Regulatory Analysis Form

Regulatory Analysis Form	This space for use by IRRC
(1) Agency Department of Health	
(2) I.D. Number (Governor's Office Use) 10-186	IRRC Number: 2654

(3) Short Title
Governor's Council on Drug and Alcohol Abuse
Management Information, Research, and Evaluation
Confidentiality of Patient Records and Information

(4) Pa Code Cite	(5) Agency Contacts & Telephone Numbers
4 Pa. Code § 255.5	Primary Contact: Janice A. Staloski, Director, Bureau of Community Program Licensure and Certification (717) 783-8665 Secondary Contact: Cheryl D. Williams, Director, Division of Drug and Alcohol Program Licensure (717) 783-8675

(6) Type of Rulemaking (Check One)	(7) Is a 120-Day Emergency Certification Attached?
√ Proposed Rulemaking	√ No
Final Order Adopting Regulation	Yes: By the Attorney General
Final Order, Proposed Rulemaking Omitted	Yes: By the Governor

(8) Briefly explain the regulation in clear and non-technical language.

The Department of Health (Department) proposes to amend regulations that relate to disclosure of confidential drug and alcohol treatment information, and to whom and for what purposes such information may be disclosed. The proposed amendment also corrects a conflict with the Federal confidentiality regulations.

(9) State the statutory authority for the regulation and any relevant state or federal court decisions.

The Department's statutory authority to regulate, inspect and license drug and alcohol treatment facilities is established in Articles IX and X of the Public Welfare Code (62 P.S. §§ 901 – 922 and 1001 – 1059) and the Pennsylvania Drug and Alcohol Abuse Control Act (71 P.S. § 1690.101 et. seq.), as transferred to the Department pursuant to Reorganization Plan No. 2 of 1977 (71 P.S. § 751-25)(transferring duties under the Public Welfare Code with regard to regulation, inspection, and licensing of drug and alcohol facilities to the Governor's Council on Drug and Alcohol Abuse (Council)) and Reorganization Plan No. 4 of 1981 (71 P.S. § 751-31) (transferring the functions of the Council to the Department).

(10) Is the regulation mandated by any federal or state law or court order, or federal regulation? If yes, cite the specific law, case or regulation, and any deadlines for action.

No.

(11) Explain the compelling public interest that justifies the regulation. What is the problem it addresses?

The Department proposes to amend 4 Pa. Code § 255.5 in order to correct a conflict with the Federal confidentiality regulations, thereby reducing any perceived complexities in the regulations that drug and alcohol treatment facilities must comply with. The Department also proposed these amendments because some of the provisions in 4 Pa. Code § 255.5 are outdated and impede service delivery and the coordination of care for individuals with substance abuse problems.

(12) State the public health, safety, environmental or general welfare risks associated with non-regulation.

The risks to public health, safety, environmental or general welfare risks associated with not making the amendments proposed by the Department are mainly increased regulatory obstacles to drug and alcohol treatment facilities in the delivery of treatment services to the individuals they serve. These obstacles may reduce the effectiveness of quality of the services the facilities provide.

(13) 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 amendments to this regulation would benefit individuals seeking treatment for substance abuse problems as they would have greater access to services, more appropriate lengths of stay, and improved coordination between various levels and types of care. In addition, these individuals would have the ability to control the disclosure of their confidential information by authorizing the release of specific protected information via a signed consent.

Licensed treatment facilities would also benefit from the proposed amendments to this regulation because the amendments would eliminate certain restrictions as to what drug and alcohol treatment information and records may be disclosed to third party payers. These facilities would also be able to coordinate care by providing specific information that is needed for utilization and review of services as requested by third party payers.

(14) Describe who will be adversely affected by the regulation. (Quantify the adverse effects as completely as possible and approximate the number of people who will be adversely affected.)

The Department does not believe any persons would be adversely affected by the proposed amendments to this regulation.

However, individuals receiving or seeking drug and alcohol treatment services, and their advocates, may perceive this amendment as lessening or eliminating certain protections on the confidentiality of their treatment records. If the regulation is amended, the confidentiality of drug and alcohol treatment records would continue to be protected by the requirements of this section as well as provisions of the Pennsylvania Drug and Alcohol Abuse Control Act, 71 P.S. § 1690.108(b) and (c) (relating to confidentiality of records), 28 Pa. Code § 709.28 (relating to confidentiality) of the Department's regulations, and the relevant Federal regulations at 42 CFR Part Two (relating to confidentiality of alcohol and drug abuse patient records).

Pennsylvania law and the Federal regulations provide that drug and alcohol treatment providers may disclose drug and alcohol treatment information to third party payers and others only if the individual consents to the release of such information. Further, these provisions also dictate that the specific information to be disclosed be identified, that the specific purpose of the disclosure be identified, that the disclosure is limited to the information necessary to carry out the purpose of the disclosure, that the specific individual or entity receiving the information be identified, that the consent be time-limited to allow for a disclosure only to the extent necessary to achieve the purposes of the disclosure, that the disclosure be signed and dated by the client and signed and dated by a witness, and that redisclosure is prohibited unless specifically reauthorized by the client.

Moreover, the amendment of this regulation does not affect the ability of one licensed treatment provider, under current law, to disclose to, transfer to, or receive from another treatment provider, with the client's consent, the treatment records of the client.

(15) List the persons, groups or entities that will be required to comply with the regulation. (Approximate the number of people who will be required to comply.)

Drug and alcohol treatment facilities licensed by the Department or seeking licensure from the Department and government agencies authorized to provide drug and alcohol treatment services would be required to comply with the proposed amendments to this regulation. Currently, the Department licenses or certifies 662 facilities and government agencies as stand-alone facilities or as portions of other health care facilities such as hospitals.

(16) Describe the communications with and input from the public in the development and drafting of the regulation. List the persons and/or groups who were involved, if applicable.

Initially, the Department had prepared a draft proposed amendment of a portion of this regulation. That draft was presented to the Advisory Council on Drug and Alcohol Abuse, and upon their advice, was posted on the Department's internet website and letters were sent to identified stakeholders, including the Drug and Alcohol Service Providers Organization of Pennsylvania, the Pennsylvania Association of County Drug and Alcohol Administrators Inc., (PACDAA), the Pennsylvania Recovery Organizations Alliance (PRO-A), Gaudenzia, Inc., and White Deer Run. The Department received several comments from stakeholders and the current proposed amendments to this regulation have taken into consideration those comments.

(17) Provide a specific estimate of the costs and/or savings to the regulated community associated with compliance, including any legal, accounting or consulting procedures that may be required.

The proposed amendments would not create any additional costs or savings to the regulated community. Under State and Federal law, drug and alcohol treatment programs are already required to have in place policies and procedures relating to the release of patient information. While programs may need to review these policies and procedures to ensure compliance with these proposed amendments, such a review and updating is expected from programs on a periodic basis under existing licensing requirements.

Further, the proposed requirements are similar to those currently contained in 28 Pa. Code § 709.30 (relating to client rights), which apply to all freestanding drug and alcohol treatment facilities. These proposed requirements are also similar to those requirements put in place by the privacy rules resulting from the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (42 C.F.R. §§ 164.524 (relating to access of individuals to protected health information)). Programs that are required to comply with HIPAA and to be licensed by the Department should already have in place systems allowing for patient accessibility to information, for appeals of patients whose access to that information is limited, and for allowing patients to correct that information and submit rebuttal data. These systems should be adequate for the requirements relating to patient access in these proposed amendments.

(18) Provide a specific estimate of the costs and/or savings to local governments associated with compliance, including any legal, accounting or consulting procedures that may be required.

The proposed amendments would not create any additional costs or savings to local governments who are not also part of the regulated community.

(19) Provide a specific estimate of the costs and/or savings to state government associated with the implementation and consulting procedures that may be required.

The proposed amendments would not create any additional costs or savings to the Commonwealth.

(20) 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.

Not measurable.

	Current FY	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
SAVINGS						
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
TOTAL SAVINGS	0	0	0	0	0	0
COSTS						
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
TOTAL COSTS	0	0	0	0	0	0
REVENUE LOSSES						
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0

State Government	0	0	0	0	0	0
TOTAL REVENUE LOSSES	0	0	0	0	0	0

(20a) Explain how the cost estimates listed above were derived.

N/A

(20b) Provide the past three-year expenditure history for programs affected by the regulation.

Program	FY – 3	FY – 2	FY – 1	Current FY
Quality Assurance	$14,157,071	$14,529,526	$16,057,000	$18,308,000

(21) Using the cost-benefit information provided above, explain how the benefits of the regulation outweigh the adverse effects and costs.

As the Department does not expect any measurable costs for the proposed amendment to this regulation, the benefits in simplification of the regulatory requirements that facilities must comply with outweighs any negligible costs which may be incurred.

(22) Describe the nonregulatory alternatives considered and the costs associated with those alternatives. Provide the reasons for their dismissal.

The Department does not believe any nonregulatory alternatives are available as the appropriate method for amending existing regulatory language is through regulations.

(23) Describe alternative regulatory schemes considered and the costs associated with those schemes. Provide the reasons for their dismissal.

In fall of 2006, the Department had prepared a draft proposed amendment of a portion of this regulation and posted the draft on its internet website. As with this proposed amendment, there are no measurable costs associated with that draft amendment.

(24) 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.

The purpose of this proposed amendment is to bring the Department's regulations more in line with federal requirements. Accordingly, the proposed amendment, while still more stringent than the federal regulations in some respects, due to the requirements of Act 63, brings the regulations closer to the federal regulations.

(25) How does this regulation compare with those of other states? Will the regulation put Pennsylvania at a competitive disadvantage with other states?

The proposed regulation will not put Pennsylvania at a competitive disadvantage with other states. Because this proposed amendment would bring the Department's regulations more in-line with federal standards, it will make Pennsylvania's regulations in this area more similar to other states requirements.

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

No.

(27) Will any public hearings or information meetings be scheduled? Please provide the dates, times, and locations, if available.

No public hearings or information meetings have been scheduled at this time. Public meetings remain an option if it is determined that such are necessary.

(28) Will the regulation change existing reporting, record keeping, or other paperwork requirements? Describe the changes and attach copies of forms or reports that will be required as a result of implementation, if available.

The proposed amendments would not change existing reporting, record keeping, or other paperwork requirements. Under State and Federal law, drug and alcohol treatment programs are already required to have in place policies and procedures relating to the release of patient information. While programs may need to review these policies and procedures to ensure compliance with these proposed amendments, such a review and updating is expected from programs on a periodic basis under existing licensing requirements. Further many of the requirements in the proposed amendments are substantially similar or identical to other State and Federal requirements, meaning that the reporting, recordkeeping, or other paperwork requirements would also be substantially similar or identical.

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

None.

(30) What is the anticipated effective date of the regulation; the date by which compliance with the regulation will be required; and the date by which any required permits, licenses or other approvals must be obtained?

The proposed amendment would become effective upon publication as final rulemaking in the *Pennsylvania Bulletin.*

(31) Provide the schedule for continual review of the regulation.

The Department would continue to review the regulation and its application on a regular basis in its inspection and licensing of facilities on a regular basis.

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Copy below is hereby approved as to form and legality. Attorney General	Copy below is hereby 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 NOV 16 2007 DATE OF APPROVAL	DEPARTMENT OF HEALTH (AGENCY) DOCUMENT/FISCAL NOTE NO. 10-186 DATE OF ADOPTION: _____ BY: Calvin B. Johnson, M.D., M.P.H. TITLE : SECRETARY OF HEALTH	BY _____ Andrew C. Clark SEP 24 2007 DATE OF APPROVAL (Deputy General Counsel) (~~Chief Counsel, Independent Agency~~) (~~Strike inapplicable title~~)
Check if applicable. Copy not approved. Objections attached.		Check if applicable. No Attorney General approval or objection within 30 days after submission.

DEPARTMENT OF HEALTH

PROPOSED RULEMAKING

TITLE 4. ADMINISTRATION

PART XI. GOVERNOR'S COUNCIL ON DRUG AND ALCOHOL ABUSE

4 PA.CODE CHAPTER 255 - MANAGEMENT INFORMATION, RESEARCH, AND EVALUATION

SECTION 255.5 – Confidentiality of Patient Records and Information

The Department of Health (Department) proposes to amend 4 Pa. Code § 255.5 (relating to projects and coordinating bodies: disclosure of client-oriented information) (Section 255.5) by deleting the existing regulation, and replacing it with the proposed amendments included in Annex A.

A. PURPOSE OF THE PROPOSED AMENDMENTS

The Department's regulations relating to disclosure of client-oriented information have become outdated and an impediment to service delivery and the coordination of care for individuals with substance abuse problems. The Department initially considered rescinding subsection (b) of Section 255.5, and amending portions of subsection (a) to conform it to those changes, but after consultation with, and upon the advice of, the Advisory Council on Drug and Alcohol Abuse, the Department decided against that course of action. Instead, after receiving comments from various stakeholders, the Department has chosen to propose amendments that would protect the interest of the patient in confidentiality of extremely sensitive and stigmatizing personal information, while at the same time providing sufficient information to persons providing treatment and benefits to those individuals, as well as allowing a client autonomy in choosing when and how to release that client's information. In general, the intent of the proposed rulemaking is to expand the amount of information treatment providers may release to other entities in accordance with the existing statute, and to clarify for treatment providers and patients what the rules relating to confidentiality and disclosure of patient-identifying information are.

B. REQUIREMENTS OF THE REGULATION

PART IX. **GOVERNOR'S COUNCIL ON DRUG AND ALCOHOL ABUSE**

CHAPTER 255. **MANAGEMENT INFORMATION RESEARCH AND EVALUATION.**

Section 255.5. **Confidentiality of Patient Records and Information**

(a) Definitions.

This section would be new. The Department is adding a definition section to the regulations to clarify certain terms used in section 108 of the Pennsylvania Drug and Alcohol Abuse Control Act (Act 63) (71 P.S. §§ 1690.101, 1690.108). Section 255.5 is based on language included in Section 108. That section contains several terms not defined in Act 63 that are integral to the understanding of the scope of confidentiality promised to the patient, for example, "medical authorities and medical personnel" and "government officials." The Department has attempted to define those terms as well as the terms, "program," "patient record," and "third party payer," in keeping with the intent of the General Assembly contained in Section 108, as well as the practice of the providers of drug and alcohol abuse treatment.

(b) Scope and Policy.

This section would be new. The Department has added this section not only to set out who will be subject to the proposed regulation, and what information will be subject to it, but also to reaffirm the Department's commitment to confidentiality for persons seeking

drug and alcohol abuse treatment, and to set out some basic tenets with regard to how such information should be treated by providers and persons to whom information is disclosed. (See proposed paragraphs (2) – (5)). The Department is also clarifying to whom the record belongs (the facility), but stating that the individual has control over his or her record, except as limited by the proposed regulation itself. (See proposed paragraph (3)). Finally, this section would place limits on redisclosure. (See proposed paragraphs (5) & (6)).

(c) Consensual Release of Patient Records and Information.

This proposed subsection would set out the circumstances under which a patient may consent to the release of records. This proposed subsection would expand the amount of information that treatment providers may disclose to other entities, and impose certain restrictions on the amount of information that may be disclosed to third party payers. Paragraphs (1) and (2) of this subsection reflect the requirements of section 108 of Act 63, and would provide that a program may release a patient record to medical personnel for the purpose of diagnosis, treatment or referral for treatment, and to government officials and third party payers to obtain benefits due the patient as the result of the patient's drug or alcohol abuse or dependence.

Proposed paragraph (2) would limit the information that may be released to government officials or third party payers to information necessary to accomplish the purpose of the disclosure. Proposed paragraph (2) incorporates the federal standard relating to release of confidential patient-related information. Further, in the case of disclosure to these

specified groups, information that is requested for the purposes of determining medical necessity for service admission, continued stay, discharge, referral, concurrent review, and coordination of care and payment would be limited to an even greater extent. (See subparagraphs (i) – (vii)). This information is in keeping with the American Society of Addiction Medicine (ASAM)'s six dimensional criteria accepted by drug and alcohol abuse treatment providers and payers of services as the appropriate criteria by which to assess an individual seeking or in treatment. Under the proposed regulation, a provider would have protection against requests by third party payers for information that is highly personal and has no bearing on payment for treatment services. This provision would protect a patient's privacy rights.

At the same time, the proposed regulation would provide third party payers, including managed care plans, with sufficient information with which to make a determination of the medical necessity of the service requested. Proposed subsection (c)(2) would make it more difficult for a third party payer to refuse coverage for services on the basis of insufficient information.

The proposed regulation would also include provisions allowing release with patient consent to probation and parole officers and to the patient's lawyer. (See proposed paragraphs (3) and (4)). The current regulation allows for release to these individuals. (See 4 Pa. Code § 255.5(a)(2) and (4)).

(d) Non-Consensual Release of Patient Records and Information

This proposed subsection would be new, and would include Section 108's provisions allowing disclosure to be made without patient consent in emergency medical situations where the patient's life is in immediate jeopardy (see proposed paragraph (1)), and where there is a court order issued pursuant to the statute. (See proposed paragraph (2)).

The proposed section would also import from the federal rules relating to confidentiality of alcohol and drug abuse patient records (see 42 C.F.R. Part 2) several provisions intended to balance the rights and protections of the patient whose information is being released against the rights and safety of the other persons present in treatment. These sections include proposed paragraph (3), which would allow the release of patient identifying information without a patient's consent to law enforcement when such a release is directly related either to the patient's commission of a crime on the treatment premises, or the threat to commit a crime. (See proposed paragraph (3)). In order to balance the need to protect the patient in question with the need to protect other patients at the facility, the Department has included in proposed paragraph (3) a limitation on what information could be released under these circumstances. The proposed paragraph only allows the release to law enforcement of that information that is related to the circumstances of the incident. (Id.) The disclosure would include the patient's name and address, the fact that the patient was a patient of the facility, and the patient's last known whereabouts. (Id.)

Proposed paragraph (4) would allow programs to report child abuse under state law without violating patient confidentiality. The proposed language in this paragraph, too, is

a provision that is included in federal regulation (see 42 C.F.R. § 2.12(c)(6) (relating to exceptions to non disclosure – reports of suspected child abuse and neglect). This provision is intended to protect a most vulnerable portion of society, children, and is particularly applicable since the Department does license facilities that serve parents and children.

Another federal regulation that the Department has chosen to include in this proposed rulemaking is the regulation relating to the conduct of scientific research. Proposed paragraph (5) would allow programs to disclose information from patient records for the conduct of scientific research if that disclosure is made in accordance with 42 C.F.R. § 2.52 (relating to research activities) and if there is an agreement in writing that patient names and other identifying information will not be disclosed. (See proposed paragraph (5)).

The Department has also included in this proposed rulemaking language similar to the federal regulation dealing with audit and evaluation activities. (See proposed paragraph (6)). This proposed regulation would allow state, federal, or local agency staff providing financial assistance or reimbursement to the program or authorized by law to regulate the program, or staff of third party payers performing utilization or quality control review to have access to patient records on site for purposes of audit or evaluation activities. Disclosure under this proposed paragraph would be required to be in accordance with 42 C.F.R. § 2.53 (relating to audit and evaluation activities). Such access and review is necessary for both fiscal and programmatic accountability on the part of the treatment

provider. In actual practice, Department staff and local agency staff, along with the staff of third party payers have reviewed patient records for these purposes; the inclusion of this language in the proposed regulation acknowledges existing practice. In order to protect the patient, the proposed regulation would include a prohibition on the inclusion of any patient identifying information in reports resulting from such reviews and audits.

Finally, proposed paragraph (7) is a general provision that makes it clear that even though patient information may be disclosed without consent in those instances enumerated in the proposed subsection, the information made available must be limited to that information that is relevant and necessary to the purpose for which the information is sought.

(e) Patient's Access to Records.

This proposed subsection contains new subject matter. The Department has included a provision that would allow a patient to have access to the patient's own records. Again, in an effort to balance the need to protect the patient, the Department has acknowledged that a program may remove portions of the record prior to the patient's inspection, if the program determines the information may be detrimental to the patient. The patient may appeal this decision, request the removal of information the patient believes to be inaccurate, irrelevant, outdated or incomplete. The patient may also submit rebuttal data or memoranda if he patient chooses to do so.

(f) Consent Form.

In order to eliminate questions over what makes a consent valid and to streamline the disclosure process, the Department has proposed minimum requirements for a valid consent form to be used by programs to obtain consent from a patient to disclose information. (See proposed subsection (f)). These elements must be present in a consent form for it to be valid. In addition to requirements such as the patient's name, the name of the program, the specific information being disclosed, the specific purpose of the disclosure and a signature, the proposed subsection would include a requirement that there be included on the form a place for a recordation of an oral consent to be made by a person physically unable to provide a signature. (See proposed paragraph (viii)). There would also be a requirement that the consent include either a date of expiration, or an event or condition upon which expiration would be conditioned. (See proposed paragraph (ix)). Finally, the consent would require a statement that the consent is subject to revocation at any time, except to the extent that the program or person who is to make the disclosure has already acted upon it. (See proposed paragraph (x)).

C. AFFECTED PERSONS

The proposed amendment to Section 255.5 would benefit individuals seeking treatment for substance abuse problems. Individuals seeking treatment would benefit from the amendments because they would have greater access to services, more appropriate lengths of stay, and improved coordination between various levels and types of care. In addition, individuals seeking treatment would have the ability to control the disclosure of their confidential information by authorizing the release of specific protected information by a signed consent.

Programs would also benefit from the proposed amendments because the proposed amendments would expand the amount of drug and alcohol treatment information that may be disclosed to third party payers, while still restricting release of personal and possibly stigmatizing information that would not aid in the determination of appropriate levels of care or the need for treatment. Further, programs would be able to coordinate care by providing specific information that would be required for utilization and review of services as requested by third party payers.

D. COST AND PAPERWORK ESTIMATE

The proposed amendments would have no fiscal impact on the Commonwealth, local governments that do not operate licensed drug or alcohol abuse programs, or the general public, nor would they create any measurable additional fiscal or paperwork requirements for the regulated community or those local governments that operate licensed programs. Programs are already required to have in place policies and procedures relating to disclosure of confidential information; these proposed amendments would require some updating to those policies and procedures to address the expansion of what information may be released, but this should take minimal effort.

Further, since several of the proposed amendments closely follow existing federal requirements, again, little effort should be required to come into compliance with the proposed amendments. For example, there should be little additional paperwork or cost stemming from the proposed regulation setting out the minimum elements for a consent

form; these requirements follow existing federal regulatory provisions relating to consent forms for release of drug and alcohol abuse patient information. (See 42 C.F.R. § 2.31 (form of written consent).

In addition, there should be no measurable additional paperwork or cost impact to the regulated community from the proposed requirement relating to patient access to records. The proposed requirements are similar to those currently contained in 28 Pa. Code § 709.30 (relating to client rights), which apply to all freestanding drug and alcohol treatment facilities. These proposed requirements are also similar to those requirements put in place by the privacy rules resulting from the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (42 C.F.R. §§ 164.524 (relating to access of individuals to protected health information)). Programs that are required to comply with HIPAA and to be licensed by the Department should already have in place systems allowing for patient accessibility to information, for appeals of patients whose access to that information is limited, and for allowing patients to correct that information and submit rebuttal data. These systems should be adequate for the requirements relating to patient access in these proposed amendments.

E. STATUTORY AUTHORITY

The Department is authorized to regulate drug and alcohol abuse treatment facilities pursuant to Articles IX and X of the Public Welfare Code (62 P.S. §§ 901-1087) as transferred to the Department under Reorganization Plan No. 2. of 1977 (71 P.S. § 751-25) (transferring duties under the Public Welfare Code with regard to regulation,

supervision, and licensing of drug and alcohol abuse treatment facilities to the Governor's Council on Drug and Alcohol Abuse (Council)) and Reorganization Plan No. 4 of 1981 (71 P.S. § 751-31) (transferring the functions of the Council to the Department). The Department is also authorized to promulgate regulations under Section 4 of the Pennsylvania Drug and Alcohol Abuse Control Act (71 P.S. §§ 1690.101, 1690.104).

F. EFFECTIVENESS/SUNSET DATES

The proposed amendments would become effective upon their publication in the Pennsylvania Bulletin as final rulemaking. No sunset date has been established. The Department will continually review and monitor the effectiveness of these regulations.

G. REGULATORY REVIEW

Under Section 5(a) of the Regulatory Review Act (71 P.S. §§ 745.1 – 745.15), the Department submitted a copy of this proposed regulation on November 29, 2007, to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the House Health and Human Services Committee and the Senate Public Health and Welfare Committee. In addition to submitting the proposed amendments, the Department has provided IRRC and the Committees with a copy of a Regulatory Analysis Form prepared by the Department in compliance with Executive Order 1996-1, "Regulatory Review and Promulgation." A copy of this material is available to the public upon request.

If IRRC has any objections to any portion of the proposed amendments, it will notify the Department by _____. The notifications shall specify the regulatory review criteria which have not been met by that portion. The Act specifies detailed procedures for review, prior to final publication of the regulation by the Department, the General Assembly and the Governor, of objections raised.

H. CONTACT PERSON

Interested persons are invited to submit written comments, suggestions or objections regarding the proposed regulation to Janice Staloski, Director, Bureau of Community Program Licensure and Certification, Department of Health, 132 Kline Plaza, Suite A, Harrisburg, PA 17104-1579, (717) 783-8665, within 30 days after publication of this notice in the Pennsylvania Bulletin. Persons with a disability who wish to submit comments, suggestions, or objections regarding the proposed regulation may do so by using the above number or address. Speech and/or hearing impaired persons may use V/TT (717) 783-6514 or the Pennsylvania AT&T Relay Service at (800-654-5984[TT]). Persons who require an alternative format of this document may contact Ms. Staloski so that necessary arrangements may be made.

ANNEX A

DEPARTMENT OF HEALTH

TITLE 4 – ADMINISTRATION

***

PART XI. GOVERNOR'S COUNCIL ON DRUG AND ALCOHOL ABUSE

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CHAPTER 255. MANAGEMENT INFORMATION, RESEARCH AND EVALUATION

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§ 255.5. [Projects and coordinating bodies: disclosure of client-oriented information] Confidentiality of Patient Records and Information.

[(a) *Disclosure.* Information systems and reporting systems shall not disclose or be used to disclose client oriented data which reasonably may be utilized to identify the client to any person, agency, institution, governmental unit, or law enforcement personnel. Project staff may disclose client oriented data only under the following situations:

(1) With or without the consent of the client information may be released to those judges who have imposed sentence on a particular client where such sentence is conditioned upon the client entering a project. Information released shall be limited to that provided for in subsection (b).

(2) With or without the consent of the client, information may be released to those duly authorized probation or parole officers or both who have assigned responsibility to clients in treatment if the probation or parole of the client is

conditioned upon his being in treatment. Information released shall be limited to that provided for in subsection (b).

(3) With or without the consent of the client, information may be released to judges who have assigned a client to a project under a pre-sentence, conditional release program. Presentence conditional release programs include preindictment or preconviction conditional release such as Accelerated Rehabilitative Disposition, probation without verdict or disposition in lieu of trial under sections 17 and 18 of Act 64 (35 P.S. §§ 780-117 and 780-118).

(4) With the consent of the client, information may be released in writing, to a judge in order to assist that judge in deciding whether to initiate conditional release programs including those specified in paragraph (3).

(5) Projects may disclose any information to the attorney of a client provided as follows:

(i) The client consents, in writing to the disclosure of information.

(ii) The attorney is representing the client in a criminal, civil or administrative proceeding.

(6) Projects may disclose with the consent of a client, in writing, the information to employers of a client to further the rehabilitation of a client; or, to a prospective employer who affirmatively expresses that information is sought to enable the employer to engage the client as an employe. Such information shall be limited to whether the client has or is receiving treatment with the project.

(7) Projects may disclose information as set forth in subsection (b) with the consent of a client, in writing, to an insurance company, health, or hospital plan or

facsimile thereof, which has contracted with the client to provide or will provide medical, hospital, disability or similar benefits. In the event that an insurance company, health, or hospital plan remains dissatisfied with the content of the information released with regard to a client in accordance with this paragraph, such insurance company, health or hospital plan may apply to the Executive Director for additional information with the written consent of the client and, upon approval by the Executive Director, such information may be released.

(8) Projects may disclose information as set forth in subsection (b) with the consent of a client, in writing, to governmental officials for the purpose of obtaining governmental benefits due the client as a result of his drug or alcohol abuse or dependence.

(9) In emergency medical situations where the life of the client is in immediate jeopardy, projects may release client records without the consent of the client to proper medical authorities solely for the purpose of providing medical treatment to the client.

(10) Projects shall keep and maintain a written record of all information and data which are disclosed under this section.

(b) *Restrictions*. Information released to judges, probation or parole officers, insurance company health or hospital plan or governmental officials, under subsection (a)(1), (2), (4), (7) and (8), is for the purpose of determining the advisability of continuing the client with the assigned project and shall be restricted to the following:

(1) Whether the client is or is not in treatment.

(2) The prognosis of the client.

(3) The nature of the project.

(4) A brief description of the progress of the client.

(5) A short statement as to whether the client has relapsed into drug, or alcohol abuse and the frequency of such relapse.

(c) *Record Transfer*. The Client Admission Forms, the treatment/Discharge Forms, and Discharge Summary records are the only client records which may be transferred for treatment purposes. The transfer may be initiated upon the request of a client or by the present project of a client. In any case, the client shall fully understand the nature of the information, the purpose of the record transfer and the identity of the recipient of the information. Only after these conditions are met, may the client authorize the transfer by signing a release Form provided by the UDCS.

(d) *Coordinating bodies*. Coordinating bodies can gather and retain client oriented data provided they will receive or send only those forms as listed in subsection (c) in assigning or transferring clients and those bodies will not disclose such data, except to the Council, in manner that is consistent with this chapter and Act 63.]

(a) Definitions.

The following words and terms, when used in this section, have the following meanings, unless the context clearly indicates otherwise:

Program – A medical facility, clinic, rehabilitation or treatment program, institution, practitioner, project or other entity licensed or holding itself out to provide treatment for

drug or alcohol abuse or dependence or any government agency authorized to provide treatment for drug or alcohol abuse or dependence.

Patient record -- A record, document or other information, whether written, electronic, or in any other form or format, relating to a patient's treatment for drug or alcohol abuse or dependence that is prepared or obtained by a program. A patient record may include medical, psychological, social, occupational, financial and other data prepared or obtained as part of the diagnosis, classification and treatment of a patient.

Patient information – A patient record.

Medical authorities and medical personnel – A physician, nurse, emergency medical technician or other person employed, licensed, certified, or otherwise authorized by law to provide medical, mental health or addiction treatment to a patient.

Government officials – Officials or employees of federal, state or local government agencies responsible for assisting a patient to obtain benefits or services due to the patient as a result of the patient's drug or alcohol abuse or dependence.

Third party payer – An entity, such as an insurance company, that pays for diagnosis, treatment, or referral for treatment services provided to a patient as a result of the patient's drug or alcohol abuse or dependence.

(b) Scope and Policy.

(1) This section applies to the record of a patient seeking, receiving or having received addiction treatment services from any program.

(2) A patient seeking or receiving services from an addiction treatment program is entitled to do so with the expectation that information about the patient will be treated with respect and confidentiality by those providing services. Confidentiality between a provider of addiction treatment services and the provider's patient is necessary to develop the trust and confidence that is important for therapeutic intervention.

(3) The patient record of a patient receiving addiction treatment services is the property of the program providing services. The patient shall exercise control over the release of information contained in the patient record except as limited by subsections (c) and (d), and shall be provided with access to the patient record except as limited by subsection (e).

(4) Program staff shall respect the patient's privacy and confidentiality when using or discussing patient information.

(5) Unless otherwise noted, redisclosure of patient information is prohibited unless specifically reauthorized by the patient.

(6) The disclosure of a patient record or information from the patient record may not be used to initiate or substantiate criminal charges against the patient.

(c) Consensual Release of Patient Records and Information.

(1) With the patient's written consent, a program may release a patient record to medical personnel, as defined above, for the purpose of diagnosis, treatment or referral for treatment.

(2) With the patient's written consent, a program may release a patient record to government officials and third-party payers to obtain benefits due the patient as a result of his or her drug or alcohol abuse or dependence.

(i) A program shall limit the patient information released to government officials and third-party payers to the information necessary to accomplish the specific purpose for the disclosure.

(ii) If the patient information requested by a government official or third party payer is necessary to determine medical necessity for service admission, continued stay, discharge, referral, concurrent review, coordination of care and payment for entitled service benefits, a program shall limit the patient information released to the government official or third-party payer to the following:

(A) A statement of whether or not the patient is in treatment for drug or alcohol abuse or dependence.

(B) The patient's level of intoxication from alcohol, illicit drugs or medication, including the quantity, frequency and duration of use, and any specific withdrawal symptoms exhibited by the patient currently or in the past.

(C) The patient's vital signs, specific medical conditions to include pregnancy, specific medications taken and laboratory test results.

(D) The patient's specific diagnosis, mental status, level of functioning and treatment history.

(E) A brief description of the patient's progress in treatment related to the impact of substance use, abuse or dependence on life problems, participation in program activities and motivation to change.

(F) The patient's risk level for resuming substance use, abuse or dependence based on patterns of use, relapse history, existing relapse triggers and coping skills to maintain recovery.

(G) The patient's social support system, environmental supports and stressors that may impact ongoing recovery.

(3) With the patient's written consent that includes confirmation of legal representation, a program may disclose patient information to any lawyer(s) representing the patient as a client.

(4) With the patient's written consent, a program may disclose patient information to the patient's probation or parole office if the following occur:

(i) Participation in the program is a condition of the patient's probation or parole; and

(ii) The probation or parole office has a need for the information in connection with its duty to monitor the patient's progress. The probation or parole office that receives patient information under this section may only use or redisclose the information to carry out its official duties with regard to the patient's conditional release from custody.

(d) Non-Consensual Release of Patient Records and Information.

(1) A program may disclose a patient record, without the patient's consent, to proper medical authorities in emergency medical situations where the patient's life is in immediate jeopardy.

(2) A program may disclose a patient record, without the patient's consent, pursuant to an order of a court of competent jurisdiction issued after an application showing good cause for the disclosure.

(3) A program may disclose the following communications from programs to law enforcement personnel:

(i) Communications that are directly related to a patient's commission of a crime on the premises of the program or against program personnel or a threat to commit such a crime;

(ii) Communications that are limited to the circumstances of the incident, including the patient status of the individual committing or threatening to commit the crime, that individual's name and address and that individual's last known whereabouts.

(4) A program may disclose information from patient records when reporting incidents of suspected child abuse in accordance with the Child Protective Services Law (23 Pa.C.S. § 6301, et. seq.) to the appropriate State or local authorities, except that restrictions on redisclosure of patient records in this section and in federal law and regulations relating to confidentiality of drug and alcohol abuse client information, including the prohibition against redisclosure and use in civil or criminal proceedings that may arise out of the report of suspected child abuse and neglect continue to apply.

(5) A program may disclose information from patient records for the purpose of conducting scientific research if the disclosure is made in accordance with 42 CFR § 2.52 and upon agreement in writing that patient names and other patient identifying information will not be disclosed.

(6) A program may disclose information from patient records to persons reviewing records on program premises in the course of performing audits or evaluations on behalf of any federal, state or local agency which provides financial assistance to the program or is authorized by law to regulate its activities, or on behalf of any third-party payer providing financial assistance or reimbursement to the program or performing utilization or quality control reviews of the program.

(i) A disclosure made in the course of audit or evaluation activities shall be made in accordance with 42 CFR § 2.53.

(ii) A report produced as a result of an audit or evaluation may not disclose patient names or other patient identifying information.

(7) Patient information made available under this section shall be limited to that information relevant and necessary to the purpose for which the information is sought.

(e) Patient's Access to Records.

(1) A patient has the right to inspect the patient's own records.

(i) The program may temporarily remove portions of the records prior to inspection by the patient if the program determines that the information may be detrimental if presented to the patient.

(ii) The program shall document reasons for removing portions of the records keep them on file.

(2) The patient has the right to appeal a decision limiting access to his or her own records to the program.

(3) The patient has the right to request the correction of inaccurate, irrelevant, outdated or incomplete information from his or her records.

(4) The patient has the right to submit rebuttal data or memoranda to his or her own records.

(f) Consent Form.

(1) A patient's consent to disclose information shall be in writing and include:

(i) The name of the patient;

(ii) The name of the program or person making the disclosure;

(iii) The name and title of the person to whom disclosure is being made or the name of the organization to which disclosure is being made or both;

(iv) The specific information being disclosed;

(v) The specific purpose of the disclosure;

(vi) The dated signature of the patient, following a statement that the patient understands the nature of the release;

(vii) The dated signature of the person obtaining the consent from the patient;

(viii) A place to record an oral consent to release of information given by a person physically unable to provide a signature and a place for the signatures of two responsible persons who witnessed that the person understood the nature of the release and freely gave oral consent;

(ix) The expiration date of the consent, or the event or condition the occurrence of which will cause the consent to expire; and

(x) A statement that the consent is subject to revocation at any time except to the extent that the program or person who is to make the disclosure has already acted in reliance on it.

Commonwealth of Pennsylvania

DEPARTMENT OF HEALTH

HARRISBURG

THE SECRETARY

November 28, 2007

Mr. Kim Kaufman
Executive Director
Independent Regulatory Review Commission
14th Floor, 333 Market Street
Harrisburg, PA 17101

Re: Department of Health – Proposed Regulations No. 10-186
Confidentiality of Drug and Alcohol Treatment Patient Records and Information

Dear Mr. Kaufman:

Enclosed are proposed regulations for review by the Commission in accordance with the Regulatory Review Act (71 P.S. §§745.1-745.15). The proposed regulations amend the client confidentiality provisions for patients who are receiving or have received services from licensed drug and alcohol treatment facilities. The proposed regulations clarify under what circumstances certain individuals may receive confidential client information and for what purposes such information may be used.

Section 5(g) of the Regulatory Review Act, 71 P.S. §745.5(g), provides that the Commission may, within 30 days after the close of the public comment period, convey to the proposing agency and the Standing Committees any comments, recommendations and objections to the proposed regulations. The Department expects the regulations to be published on December 15, 2007. A 30-day comment period is provided.

Section 5.1(a) of the Regulatory Review Act, 71 P.S. §745.5a(a), provides that upon completion of the agency's review of comments, the agency shall submit to the Commission a copy of the agency's response to the comments received, the names and addresses of the commentators who have requested additional information relating to the final-form regulations, and the text of the final-form regulations which the agency intends to adopt.

POST OFFICE BOX 90, HARRISBURG, PA 17108 717-787-6436

The Department will provide the Commission within 5 business days of receipt, a copy of any comment received pertaining to the proposed regulations. The Department will also provide the Commission with any assistance it requires to facilitate a thorough review of the proposed regulations. If you have any questions, please contact Brent Ennis, Director of the Office of Legislative Affairs, at (717) 783-3985.

Sincerely,

Calvin B. Johnson, M.D., M.P.H.
Secretary of Health

Enclosures

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER:	10-186
SUBJECT:	CONFIDENTIALITY OF PATIENT RECORDS AND INFORMATION
AGENCY:	DEPARTMENT OF HEALTH

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

RECEIVED
2007 NOV 29 PM 3:35
INDEPENDENT REGULATORY REVIEW COMMISSION

FILING OF REGULATION

DATE	SIGNATURE	DESIGNATION
11/29/07		HOUSE COMMITTEE ON HEALTH & HUMAN SERVICES
11/28/07		MAJORITY CHAIRMAN Frank Louis Oliver Minority Chairman, George Kenney
11/29		SENATE COMMITTEE ON PUBLIC HEALTH & WELFARE
11/29		MAJORITY CHAIRMAN Edwin B. Erickson
11/29/07	Kathy Cooper	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
		LEGISLATIVE REFERENCE BUREAU (for Proposed only)

November 19, 2007