elements regarding quality and safety.

The Department is satisfied there is no reasonable alternative to proceeding with the final-form rulemaking. The Department is also satisfied that the final-form rulemaking meets the requirements of Executive Order No. 1996-1, "Regulatory Review and Promulgation."

E. Summary of Regulatory Requirements

Reduction of regulatory requirements

Except for the addition of the reporting of unusual incidents in § 709.34, this final-form rulemaking reduces the burden on the regulated community currently imposed by Chapter 709 (relating to standards for licensure of freestanding treatment facilities). For instance, the Department is deleting regulatory requirements that specifically provide how the facility should be governed and how the facility should manage its personnel policies, procedures and records. The following is an explanation of why the Department has deleted certain requirements.

§ 709.22. Governing body

This final-form rulemaking deletes former subsections (b) and (c) and (e)(1)—(3) because these requirements are no longer necessary. Specifically, at the time these regulations were put into place, there were not credential or experiential requirements for individuals and staff operating the facility. As a result, regulatory guidance concerning how to run a business was needed. Now, under Chapter 704 (relating to staffing requirements for drug and alcohol treatment activities), individuals in key positions have credential and experiential requirements relative to operating a business. In addition, the Department of State is responsible for providing guidance for corporations. In final-form subsections (b) and (c), the Department clarifies the duties of the governing body. For example, in final-form subsection (c), it is no longer necessary to tell a business what should be included in an annual report.

§ 709.23. Project director

This final-form rulemaking deletes business-oriented requirements that are a normal part of business operation and no longer need to be dictated by Department regulations.

§ 709.24. *Treatment/rehabilitation management*

This final-form rulemaking deletes former subsection (b), which required projects to identify primary referral sources (entities that are most likely to refer clients in need of treatment services to the project) and provide proof by getting a letter agreement signed with that entity because it is no longer necessary to direct a project to establish these business relationships that are necessary to run a successful project. Former subsection (d) is no longer necessary due to the implementation and amendment of the Hill-Burton Act, in the late 1970s, which required hospitals to provide emergency services despite the inability to pay.

§ 709.25. *Fiscal management*

This final-form rulemaking makes clarifications to subsection (a) and deletes subsection (b) because in this age of managed care and sliding fee scales, there are no longer set fee schedules.

§ 709.26. *Personnel management*

For the most part requirements removed from the policies and procedures are governed by other State and Federal employment law. Concerning the deletion of former subsection (c), similar language appears in § 704.11(a) (relating to staff development program). Requirements retained in this section are for maintained for specific reasons. For example, the retention of the requirement concerning volunteers is necessary because the Department needs to ensure that the volunteers are adequately trained in areas of client confidentiality and client boundary issues. Also, see the response to comment 3. Concerning the subsections regarding personnel records, the Department revised the language by deleting requirements that are superfluous because the Department does not take action if a personnel record is less than satisfactory. For instance, in relation to former subsection (d)(2) and (4), if the project hired an individual with a negative prior employment reference or was paying its employees disparately, the Department would not have authority to object to those employment decisions, so review of those employment records did not serve a purpose.

§ 709.28. *Confidentiality*

§ 709.29. *Retention of client records*

The amendments to these sections are for clarification and in recognition of electronic recordkeeping.

§ 709.30. *Client rights*

Amendments to this section are for clarity and consistency.

§ 709.31. *Data collection system*

This section is amended to delete a reference in subsection (a) to the old data collection system (UDCS) and refer to the system generally because current software used for the Department's data collection system is likely to be replaced in the future and the regulation would be outdated. Subsection (b) was added to state the essential function of the recordkeeping system.

§ 709.32. Medication control

The Department amended this section to recognize that medical professionals other than physicians are authorized by law to give and receive verbal orders for medication. In addition, the inventory requirement was deleted because the projects have contractual agreements with pharmacies that are responsible for keeping inventories of bulk medication supplies. Lastly, individually prescribed medication for clients are not subject to the inventory requirements.

Increase in regulatory requirements

In most instances where it appears that the Department is increasing requirements, it is instead incorporating or restating Department of Health interpretive guidelines that did not have the force and effect of law but were used by the Department of Health to explain or augment the regulatory requirements.

§ 709.34. Reporting of unusual incidents

With the addition of § 709.34, the Department is requiring that drug and alcohol facilities develop and implement policies and procedures to respond to and report specific unusual incidents. This requirement is not overly burdensome as some treatment facilities are already required under § 715.28 to report unusual incidents and most other facilities are also providing these reports on a voluntary basis under a Department of Health-issued Licensing Alert, which, similar to interpretive guidelines, does not have the force and effect of law.

F. Comments and Responses

Notice of proposed rulemaking was published at 44 Pa.B. 1317 (March 8, 2014), affording the public, the General Assembly and IRRC the opportunity to offer comments.

Comments were received from IRRC and the PSPA. The comments and the Department's responses follow.

Comment 1: IRRC raised "concerns regarding the clarity of the regulation as proposed" because § 701.1 (relating to general definitions) defines "Department" as the Department of Health and not the Department. IRRC stated that this is likely to cause the reader confusion. Therefore, IRRC recommended that the Department "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 addition, IRRC recommended that the Department change the heading of Part V to "Department of Drug and Alcohol Programs" to avoid confusion and to more clearly distinguish the Department's regulations from those of the Department of Health.

Response: The Department has fully addressed IRRC's concerns. Specifically, in accordance with section 204 of the act of July 31, 1968 (P. L. 769, No. 240) (45 P. S. § 1204), known as the Commonwealth Documents Law (CDL) the Secretary of the Department requested and received approval from the Office of General Counsel and the Office of Attorney General to proceed with a final-omitted rulemaking that will serve several housekeeping functions.

Specifically, the final-omitted rulemaking provides clarity in § 701.1 by changing the definition of "Department" from the Department of Health to the Department, updating § 701.3 (relating to legal base) to include Act 50 and updating § 701.13 (relating to contact person) from the Department of Health to the Department. Lastly, to further provide clarity, the final-omitted rulemaking changes the heading of Part V from "Drug and Alcohol Facilities and Services" to "Department of Drug and Alcohol Programs" as suggested by IRRC. See 44 Pa.B. 6658 (October 18, 2014) for this final-omitted rulemaking.

Comment 2: IRRC requested that the Department comply with the Regulatory Review Act (71 P. S. §§ 745.1—745.12a) by providing more detailed information in the Regulatory Analysis Form (RAF) and the preamble to enable IRRC to determine whether the final-form rulemaking is in the public interest.

Response: The Department significantly revised the RAF and the preamble to provide IRRC with sufficient information to determine that the final-form rulemaking is in the public interest.

Comment 3: IRRC raised a concern that proposed amendments to § 709.26 (relating to personnel management) lack clarity.

Response: The Department addressed IRRC's concern and further revised this section for the sake of clarity. Specifically, additional language has been added to the second sentence of § 709.26(a).

Comment 4: IRRC and the PSPA requested that the Department revise the final-form rulemaking by specifically listing "physician assistants" as an authorized medical professional in § 709.32 (relating to medication control).

Response: The Department is not comfortable with specifically including physician assistants because the laws concerning medical professionals authorized to prescribe and receive prescriptions have been frequently revised over time. The Department does not want the regulation to be quickly outdated. However, for consistency, the Department further revised subsection (b) to delete references to "pharmacist" or "nurse" and therefore is not specifically referencing any authorized medical professionals.

Comment 5: IRRC requested that the Department revise the final-form rulemaking in accordance with the *Pennsylvania Code & Bulletin Style Manual* by deleting the phrase "includes, but is not limited to" and instead use "includes."

Response: The Department disagrees with this comment and uses the phrase "includes, but is not limited to" in the final-form rulemaking because the Department is setting the floor of what

should be included in the project's written policy and procedure, but not providing the exhaustive list. For instance, in a written treatment plan proscribed by § 709.24 (relating to treatment/rehabilitation management), the Department has identified elements that must be included in that document but knows that the project's client will be well served by the inclusion of other elements not regulated by the Department.

The Department received a comment following the public comment period from Blue Cross of Northeastern Pennsylvania supporting the proposed rulemaking and urging the Department to amend 4 Pa. Code § 255.5 (relating to projects and coordinating bodies: disclosure of client-oriented information).

G. Benefits, Cost and Compliance

Benefits

The final-form rulemaking will benefit drug and alcohol facilities by reducing the Department's inspection time at a facility. Specifically, the Division of Program Licensure will no longer be reviewing the policies, procedures and records that were reviewed under the former regulations.

Compliance costs

There are no compliance costs for drug and alcohol facilities associated with this final-form rulemaking.

Paperwork requirements

There are no additional paperwork requirements associated with this final-form rulemaking as the unusual incident reports required under § 709.34 are currently being submitted by the regulated community as explained in Section E of this preamble.

H. Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on February 26, 2014, the Department submitted a copy of the notice of proposed rulemaking, published at 44 Pa.B. 1317, to IRRC and the Chairpersons of the House Human Services Committee and the Senate Committees on Public Health and Welfare for review and comment.

Under section 5(c) of the Regulatory Review Act, IRRC and the House and Senate Committees were provided with copies of the comments received during the public comment period, as well as other documents when requested. In preparing the final-form rulemaking, the Department has considered all comments from IRRC, the House and Senate Committees and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P. S. § 745.5a(j.2)), on September 3, 2014, the final-form rulemaking was deemed approved by the House and Senate Committees.

Under section 5.1(e) of the Regulatory Review Act, IRRC met on September 4, 2014, and approved the final-form rulemaking.

Findings

The Department finds that:

(1) Public notice of the intention to adopt these regulations has been given under sections 201 and 202 of the CDL (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 as required by law and all comments were considered.

(3) The amendments to this final-form rulemaking do not enlarge the purpose of the proposed rulemaking published at 44 Pa.B. 1317.

(4) The adoption of the final-form rulemaking in the manner provided in this order is necessary and appropriate for the administration of the authorizing statute.

Order

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

(a) The regulations of the Department, 28 Pa. Code Chapter 709, are amended by adding § 709.34 and by amending §§ 709.21—709.26 and 709.28—709.32 to read as set forth in Annex A.

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

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

GAROLD E. TENNIS,
Secretary

(Editor's Note: See 44 Pa.B. 6658 (October 18, 2014) for both a final-omitted rulemaking by the Department relating to this final-form rulemaking and for a document transferring Department regulations.)

(Editor's Note: For the text of the order of the Independent Regulatory Review Commission relating to this document, see 44 Pa.B. 6051 (September 20, 2014).)

Fiscal Note: Fiscal Note 74-1 remains valid for the final adoption of the subject regulations.

Annex A

TITLE 28. HEALTH AND SAFETY

PART V. DEPARTMENT OF DRUG AND ALCOHOL PROGRAMS

CHAPTER 709. STANDARDS FOR LICENSURE OF FREESTANDING TREATMENT FACILITIES

Subchapter C. GENERAL STANDARDS FOR FREESTANDING TREATMENT ACTIVITIES

§ 709.21. Applicability.

(a) The intake, evaluation and referral, inpatient nonhospital, partial hospitalization, outpatient and inpatient hospital activities shall comply with this chapter.

(b) A facility in which freestanding treatment activities are provided that has a valid full license from the Department of Public Welfare under 55 Pa. Code Chapters 5300 and 5310 (relating to private psychiatric hospitals; and community residential rehabilitation services for the mentally ill) is deemed to be in compliance with §§ 709.22—709.26, 709.29 and 709.32. This subsection shall remain in effect as long as the Department finds the standards in 55 Pa. Code Chapters 5300 and 5310 to be consistent with the requirements of this subchapter.

§ 709.22. Governing body.

(a) A project shall have a governing body and legal responsibility for the project rests in the governing body.

(b) The duties of the governing body include, but are not limited to, the following:

(1) Designating the position to serve as project director as the person officially responsible to the governing body either directly or indirectly.

(2) Identifying the project's purpose and philosophy directly related to drug and alcohol services.

(3) Documenting the project's organizational structure.

(c) If a facility is publicly funded, the governing body shall make available to the public an annual report which includes, but is not limited to, a statement disclosing the names of officers, directors and principal shareholders, when applicable.

§ 709.23. Project director.

Project directors shall prepare, annually update and sign a written manual delineating project policies and procedures.

§ 709.24. Treatment/rehabilitation management.

(a) The governing body shall adopt a written plan for the coordination of client treatment and rehabilitation services which includes, but is not limited to:

- (1) Definition of the target population toward whom facility services are directed.
- (2) Identification of the treatment models and practices utilized by the project.
- (3) Written procedures for the management of treatment/rehabilitation services for clients.
- (4) Written procedures for referral outlining cooperation with other service providers including, but not limited to, provisions for access to emergency services.

(b) The project shall maintain a current community resource listing of other health and social service agencies.

§ 709.25. Fiscal management.

The project shall obtain the services of an independent certified public accountant for an annual financial audit of activities associated with the project's drug/alcohol abuse services, in accordance with generally accepted accounting principles which include reference to the drug and alcohol treatment activities.

§ 709.26. Personnel management.

(a) The governing body shall adopt and have implemented written project personnel policies and procedures in compliance with State and Federal employment laws. In addition, the written policies and procedures must specifically include, but are not limited to:

- (1) Utilization of volunteers.
- (2) Rules of conduct.
- (3) Supervision of staff.
- (4) Orientation of new employees.

(b) The personnel records must include, but are not limited to:

- (1) Application or resume for employment.

(2) Written verification of qualifying professional credentials.

(3) Annual written individual staff performance evaluations, copies of which shall be reviewed and signed by the employee.

(4) Disciplinary actions.

(c) There shall be written job descriptions for project positions.

§ 709.28. Confidentiality.

(a) A written procedure shall be developed by the project director which shall comply with 4 Pa. Code § 255.5 (relating to projects and coordinating bodies: disclosure of client-oriented information). The procedure must include, but not be limited to:

(1) Confidentiality of client identity and records. Procedures must include a description of how the project plans to address security and release of electronic and paper records and identification of the person responsible for maintenance of client records.

(2) Identification of project staff having access to records, and the methods by which staff gain access.

(b) The project shall secure hard copy client records within locked storage containers. Electronic records must be stored on secure, password protected data bases.

(c) The project shall obtain an informed and voluntary consent from the client for the disclosure of information contained in the client record. The consent must be in writing and include, but not be limited to:

(1) Name of the person, agency or organization to whom disclosure is made.

(2) Specific information disclosed.

(3) Purpose of disclosure.

(4) Dated signature of client or guardian as provided for under 42 CFR 2.14(a) and (b) and 2.15 (relating to minor patients; and incompetent and deceased patients).

(5) Dated signature of witness.

(6) Date, event or condition upon which the consent will expire.

(d) A copy of a client consent shall be offered to the client and a copy maintained in the client record.

(e) When consent is not required, the project personnel shall:

(1) Fully document the disclosure in the client records.

(2) Inform the client, as readily as possible, that the information was disclosed, for what purposes and to whom.

§ 709.29. Retention of client records.

(a) Client records, regardless of format, shall be readily accessible for a minimum of 4 years following the discharge of a client.

(b) If the project discontinues operation, it shall make known to the Department where its records are stored.

§ 709.30. Client rights.

The project shall develop written policies and procedures on client rights and document written acknowledgement by clients that they have been notified of those rights.

(1) A client receiving care or treatment under section 7 of the act (71 P. S. § 1690.107) shall retain civil rights and liberties except as provided by statute. No client may be deprived of a civil right solely by reason of treatment.

(2) The project may not discriminate in the provision of services on the basis of age, race, creed, sex, ethnicity, color, national origin, marital status, sexual orientation, handicap or religion.

(3) Clients have the right to inspect their own records. The project, facility or clinical director may temporarily remove portions of the records prior to the inspection by the client if the director determines that the information may be detrimental if presented to the client. Reasons for removing sections shall be documented in the record.

(4) Clients have the right to appeal a decision limiting access to their records to the director.

(5) Clients have the right to request the correction of inaccurate, irrelevant, outdated or incomplete information in their records.

(6) Clients have the right to submit rebuttal data or memoranda to their own records.

§ 709.31. Data collection system.

(a) A data collection and recordkeeping system shall be developed that allows for the efficient retrieval of data needed to measure the project's performance in relationship to its stated goals and objectives.

(b) The recordkeeping system must allow for the identification of clients' admissions and discharges within a specific time period.

§ 709.32. Medication control.

(a) Projects furnishing pharmaceutical services shall present a license from the Department of Health's Board of Examiners or the Department of State's State Board of Pharmacy and a DEA registration to Department employees. Other notices of review or inspection, or both, shall be made available upon request.

(b) 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 or medical professional authorized by State and Federal law to receive verbal orders. When a verbal or telephone order is given, it has to be authenticated in writing by a physician or other medical professional authorized by State and Federal law to prescribe medication. In detoxification levels of care, written authentication shall occur no later than 24 hours from the time the order was given. Otherwise, written authentication shall occur within 3 business days from the time the order was given.

(c) The project shall have and implement a written policy and procedures regarding all medications used by clients which shall include, but not be limited to:

(1) Administration of medication, including the documentation of the administration of medication:

(i) By individuals permitted to administer by Pennsylvania law.

(ii) When self administered by the client.

(2) Drug storage areas including, but not limited to, the secure storage of controlled substances and other abusable drugs in accordance with State and Federal regulations and program requirements.

(3) Inspection of storage areas that ensures compliance with State and Federal laws and program policy. The policy must include, but not be limited to:

(i) What is to be verified through the inspection, who inspects, how often, but not less than quarterly, and in what manner it is to be recorded.

(ii) Disinfectants and drugs for external use are stored separately from oral and injectable drugs.

(iii) Drugs requiring special conditions for storage to insure stability are properly stored.

(iv) Outdated drugs are removed.

(v) Copies of drug-related regulations are available in appropriate areas.

(4) Methods for control and accountability of drugs, including, but not limited to:

(i) Who is authorized to remove drug.

(ii) The program's system for recording drugs, which includes the name of the drug, the dosage, the staff person, the time and the date.

(5) Security of drugs, including, but not limited to, the loss, theft or misuse of drugs.

(6) Medication errors and drug reactions shall be recorded in the client record. This may be the medical record if a separate medical record is maintained for all clients.

§ 709.34. Reporting of unusual incidents.

(a) The project shall develop and implement policies and procedures to respond to the following unusual incidents:

(1) Physical assault or sexual assault by staff or a client.

(2) Selling or use of illicit drugs on the premises.

(3) Death or serious injury due to trauma, suicide, medication error or unusual circumstances while in residential treatment or, when known by facility, for ambulatory services.

(4) Significant disruption of services due to disaster such as fire, storm, flood or other occurrence which closes the facility for more than 1 day.

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

(6) Event at the facility requiring the presence of police, fire or ambulance personnel.

(7) Fire or structural damage to the facility.

(8) Outbreak of a contagious disease requiring Centers for Disease Control (CDC) notification.

(b) Policies and procedures must include the following:

(1) Documentation of the unusual incident.

(2) Prompt review and identification of the causes directly or indirectly responsible for the unusual incident.

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

(4) Ongoing monitoring of the corrective action plan.

(5) Reporting mechanism to ensure that reporting of an unusual incident to an entity is in compliance with State and Federal confidentiality laws.

(c) To the extent permitted by State and Federal confidentiality laws, the project shall file a written unusual incident report with the Department within 3 business days following an unusual incident involving:

- (1) Physical or sexual assault by staff or a client.
- (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 that results in the closure of a facility for more than 1 day.
- (4) Event at the facility requiring the presence of police, fire or ambulance personnel.
- (5) Outbreak of a contagious disease requiring CDC notification.

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