

Commonwealth of Pennsylvania



DEPARTMENT OF HEALTH
HARRISBURG

NOV 29 2007

THE SECRETARY

November 28, 2007

The Honorable Edwin B. Erickson
Majority Chairperson
Senate Public Health and Welfare Committee
281 Main Capitol Building
Harrisburg, PA 17120-3026

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

Dear Senator Erickson:

Enclosed are proposed regulations for review by your Committee 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(d) of the Regulatory Review Act, 71 P.S. §745.5(d), provides that the Committee may, at any time prior to the submittal of the regulation in final form, convey to the proposing agency and the Independent Regulatory Review Commission its comments, recommendations and objections to the proposed regulations and provide the agency with any pertinent staff reports. 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 Committee 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.

The Department will provide the Committee within 5 business days of receipt, a copy of any comment received pertaining to the proposed regulations. The Department will also provide the Committee 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,

A handwritten signature in black ink, appearing to read 'C. Johnson', written over a horizontal line.

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

Enclosures

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

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<p>Copy below is hereby approved as to form and legality. Attorney General</p> <p><i>Andrew W. Elliott</i></p> <p>BY _____ DEPUTY ATTORNEY GENERAL NOV 16 2007 DATE OF APPROVAL</p> <p>Check if applicable. Copy not approved. Objections attached.</p>	<p>Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by:</p> <p>DEPARTMENT OF HEALTH (AGENCY)</p> <p>DOCUMENT/FISCAL NOTE NO. <u>10-186</u> DATE OF ADOPTION: _____</p> <p><i>Calvin B. Johnson</i></p> <p>BY: <u>Calvin B. Johnson, M.D., M.P.H.</u></p> <p>TITLE: <u>SECRETARY OF HEALTH</u></p>	<p>Copy below is hereby approved as to form and legality. Executive or independent Agencies</p> <p><i>Andrew C. Clark</i></p> <p>BY _____ SEP 24 2007 DATE OF APPROVAL</p> <p>(Deputy General Counsel) (Chief Counsel, Independent Agency) (Strike inapplicable title)</p> <p>Check if applicable. No Attorney General approval or objection within 30 days after submission.</p>
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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.