Regulatory Analysis Form

(Completed by Promulgating Agency)

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

INDEPENDENT REGULATORY REVIEW COMMISSION

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IRRC

(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:
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):

Proposed Regulation
X 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)

The regulation amends 28 Pa. Code §§ 709.21 – 709.33 and adds §709.34 (relating to the Standards for Licensure of Freestanding Treatment Facilities). The purpose of the final-form regulation is to reduce redundant and outdated requirements, but maintain the elements related to quality and safety.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 final-form 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 final-form 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 final-form regulation is needed to streamline DDAP's review of drug and alcohol facilities. It will benefit the drug and alcohol facilities in that DDAP's inspection time at each 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. The following is a section by section description of why DDAP has removed certain requirements:

Section 709.22 Governing body – Removed prior subsections (b) and (c) and (d)(1) – (3) because these requirements are no longer necessary. Specifically, at the time these regulations were put into place there was no 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, with the passage of the staffing regulation found at 28 Pa Code Chapter 704, 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 new subsections (b) and (c), DDAP simply clarified the duties of the governing body. For example, in new subsection (c), it is no longer necessary to tell a business what should be included in an annual report.

Section 709.23 Project director – Language removed is again business oriented requirements that are a normal part of business operation and no longer needs to be dictated by DDAP regulation.

Section 709.24 Treatment/rehabilitation management – Removed prior subsection (b) requiring 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. Prior subsection (d) is no longer necessary due to the implementation and

amendment of the Hill-Burton Act in the late 1970's, which required hospitals to provide emergency services despite the inability to pay.

Section 709.25 Fiscal management – Made clarifications to prior subsection (a) and removed (b) because in this age of managed care and sliding fee scales, there are no longer set fee schedules.

Section 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 removal of subsection (c), this subsection is also codified at 28 Pa. Code Section 704.11 (a)(1)-(4). Requirements retained in this section were for specific reasons. For example, the retention of the requirement concerning volunteers was necessary, because DDAP needs to ensure that the volunteers are adequately trained in areas of client confidentiality and client boundary issues. Concerning the subsections related to personnel records, DDAP revised by removing requirements that are superfluous because DDAP does not take action if a personnel record is less than satisfactory. For instance, in relation to prior subsections (d)(2) and (d)(4), if the project hired an individual with a negative prior employment reference or was paying its employees disparately, DDAP would not have authority to object to those employment decisions, so review of those employment records served no purpose.

Section 709.28 Confidentiality and Section 709.29 Retention of client records –All revisions by DDAP to these sections are for clarification and in recognition of electronic record keeping.

Section 709.30 Client rights – Revisions made in this section were for clarity and consistency.

Section 709.31 Data Collection System – This section was revised to remove reference to the old data collection system (UDCS) in subsection (a) and refer to the system generally because current software used for DDAP's data collection system is likely to be replaced in the future and the regulation would, once again, be outdated. Subsection (b) was added to state the essential function of the record keeping system.

Section 709.32 Medication control – DDAP made clarification to this section to recognize that other medical professional, other than physicians, are authorized by law to give and receive verbal orders for medication. In addition, the inventory requirement was removed because the projects have contractual agreements with pharmacies that are responsible for keeping inventories of bulk medication supplies. Lastly, individual prescribed medication for clients are not subject to the inventory requirements.

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. Reporting 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.

The final-form regulation applies to all freestanding drug and alcohol facilities in Pennsylvania but not to the drug and alcohol facilities located within a hospital. Accordingly, this regulation will impact 631 (of the total 688) current facilities operating in Pennsylvania. Ultimately, all of the clients of these facilities will also benefit as more time can be dedicated to providing them with services. The exact number of clients receiving treatment in these facilities at any one time is not known. However, the total, maximum capacity of these 631 facilities is currently 89,200 clients.

(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 final-form 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 final-form 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 twenty-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 Psych 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. Revisions were also made in the final-form regulation in response to comments by IRRC and the Pennsylvania Society of Physician Assistants.

(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 final-form regulation applies to all freestanding drug and alcohol facilities in Pennsylvania but not to the drug and alcohol facilities located within a hospital. Accordingly, this regulation will impact 631current facilities operating in Pennsylvania. The final-form regulation will benefit those 631 licensed freestanding facilities in that DDAP's inspection time at each of the facilities will be reduced as the Division of Program Licensure will no longer be reviewing all of the policies, procedures and records that are reviewed pursuant to the current regulation. Ultimately, all of the clients of these facilities will also benefit as more time can be dedicated to providing them with services. The exact number of clients receiving treatment in these facilities at any one time is not known. However, the total, maximum capacity of these 631 facilities is currently 89,200 clients.

Small businesses are defined in Section 3 of the Regulatory Review Act, Act 76 of 2012, which provides that a small business is defined by the U.S. Small Business Administration's Small Business Size Regulations under 13 CFR Ch. 1 Part 121. Specifically, size standards are provided at 13 CFR § 121.201. These size standards have been established for types of businesses under the North American Industry Classification System (NAICS). In applying the NAICS standards to the 631 facilities noted above (believed to be NAICS Codes 624190 and 623220), a small business is one with $7 million or less in average annual receipts. DDAP believes that many of the free standing drug and alcohol facilities licensed by DDAP are considered small businesses because they fall under the threshold amount.

Given that this final-form regulation will not have a cost or savings affect on any of the 631 licensed, free standing facilities regulated by DDAP, it will not affect those facilities that are defined as a small business.

(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 final-form regulation applies to all freestanding drug and alcohol facilities in Pennsylvania but not to the drug and alcohol facilities located within a hospital. Accordingly, 631 current facilities operating in Pennsylvania will be required to comply with the regulation. The final-form regulation will benefit those 631 licensed facilities in that DDAP's inspection time at a facility will be reduced as the Division of Program Licensure will no longer be reviewing all of the policies, procedures and records that are reviewed pursuant to the current regulation.

(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 final-form 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 final-form regulation is not quantifiable in a dollar figure, because there will be a saving of facility time that, we believe, will then be devoted to client 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 final-form 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. The estimate of the fiscal savings and cost associated with this final-form regulation is not

quantifiable in a dollar figure, because there will be a saving of facility time that, we believe, will then be devoted to client services.

	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.

Program	FY -3	FY -2	FY -1	Current FY
Division of Program Licensure	2,097,698.48	2,068,291.36	1,799,699.18	1,386,011.13 (Thru 03/31/14)

(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 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 regulation.

N/A. While many drug and alcohol freestanding facilities currently operating in PA may be a small business as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012, the final-form regulation does not have an adverse impact on any of the drug and alcohol facilities, 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 final-form 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 many drug and alcohol freestanding facilities currently operating in PA may be a small business as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012, the final-form regulation does not have an adverse impact on any of the drug and alcohol facilities, 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 final-form regulation.

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

A. The date by which the agency must receive public comments: April 7, 2014

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: 8/2014

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 final-form regulation is not effective, DDAP will consider seeking further revision.

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FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

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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 Executive Deputy General Counsel
_____ DATE OF APPROVAL	DOCUMENT/FISCAL NOTE NO. 74-1 DATE OF ADOPTION: June 9, 2014	6/20/14 DATE OF APPROVAL
☐ Check if applicable Copy not approved. Objections attached.	BY: _____ TITLE Garold E. Tennis, Secretary (EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)	(Chief Counsel, Independent Agency) (Strike inapplicable title) ☐ Check if applicable. No Attorney General approval or objection within 30 days after submission.

NOTICE OF FINAL RULEMAKING

DEPARTMENT OF DRUG AND ALCOHOL PROGRAMS

Standards for Licensure of Freestanding Treatment Facilities

28 Pa. Code, Chapter 709, Subchapter C

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

The Department of Drug and Alcohol Programs (DDAP) hereby amends §§ 709.21 – 709.33 and adds §709.34 (relating to the General Standards for Freestanding Treatment Activities) to read as set forth in Annex A. This 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. 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 regulation in response to comments by IRRC and the Pennsylvania Society of Physician Assistants.

A. *Effective Date*

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

B. *Contact Persons*

For further information concerning the final-form regulation, 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, (717-783-6563). The final-form regulation is electronically available on DDAP's website at www.ddap.pa.gov.

C. *Statutory Authority*

This final 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.

DDAP is satisfied there is no reasonable alternative to proceeding with the regulation. DDAP is also satisfied the regulation meets the requirements of Executive Order No. 1996-1, "Regulatory Review and Promulgation."

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. The following is a section by section description of why DDAP has removed certain requirements:

Section 709.22 Governing body – Removed prior 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 was no 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, with the passage of the staffing regulation found at 28 Pa. Code Chapter 704, 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 new subsections (b) and (c), DDAP simply clarified the duties of the governing body. For example, in new subsection (c), it is no longer necessary to tell a business what should be included in an annual report.

Section 709.23 Project director – Language removed is again business oriented requirements that are a normal part of business operation and no longer needs to be dictated by DDAP regulation.

Section 709.24 Treatment/rehabilitation management – Removed prior subsection (b) requiring 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. Prior subsection (d) is no longer necessary due to the implementation and amendment of the Hill-Burton Act, in the late 1970's, which required hospitals to provide emergency services despite the inability to pay.

Section 709.25 Fiscal management – Made clarifications to prior subsection (a) and removed (b) because in this age of managed care and sliding fee scales, there are no longer set fee schedules.

Section 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 removal of subsection (c), this subsection also codified at 28 Pa. Code Section 704.11 (a)(1)-(4). Requirements retained in this section were for specific reasons. For example, the retention of the requirement concerning volunteers was necessary because DDAP needs to ensure that the volunteers are adequately trained in areas of client confidentiality and client boundary issues. Also, see response to comment number 3. Concerning the subsections related to personnel records, DDAP revised by removing requirements that are superfluous because DDAP does not take action if a personnel record is less than satisfactory. For instance, in relation to prior subsections (d)(2) and (d)(4), if the project hired an individual with a negative prior employment reference or was paying its employees disparately, DDAP would not have authority to object to those employment decisions, so review of those employment records served no purpose.

Section 709.28 Confidentiality and *Section 709.29 Retention of client records* – All revisions by DDAP to these sections are for clarification and in recognition of electronic record keeping.

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Section 709.32 Medication control – DDAP made clarification to this section to recognize that other medical professionals other than physicians are authorized by law to give and receive verbal order for medication. In addition, the inventory requirement was removed 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 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. Reporting of 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. *Comments and Responses*

A notice of proposed rulemaking was published at 44 Pennsylvania Bulletin 1317 (44 Pa.B. 1317) on March 8, 2014, affording the public, the Legislature and the Independent Regulatory Review Commission (IRRC) the opportunity to offer comments.

Comments were received from IRRC and the Pennsylvania Society of Physician Assistants (PSPA). (It should be noted that DDAP received an untimely comment, simply supporting the proposed rulemaking and urging DDAP to amend 4 Pa. Code 255.5, from Blue Cross of Northeastern Pennsylvania). The timely comments and DDAP's responses follow:

Comment 1: IRRC raised "concerns regarding the clarity of the regulation as proposed" because the definition section of Title 28 of the Pennsylvania Code (28 Pa. Code § 701) defines "Department" as the Department of Health and not DDAP. This is likely to cause the reader confusion and therefore, IRRC recommends 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 addition, IRRC recommends 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 the Department of Health.

Response: DDAP has fully addressed IRRC's concerns. Specifically, in accordance with Section 204 of the Commonwealth Documents Law, the Secretary of DDAP requested and received approval from the Office of General Counsel and the Office of Attorney General to proceed with a final-omitted regulation that will serve several housekeeping functions. Specifically, the final-omitted regulation submitted to IRRC on _____, 2014 (simultaneously with this final-form rulemaking) will provide clarity at 28 Pa. Code Chapter 701, Subchapter A, by changing the definition of "Department" in §701.1 (General definitions) from the Department of Health (DOH) to DDAP, updating §701.3 (Legal base) to include Act 50 of 2010, and updating §701.13 (Contact person) from DOH to DDAP. Lastly, to further provide clarity, DDAP's final-omitted regulation changes the title of Part V from "Drug and Alcohol Facilities and Services" to "Department of Drug and Alcohol Programs" as suggested by IRRC.

Comment 2: IRRC requested that DDAP comply with the Regulatory Review Act by providing more detailed information in the Regulatory Analysis Form (RAF) and the Preamble to enable IRRC to determine whether the regulation is in the public interest.

Response: DDAP has significantly revised the RAF and Preamble to provide IRRC with sufficient information to determine that the regulation is in the public interest.

Comment 3: IRRC raised a concern that Section 709.26. Personnel management as amended by DDAP lacks clarity.

Response: DDAP has addressed IRRC's concern and has further revised this section for the sake of clarity. Specifically, the second sentence of Section 709.26(a) now reads, "In addition, the written project policies and procedures shall specifically include, but are not limited to:"

Comment 4: IRRC and PSPA request that DDAP revise the final-form regulation by specifically listing "physician assistants" as an authorized medical professional in Section 709.32 Medication control.

Response: (Please note that the heading for IRRC's comment is erroneous. This comment is related to Section 709.32 Medication control and not 709.31 Data Collection System.) DDAP 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, DDAP does not want its regulation to be quickly outdated. However, for consistency, DDAP has further revised subsection (b) to delete references to "pharmacist" or "nurse" and therefore is not specifically referencing any authorized medical professionals.

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

Response: DDAP disagrees and has left the phrase "includes, but is not limited to" in the final-form regulation, because DDAP 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 Section 709.24, Treatment/rehabilitation management, DDAP 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 DDAP.

G. *Benefits, Cost and Compliance*

Benefits. The final-form rulemaking will benefit the drug and alcohol facilities by reducing DDAP's inspection time at a facility. Specifically, the Division of Program Licensure 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 final-form rulemaking.

Paperwork Requirements. There are no additional paperwork requirements associated with this final-form 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.

H. *Regulatory Review*

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

Under Section 5(c) of the Regulatory Review Act (71 P.S. § 745.5(c)), DDAP provided IRRC and the referenced Committees with copies of all comments received during the public comment period.

Under Section 5a(j.2) of the Regulatory Review Act (71 P.S. § 745.5a(j.2)), on _____, 2014, the final-form regulation was _____ approved by the House Committee and on _____, 2014 the final-form regulation was _____ approved by the Senate Committee. Under Section 5a(e) of the Regulatory Review Act (71 P.S. § 745.5a (e)), the final-form regulation was approved by IRRC on _____, 2014.

I. *Findings*

DDAP finds that:

(1) Public notice of the intention to adopt this final-form regulation has been given under sections 201 and 202 of Act 240 of 1968 (P.L. 769, No. 240) (45 P.S. §§1201 and 1202) and the regulations thereunder, 1 Pa. Code §§ 7.1 and 7.2.

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

(3) The modifications that were made to this regulation in response to comments received do not enlarge the purpose of the proposed regulation published at 44 Pa.B. 1317 (March 8, 2014).

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

J. *Order*

DDAP, acting under the authorizing statute, orders the following:

(1) The current regulation at 28 Pa. Code Chapter 709, Subchapter C (relating to the General Standards for Freestanding Treatment Activities) is hereby amended to read as set forth in Annex A.

(2) The Secretary of DDAP shall submit this order, 44 Pa.B. 1317 and Annex A to the Office of General Counsel and the Office of Attorney General for approval as required by law.

(3) The Secretary of DDAP shall certify and deposit under this order, 44 Pa.B. 1317 and Annex A with the Legislative Reference Bureau as required by law.

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

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

Annex A

TITLE 28. HEALTH AND SAFETY

PART V. DRUG AND ALCOHOL FACILITIES AND SERVICES

CHAPTER 709. STANDARDS FOR LICENSURE OF FREESTANDING TREATMENT FACILITIES

Subchapter C. GENERAL STANDARDS FOR FREESTANDING TREATMENT ACTIVITIES

§ 709.21. Applicability.

* * * * *

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

[~~(c)~~] **(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.**

[~~(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 project director~~] **Project directors** 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 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.~~] **Definition of the target population toward whom facility services are directed.**

(2) [~~Treatment~~] **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 servicse**.

[~~(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 [~~which~~] **in compliance with state and federal employment laws.** ~~These laws~~ **IN ADDITION, THE WRITTEN POLICIES AND PROCEDURES SHALL SPECIFICALLY** include, but are not limited to:

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

~~(2) Utilization of volunteers.~~

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

~~(4) Employe benefits.~~

~~(5) Working hours.~~

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

~~(7) Rules of conduct.~~

~~(8) Disciplinary actions.~~

~~(9) Supervision of staff.~~

~~(10) Work performance evaluations.~~

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

~~(12) Employe grievances.~~]

(1) Utilization of volunteers.

(2) Rules of conduct.

(3) Supervision of staff.

(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~~] **must** include, but **are** not [~~be~~] limited to:

[~~(1) The application for employment.~~

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

~~(3) The verification of training experience and professional licensure or registration, where applicable.~~

~~(4) Salary information.~~

~~(5) 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 the annual evaluation.~~

~~(6) Disciplinary actions.~~]

(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.

[~~(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 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.~~]

§ 709.28. 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~~] **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) [~~Staff access to client records.~~] **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 shall be in writing and include, but not be limited to:

* * * * *

(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) [~~Expiration date of the consent.~~] **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 [~~records~~] **record**.

* * * * *

§ 709.29. Retention of client records.

(a) Client records, [~~whether original, reproductions or microfilm, shall be kept on file~~] **regardless of format, shall be readily accessible** for a minimum of 4 years following the discharge of a client.

* * * * *

§ 709.30. Client rights.

The project [~~director~~] shall develop written policies and procedures on client rights and [~~shall demonstrate efforts toward informing clients of the following:~~] **document written acknowledgement by clients that they have been notified of those rights.**

(1) A [~~person~~] **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) [~~A client has the right to inspect his own records.~~] **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 [~~and kept on file~~] **in the record**.

(4) [~~The client has~~] **Clients have** the right to appeal a decision limiting access to [~~his~~] **their** 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 [~~his~~] **their** 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 recordkeeping system must 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 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 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 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. 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) 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.**

§ 709.34. 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 peronnel.

(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.

pennsylvania
DEPARTMENT OF DRUG AND
ALCOHOL PROGRAMS

July 3, 2014

VIA HAND DELIVERY
John F. Mizner, Esquire
Chairman
Independent Regulatory Review Commission
333 Market Street, 14th Floor
Harrisburg, PA 17101

Re: Agency/ID/Docket No. 74-1
Final-Form Rulemaking
Department of Drug and Alcohol Programs
28 Pa. Code §§ 709.21, *et seq.*
Standards for Licensure of Freestanding Treatment Facilities

Dear Chairman Mizner:

Enclosed please find one (l) copy of the regulatory documents concerning the above-captioned rulemaking. Pursuant to Section 745.5(a) of the Regulatory Review Act (71 P.S. §§745.1-745.15), the Department of Drug and Alcohol Programs (DDAP) submitted a copy of the Notice of Proposed Rulemaking to the Independent Regulatory Review Commission (IRRC), DDAP's standing committees and the Legislative Reference Bureau on February 26, 2014. The notice of proposed rulemaking was published at 44 Pa.B 1317 on March 8, 2014.

In preparing this final-form rulemaking, DDAP has considered all comments received from IRRC and the public. We have notified all commentators of this final-form rulemaking and have enclosed the list of commentators.

The undersigned is the contact person for this rulemaking.

Sincerely,

Tawny K. Mummah
Deputy General Counsel
Counsel to DDAP
(717) 787-9354

TKM/krm
Enclosures
cc: Shawn E. Smith, Office of General Counsel
Senator Patricia Vance
Representative Gene DiGirolamo

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

Proposed Regulation

X Final Regulation (re-delivery w/revisions)

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 Withdrawn Regulation
a. With Revisions b. Without Revisions

RECEIVED
IRRC
2014 JUL -8 PM 2:55

DELIVERY OF REGULATION

DATE	SIGNATURE	DESIGNATION
		HOUSE COMMITTEE ON HEALTH SERVICS OR HUMAN SERVICES
7/8/14		MAJORITY CHAIR Gene DiGirolamo
		MINORITY CHAIR
		SENATE COMMITTEE ON PUBLIC HEALTH & WELFARE
		MAJORITY CHAIR Patricia H. Vance
		MINORITY CHAIR
7/8/14		*INDEPENDENT REGULATORY REVIEW COMMISSION*
		ATTORNEY GENERAL (for Final Omitted only)
		LEGISLATIVE REFERENCE BUREAU (for Proposed only)