Regulatory Analysis Form

(Completed by Promulgating Agency)

(All Comments submitted on this regulation will appear on IRRC's website)

(1) Agency
Department of Drug and Alcohol Programs (DDAP)

(2) Agency Number:
Identification Number: #74-1

3049.

(3) PA Code Cite: 28 Pa. Code §709.21, *et seq.*

(4) Short Title:
Chapter 709 Standards for Licensure of Freestanding Treatment Facilities

(5) Agency Contacts (List Telephone Number and Email Address):

Primary Contact:

Ronald G. Young, Director, Division of Program Licensure — Phone No.: 717-783-8675
DDAP, 132 Kline Plaza, Harrisburg, PA, 17104
ryoung@pa.gov

Secondary Contact:

Tawny K. Mummah, Deputy General Counsel — Phone No.: 717-787-9354
OGC, 333 Market Street, 17th Floor, Harrisburg, PA, 17101
tmummah@pa.gov

(6) Type of Rulemaking (check applicable box):

X Proposed Regulation
☐ Final Regulation
☐ Final Omitted Regulation
☐ Emergency Certification Regulation;
  ☐ Certification by the Governor
  ☐ Certification by the Attorney General

(7) Briefly explain the regulation in clear and nontechnical language. (100 words or less)

DDAP proposes to amend 28 Pa. Code §§ 709.21 – 709.33 and add §709.34 (relating to the General Standards for Freestanding Treatment Activities). The purpose of the proposed amended regulation is to reduce redundant and outdated requirements, but maintain the elements related to quality and safety. With the addition of §709.34, DDAP 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 regulation (28 Pa. Code §715.28) to report unusual incidents and most other facilities are also providing these reports on a voluntary basis.

In instances where it appears that DDAP is increasing requirements, it is instead, incorporating or

restating DOH interpretive guidelines that did not have the force and effect of law but were used by DOH to explain or augment the regulatory requirements.

(8) State the statutory authority for the regulation. Include specific statutory citation.

The proposed amended regulation is authorized pursuant to Act 50 of 2010, which created DDAP. Specifically, Act 50 of 2010 amended the Administrative Code of 1929 and provided DDAP with the power to promulgate rules and regulations necessary to carryout the provisions of Article XXIII-A at 71 P.S. §613.1(9).

(9) Is the regulation mandated by any federal or state law or court order, or federal regulation? Are there any relevant state or federal court decisions? If yes, cite the specific law, case or regulation as well as, any deadlines for action.

The proposed amended regulation is not mandated by federal or state law, federal or state court order, or federal regulations.

(10) State why the regulation is needed. Explain the compelling public interest that justifies the regulation. Describe who will benefit from the regulation. Quantify the benefits as completely as possible and approximate the number of people who will benefit.

The proposed amended regulation is needed to steamline DDAP's review of drug and alcohol facilities. It will benefit the drug and alcohol facilities in that DDAP's inspection time at a facility will be reduced as the Division of Program Licensing will no longer be reviewing all of the policies, procedures and records that are reviewed pursuant to the current regulations. Ultimately, all of the clients of these facilities will also benefit as more time can be dedicated to providing them services.

(11) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulation.

No.

(12) How does this regulation compare with those of the other states? How will this affect Pennsylvania's ability to compete with other states?

Historically, Pennsylvania has had a robust regulatory scheme for drug and alcohol facilities. This current regulation has been in place for a quarter of a century. DDAP is proposing to eliminate redundant or outdated requirements and maintain or strengthen the elements related to quality and safety. Therefore, it is anticipated that the proposed amended regulation will not affect Pennsylvania's ability to

compete with other states.

(13) Will the regulation affect any other regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

The proposed amended regulation at §709.28 does speak to 4 Pa. Code §255.5 (Confidentiality - relating to projects and coordinating bodies: disclosure of client-oriented information) but that reference has been in place for over tweny-five years. The only revision to this section is the incorporation or restatement of the DOH interpretive guideline into the regulation. The interpretive guideline did not have the force and effect of law but was used by DOH to explain or augment the regulatory requirement.

(14) Describe the communications with and solicitation of input from the public, any advisory council/group, small businesses and groups representing small businesses in the development and drafting of the regulation. List the specific persons and/or groups who were involved. ("Small business" is defined in Section 3 of the Regulatory Review Act, Act 76 of 2012.)

Prior to a stakeholder meeting, select stakeholder associations provided written suggestions as to how to best revise the General Standards, which were considered as DDAP developed the preliminary proposed regulation. On June 28 2013, DDAP invited CCAP, PACHSA, PCPA, PACDAA, DASPOP, PRO-A, PRO-ACT, PA Halfway House Association, PATOD and the PA Pysch Society to a stakeholder meeting to review DDAP's preliminary proposed regulation. Each section was discussed and further input was garnered. In addition, the preliminary proposed regulation was posted on the DDAP website for a 30-day comment period, which offered an e-mail address dedicated to receiving further input. Input received at the meeting and from those submitted via e-mail was considered and the preliminary proposed regulation was further revised.

(15) Identify the types and number of persons, businesses, small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012) and organizations which will be affected by the regulation. How are they affected?

The current standards regulating drug and alcohol facilities have been in place for at least twenty-five years. The proposed amended regulation will benefit the facilities in that DDAP's inspection time at a facility will be reduced as the Division of Program Licensing will no longer be reviewing all of the policies, procedures and records that are reviewed pursuant to the current regulation. The regulatory changes were well received by the stakeholders and are in compliance with Gov. Corbett's goal to ease regulatory burdens.

(16) List the persons, groups or entities, including small businesses,that will be required to comply with the regulation. Approximate the number that will be required to comply.

This proposed amended regulation does not require compliance by any additional persons, groups or entities, including small businesses, beyond the current regulated community.

(17) Identify the financial, economic and social impact of the regulation on individuals, small businesses, businesses and labor communities and other public and private organizations. Evaluate the benefits expected as a result of the regulation.

The only financial, economic or social impact of the proposed amended regulation will be reduced inspection time, which should ultimately lead to increased services to drug and alcohol facility clients.

(18) Explain how the benefits of the regulation outweigh any cost and adverse effects.

N/A. There is no cost or adverse effects.

(19) Provide a specific estimate of the costs and/or savings to the **regulated community** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

The benefit of the proposed amended regulation is not quantifiable in a dollar figure, because there will be a saving of facility time that, we believe, will be devoted to patient services.

(20) Provide a specific estimate of the costs and/or savings to the **local governments** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

N/A. There will be no costs or savings to local governments.

(21) Provide a specific estimate of the costs and/or savings to the **state government** associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required. Explain how the dollar estimates were derived.

N/A. There will be no costs or savings to state government.

(22) For each of the groups and entities identified in items (19)-(21) above, submit a statement of legal, accounting or consulting procedures and additional reporting, recordkeeping or other paperwork, including copies of forms or reports, which will be required for implementation of the regulation and an explanation of measures which have been taken to minimize these requirements.

The only additional reporting or paperwork that is required by this proposed amended regulation is found in §709.34. In this section, DDAP is requiring that all 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 facilities are already required by regulation at 28 Pa. Code. §715.28 to report unusual incidents and most other facilities are also providing these reports on a voluntary basis pursuant to a DOH issued Licensing Alert, which, similar to interpretive guidelines does not have the force and effect of law. In addition, this requirement is offset by the other regulatory changes, which in total are a significant reduction of the current regulatory burden.

(23) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

N/A. There will not be any fiscal savings and costs associated with implementation and compliance.

	Current FY Year	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
SAVINGS:	$	$	$	$	$	$
Regulated Community						
Local Government						
State Government						
Total Savings						
COSTS:						
Regulated Community						
Local Government						
State Government						
Total Costs						
REVENUE LOSSES:						
Regulated Community						
Local Government						
State Government						
Total Revenue Losses						

(23a) Provide the past three year expenditure history for programs affected by the regulation. N/A.

Program	FY -3	FY -2	FY -1	Current FY

(24) For any regulation that may have an adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), provide an economic impact statement that includes the following:

(a) An identification and estimate of the number of small businesses subject to the regulation.
(b) The projected reporting, recordkeeping and other administrative costs required for compliance with the proposed regulation, including the type of professional skills necessary for preparation of the report or record.
(c) A statement of probable effect on impacted small businesses.
(d) A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation.

N/A. While some drug and alcohol facilities currently operating in PA may be considered a small business as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012, the proposed amended regulation does not have an adverse impact on any of the drug and alcohol faclities, including those considered to be a small business.

(25) List any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, the elderly, small businesses, and farmers.

N/A. There have been no special provisions developed because this proposed amended regulation does not affect any additional groups or persons, beyond the current regulated community.

(26) Include a description of any alternative regulatory provisions which have been considered and rejected and a statement that the least burdensome acceptable alternative has been selected.

N/A. There were no other alternative regulatory provisions considered, as there is no alternative way to reduce the administrative burden of the current regulation other than to revise the current regulation as proposed here.

(27) In conducting a regulatory flexibility analysis, explain whether regulatory methods were considered that will minimize any adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), including:

a) The establishment of less stringent compliance or reporting requirements for small businesses;
b) The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses;
c) The consolidation or simplification of compliance or reporting requirements for small businesses;
d) The establishment of performing standards for small businesses to replace design or operational standards required in the regulation; and
e) The exemption of small businesses from all or any part of the requirements contained in the

regulation.

N/A. While some drug and alcohol facilities currently operating in PA may be considered a small business as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012, the proposed amended regulation does not have an adverse impact on any of the drug and alcohol faclities, including those considered to be small business.

(28) If data is the basis for this regulation, please provide a description of the data, explain in detail how the data was obtained, and how it meets the acceptability standard for empirical, replicable and testable data that is supported by documentation, statistics, reports, studies or research. Please submit data or supporting materials with the regulatory package. If the material exceeds 50 pages, please provide it in a searchable electronic format or provide a list of citations and internet links that, where possible, can be accessed in a searchable format in lieu of the actual material. If other data was considered but not used, please explain why that data was determined not to be acceptable.

N/A. Data was not a basis for the proposed amended regulation.

(29) Include a schedule for review of the regulation including:

A. The date by which the agency must receive public comments: 30 days after publication

B. The date or dates on which public meetings or hearings will be held: N/A

C. The expected date of promulgation of the proposed regulation as a final-form regulation: 1/2014

D. The expected effective date of the final-form regulation: upon publication

E. The date by which compliance with the final-form regulation will be required: upon publication

F. The date by which required permits, licenses or other approvals must be obtained: N/A

(30) Describe the plan developed for evaluating the continuing effectiveness of the regulations after its implementation.

DDAP plans to continue to update and streamline its regulations. If it is determined through stakeholder feed back that the proposed amended regulation not effective, DDAP will consider seeking further revision.

CDL-1

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

RECEIVED
FEB 26 2014
INDEPENDENT REGULATORY
REVIEW COMMISSION

DO NOT WRITE IN THIS SPACE

Copy below is hereby approved as to form and legality. Attorney General	Copy below is here by certified to be a true and correct copy of a document issued, prescribed or promulgated by:	Copy below is hereby approved as to form and legality. Executive or Independent Agencies.
BY: _____ (DEPUTY ATTORNEY GENERAL)	DEPARTMENT OF DRUG AND ALCOHOL PROGRAMS (AGENCY)	BY: _____ SHAWN E. SMITH
FEB 20 2014 _____ DATE OF APPROVAL	DOCUMENT/FISCAL NOTE NO. 74-1	JAN 10 2014 _____ DATE OF APPROVAL
☐ Check if applicable Copy not approved. Objections attached.	DATE OF ADOPTION: October 16, 2013	(DEPUTY GENERAL COUNSEL) ~~(Chief Counsel, Independent Agency)~~ (Strike inapplicable title)
	BY: _____	☐ Check if applicable. No Attorney General approval or objection within 30 days after submission.
	TITLE Garold E. Tennis, Secretary (EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)	

NOTICE OF PROPOSED RULEMAKING

DEPARTMENT OF DRUG AND ALCOHOL PROGRAMS

Standards for Licensure of Freestanding Treatment Facilities

28 Pa. Code, Chapter 709, Subchapter C

Department of Drug and Alcohol Programs – Notice of Proposed Rulemaking

PA Code Cite

28 *Pa. Code* Chapter 709

Regulation Title

Standards for Licensure of Freestanding Treatment Facilities

I.D. Number

74-1

SECRETARY'S CERTIFICATION

I, Garold Tennis, do hereby certify that I have reviewed this regulation and determined that the regulation is consistent with the principles outlined in Executive Order 1996-1.

Garold E. Tennis, Secretary
Department of Drug and Alcohol Programs

PROPOSED RULEMAKING
DEPARTMENT OF DRUG AND ALCOHOL PROGRAMS
[28 Pa. Code CH.709, SUBCH. C]

The Department of Drug and Alcohol Programs (DDAP) proposes to amend §§ 709.21 – 709.33 and add §709.34 (relating to the General Standards for Freestanding Treatment Activities) to read as set forth in Annex A. This proposed amended regulation reduces redundant and outdated requirements but maintains the elements related to quality and safety. With the addition of §709.34, DDAP 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 regulation (28 Pa. Code. §715.28) 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 DDAP's stakeholders at a meeting held on June 28, 2013, which was followed by a 30-day comment period. This proposed rulemaking is a result of comments and suggestions made at the stakeholder meeting and the comment period.

A. *Effective Date*

This proposed rulemaking will be effective after completing the regulatory process and upon final-form publication in the *Pennsylvania Bulletin.*

B. *Contact Persons*

For further information, 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 DDAP, at 333 Market Street, 17th Floor, Harrisburg, PA 17101, (717-787-9354). Information regarding submitting comments on this proposed rulemaking appears in Section H of this preamble. This proposed rulemaking is electronically available on DDAP's website at www.ddap.pa.gov.

C. *Statutory Authority*

This proposed rulemaking is authorized pursuant to Act 50 of 2010, which created DDAP. Specifically, Act 50 of 2010 amended the Administrative Code of 1929 and provided DDAP with the power to promulgate rules and regulations necessary to carryout the provisions of Article XXIII-A at 71 P.S. §613.1(9).

D. *Background and Purpose*

Act 50 of 2010 transferred the powers, duties and functions of the Department of Health concerning drug or alcohol abuse to DDAP. The goal of this proposed rulemaking is to eliminate redundant or outdated requirements and maintain or strengthen the elements related to quality and safety.

E. *Summary of Regulatory Requirements*

Reduction of Regulatory Requirements. But for the addition of the reporting of unusual incidents found in §709.34 (more fully addressed below), this proposed rulemaking reduces the burden on the regulated community currently imposed by Chapter 709. For instance, DDAP is removing regulatory requirements that specifically provide how the facility should be governed and how the facility should manage its personnel policies, procedures and records.

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

Section 709.34. Unusual Incidents. With the addition of §709.34, DDAP is requiring that all 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 by regulation at 28 Pa. Code. §715.28 to report unusual incidents and most other facilities are also providing these reports on a voluntary basis pursuant to a DOH issued Licensing Alert, which, similar to interpretive guidelines does not have the force and effect of law.

F. *Benefits, Cost and Compliance*

Benefits. This proposed rulemaking will benefit the drug and alcohol facilities by reducing DDAP's inspection time at a facility. Specifically, the Division of Program Licensing will no longer be reviewing all of the policies, procedures and records that are reviewed pursuant to the current regulation.

Compliance Costs. There are no compliance costs for the drug and alcohol facilities associated with this proposed rulemaking.

Paperwork Requirements. There are no additional paperwork requirements associated with this proposed rulemaking as the unusual incident reports required by the addition of §709.34 are currently being submitted by the regulated community as explained in Section E of this preamble.

G. *Regulatory Review*

DDAP submitted a copy of the proposed regulation to the Independent Regulatory Review Commission (IRRC) and to the Chairperson of the Senate Standing Committee on Public Health and Welfare and the Chairperson of the House Standing Committee on Human Services on February 26, 2014 in accordance with section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)). DDAP also provided IRRC and the Committees a detailed Regulatory Analysis Form prepared by DDAP in compliance with Executive Order 1996-1, "Regulatory Review and Promulgations." A copy of this material is available to the public upon request.

If IRRC has an objection to any portion of the proposed regulation, it must so notify DDAP within 30 days of the close of the public comment period. The notification shall specify the regulatory criteria that have not been met by that portion. The Regulatory Review Act sets forth detailed procedures for review of these objections by DDAP, the General Assembly and the Governor prior to formal publication of the proposed regulation.

H. *Public Comments*

Written Comments. Interested persons are invited to submit comments, suggestions or objections regarding the proposed rulemaking within 30 days following publication in the *Pennsylvania Bulletin.* These comments are public documents that will be posted on the IRRC web site. The comments may be mailed to Ronald G. Young, Director, Division of Program Licensure, 132 Kline Plaza, Harrisburg, PA, 17104. Comments submitted by facsimile will not be accepted.

Electronic Comments. Comments may be submitted electronically to DDAP at RA-licensuredivision@pa.gov and must be received by DDAP within 30 days following publication in the *Pennsylvania Bulletin.* A subject heading of proposed rulemaking and a return name and address must be included in each transmission. If the sender does not receive an acknowledgement of electronic comments within two working days, the comments should be retransmitted to ensure receipt.

Garold E. Tennis, Secretary
Department of Drug and Alcohol Programs

ANNEX A

PROPOSED REGULATION

TITLE 28. HEALTH AND SAFETY

PART V. DRUG AND ALCOHOL FACILITIES AND SERVICE

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 the following standards: Sections 709.22--709.27, 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) If a project is publicly funded, not more than one staff member of the project may sit on the governing body at a designated time.~~

~~(c) If the governing body consists of a board, it shall adopt written policies which shall include, but not be limited to:~~

~~(1) A method of selection for membership.~~

~~(2) Qualifications for membership.~~

~~(3) Criteria for continued membership.~~

~~(4) Frequency of meetings.~~

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

(1) [~~Selecting~~]Designating the position or positions to serve as [a] project director or project directors as the person or persons officially responsible to the governing body either directly or indirectly.

(2) Identifying the project's purpose and philosophy directly related to the Drug and Alcohol Services.

(3) [~~Describing~~]Documenting the project's organizational structure.

[~~(e)~~](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, where applicable.

~~[(1) Activities and accomplishments of the preceding year.~~

~~(2) A financial statement of income and expenses.~~

~~(3) A statement disclosing the names of officers, directors and principal shareholders, where applicable.~~]

§709.23. Project director.

[~~(a)~~ ~~The~~ p]Project Director~~s~~ shall prepare, [~~and~~]annually update, and sign a written manual delineating project policies and procedures.

~~[(b) The project director shall assist the governing body in formulating policy and shall present the following to the governing body at least annually:~~

~~(1) Project goals and objectives which include time frames and available resources.~~

~~(2) Written reports of project operations.~~

~~(3) A performance report summarizing the progress towards meeting goals and objectives.~~]

§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) [~~Defined target population.~~]Defining the target population toward whom facility services are directed.

(2) Identifying the ~~[T]~~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 obtain written letters of agreement or understanding with primary referral sources.~~

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

~~[(d) Provisions shall be made, through written agreement with a licensed hospital or physician, for 24-hour emergency psychiatric and medical coverage.~~]

§709.25. Fiscal management.

~~[(a)]~~ The project shall obtain the services of an independent certified public accountant for an annual financial audit of ~~financial~~ 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.

~~[(b) Projects shall develop a service fee schedule which shall be posted in a prominent place.~~]

§709.26. Personnel management.

(a) The governing body shall adopt and have implemented written project personnel policies and procedures in compliance with all state and federal employment laws. These shall [which]include, but[are] not be limited to:

~~[(1) Recruitment, selection, promotion and termination of staff.~~

~~(2)~~](1) Utilization of volunteers.

~~[(3) Wage and salary administration.~~

~~(4) Employe benefits.~~

~~(5) Working hours.~~

~~(6) Vacation and sick leave.~~

~~(7)~~](2) Rules of conduct.

[~~(8) Disciplinary actions.~~

~~(9)~~](3) Supervision of staff.

[~~(10) Work Performance evaluations.~~

~~(11) Employe accidents and safety.~~

~~(12) Employe grievances.~~]

(4) Orientation of new employees.

[~~(b) The governing body shall adopt a written policy to implement and coordinate personnel management which includes, but is not limited to:~~

~~(1) Confidential maintenance of personnel records.~~

~~(2) The dissemination of employment information to project staff.~~

~~(3) The orientation of new employes.~~

~~(4) The implementation of Federal, State and local statutes concerning fair employment practices.~~

~~(c) The project director shall develop written policies and procedures to provide for ongoing staff training and staff evaluation. Documentation shall include, but is not limited to:~~

~~(1) An assessment of staff training needs.~~

~~(2) Plans for addressing these needs.~~

~~(3) A mechanism to collect feedback on training completed.~~

~~(4) An annual evaluation of the overall training program.~~

~~(d)~~](b) The personnel records shall include, but not be limited to:

(1) [~~The a~~]Application or resume for employment.

[~~(2) The results of reference investigations.~~

~~(3)~~](2) Written [~~The~~]verification of qualifying professional credentials. [~~training experience and professional licensure or registration, where applicable.~~

~~(4) Salary information.~~

~~(5)~~](3) Annual written individual staff performance evaluations, copies of which shall be reviewed and signed by the employee.[~~Work performance evaluation including the following:~~

~~(i) Individual staff performance shall be evaluated at least annually.~~

~~(ii) The individual shall be informed, by written copy, of their annual evaluation.~~

~~(6)~~](4) Disciplinary actions.

[~~(e) The project director shall develop written policies on employe rights and demonstrate the project's efforts toward informing staff of the following:~~

~~(1) The employe's right to inspect his own records.~~

~~(2) The employe's right to request the correction or removal of inaccurate, irrelevant, outdated or incomplete information from the records.~~

~~(3) The employe's right to submit rebuttal data or memoranda to his own records.~~

~~(f)~~](c) There shall be written job descriptions for all project positions.[~~which include, but are not limited to:~~

~~(1) Job title.~~

~~(2) Tasks and responsibilities of the job.~~

~~(3) The requisite skills, knowledge and experience.~~]

§709.27. Physical plant. *RESERVED*
See Chapter 705. Physical Plant Standards

§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 shall include, but not be limited to:

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

(2) Identification of project staff having access to records, and the methods by which staff gain access. [~~Staff access to client records.~~]

(b) The project shall secure hardcopy client records within locked storage containers. Electronic records shall 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 shall 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 Part 2, Subpart B, §§ 2.14 (a) and (b) and 2.15.

(5) Dated signature of witness.

(6) [~~Expiration date~~]Date, event, or condition upon which the consent will expire. [~~of the consent.~~]

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

(e) Where 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 [~~whether original, reproductions or microfilm,~~]shall be readily accessible [~~kept on file~~]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 [~~director~~]shall develop written policies and procedures on client rights and shall document written acknowledgement by the client that they have been notified of those rights. [~~demonstrate efforts toward informing clients of the following:~~]

(1) A client [~~person~~]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) [~~A c~~]Clients have[~~s~~] the right to inspect their[~~his~~] own records. The project, facility and/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. [~~and kept on file.~~]

(4) [~~The client has~~] Clients have the right to appeal a decision limiting access to their ~~his~~ records to the [~~project~~]director.

(5) [~~The client has~~] Clients have the right to request the correction of inaccurate, irrelevant, outdated or incomplete information [~~from his~~]in their records.

(6) [~~The client~~ ~~has~~]Clients have the right to submit rebuttal data or memoranda to their[~~his~~] own records.

§709.31. [~~Uniform~~]Data collection system.

[~~(a) If a project utilizes Department funds, it shall comply with the Department's UDCS.~~

~~(b)~~](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 record keeping system shall allow for the identification of clients' admissions and discharges within a specific time period.

§709.32. Medication control.

(a) [~~Projects which furnish pharmaceutical services shall comply with applicable Federal, State and local ordinances, statutes and regulations regarding the storing, compounding, administering or dispensing of medication.~~]Projects furnishing pharmaceutical services shall present a license from the Department of State (Board of Examiners or Board of

Pharmacy) and a DEA registration to Department employees. Other notices of review and/or inspection shall be made available upon request.

(b) [~~Verbal medication orders may be accepted but shall be put in writing and signed within 24 hours thereafter by the prescribing physician.~~]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 such orders may be received only by another physician, pharmacist, or nurse, or medical professional authorized by state and federal law to receive such 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 such written authentication shall occur no later than 24 hours from the time the order was given. Otherwise, such 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 federal and state regulations and program requirements.

(3) Inspection of storage areas that ensures compliance with federal and state laws and program policy. The policy shall 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) Inventories.~~

~~(7)~~](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.

§709.33. Notification of termination.

(a) Project staff shall notify the client, in writing, of a decision to involuntarily terminate the client's treatment at the project. The notice shall include the reason for termination.

(b) The client shall have an opportunity to request reconsideration of a decision terminating treatment.

§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 one 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) These policies and procedures shall 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 all reporting of any unusual incident to any 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 one day.

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

(5) Outbreak of a contagious disease requiring Center for Disease Control (CDC) notification.

pennsylvania
DEPARTMENT OF DRUG AND
ALCOHOL PROGRAMS

February 26, 2014

David Sumner, Executive Director
The Independent Regulatory Review Commission
333 Market Street, 14th Floor
Harrisburg, PA 17101

Dear Mr. Sumner:

Pursuant to Section 5 of the Regulatory Review Act, please find enclosed for your review a proposed rulemaking relating to the passage of Act 50 of 2010 which transfers the powers, duties and functions of the Department of Health (DOH) concerning drug or alcohol abuse to the Department of Drug and Alcohol Programs (the "Department"). The purpose of this rulemaking is to eliminate redundant or outdated regulatory requirements and maintain or strengthen the elements related to quality and safety of licensed freestanding treatment facilities.

The preliminary proposed regulation was presented and discussed with the Department's stakeholders at a meeting held on June 28, 2013, followed by a 30-day comment period. This rulemaking is a result of the comments and suggestions that were made during and following that meeting.

The enclosed proposed rulemaking includes amendments to 28 *Pennsylvania Code* Chapter 709, Subchapter C, relating to the General Standards for Freestanding Treatment Activities. In most instances where it appears that the Department is increasing requirements, it is instead, incorporating or restating the interpretive guidelines, which were issued by DOH to explain or augment the regulatory requirements but did not have the force and effect of law. With the addition of the new Section 709.34, the Department is requiring that all drug and alcohol treatment facilities develop and implement policies and procedures to respond to and report specific unusual incidents. Some treatment facilities are already required by regulation at 28 Pa. Code §715.28 to report unusual incidents and most other facilities are also providing these reports on a voluntary basis pursuant to a DOH Licensing Alert, which, similar to the interpretive guidelines, does not have the force and effect of law.

The Department will provide assistance as necessary to facilitate your Committee's review of the enclosed proposed rulemaking. Please contact me at 717-787-9354 with any questions or concerns you may have.

Sincerely,

Tawny K. Mummah

Tawny K. Mummah, Deputy General Counsel
Counsel to DDAP

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER:	74-1
SUBJECT:	STANDARDS FOR LICENSURE OF FREESTANDING TREATMENT FACILITIES
AGENCY:	DEPARTMENT OF DRUG AND ALCOHOL PROGRAMS

TYPE OF REGULATION

X Proposed Regulation

Final Regulation

Final Regulation with Notice of Proposed Rulemaking Omitted

120-day Emergency Certification of the Attorney General

120-day Emergency Certification of the Governor

Delivery of Tolled Regulation
a. With Revisions b. Without Revisions

DELIVERY OF REGULATION

DATE	SIGNATURE	DESIGNATION
		HOUSE COMMITTEE ON HEALTH SERVICS OR HUMAN SERVICES
2/26/14	Pam Weiss	MAJORITY CHAIR Gene DiGirolamo
		MINORITY CHAIR
		SENATE COMMITTEE ON PUBLIC HEALTH & WELFARE
2/26/14	Tracy Evans	MAJORITY CHAIR Patricia H. Vance
		MINORITY CHAIR
2/26/14	K Cooper	*INDEPENDENT REGULATORY REVIEW COMMISSION*
		ATTORNEY GENERAL (for Final Omitted only)
2/26/14	Corinne Mount	*LEGISLATIVE REFERENCE BUREAU* (for Proposed only)