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**INDEPENDENT REGULATORY REVIEW COMMISSION**
333 MARKET STREET, 14TH FLOOR, HARRISBURG, PA 17101

February 13, 2008

Honorable Calvin B. Johnson, M.D., M.P.H., Secretary
Department of Health
802 Health and Welfare Building
Harrisburg, PA 17108

Re: Regulation #10-186 (IRRC #2654)
Department of Health
Confidentiality of Patient Records and Information

Dear Secretary Johnson:

Enclosed are the Commission's comments for consideration when you prepare the final version of this regulation. These comments are not a formal approval or disapproval of the regulation. However, they specify the regulatory review criteria that have not been met.

The comments will be available on our website at www.irrc.state.pa.us. If you would like to discuss them, please contact me.

Sincerely,

Kim Kaufman
Executive Director
wbg
Enclosure
cc: Honorable Ted B. Erickson, Chairman, Senate Public Health and Welfare Committee
Honorable Vincent J. Hughes, Minority Chairman, Senate Public Health and Welfare Committee
Honorable Frank L. Oliver, Majority Chairman, House Health and Human Services Committee
Honorable George T. Kenney, Jr., Minority Chairman, House Health and Human Services Committee

# Comments of the Independent Regulatory Review Commission

# on

# Department of Health Regulation #10-186 (IRRC #2654)

# Confidentiality of Patient Records and Information

# February 13, 2008

We submit for your consideration the following comments on the proposed rulemaking published in the December 15, 2007 *Pennsylvania Bulletin*. Our comments are based on criteria in Section 5.2 of the Regulatory Review Act (71 P.S. § 745.5b). Section 5.1(a) of the Regulatory Review Act (71 P.S. § 745.5a(a)) directs the Department of Health (Department) to respond to all comments received from us or any other source.

**1. Statutory authority; Consistency with the intent of the General Assembly.**

The Department has cited the Pennsylvania Drug and Alcohol Abuse Control Act (Act) (71 P.S. § 1690.101 et. seq.) as one of the statutes that provides it the authority to promulgate this regulation. We agree that § 1690.104(j) of the Act provides the Department broad authority to promulgate regulations necessary to carry out provisions of the Act. We note that the Act also establishes the Pennsylvania Advisory Council on Drug and Alcohol Abuse (Council) as the recognized advisory council to the Department for drug and alcohol programs. Section 1690.103(e)(2) of the Act imposes an obligation on the Department to "seek the written advice and consultation" of the Council when promulgating regulations "necessary to carry out the purposes of this act."

Commentators, including the Council, have expressed concern that the Council was not consulted as required by § 1690.103(e)(2). In addition, Representative George Kenney, Republican Chairman of the Health and Human Services Committee, and Senator Michael Stack, have submitted comments expressing a similar concern. Based on our review of the minutes of the Council's recent meetings and input from the Council, we concur that the Department did not seek the written advice and consultation of the Council on this version of the proposed rulemaking in a meaningful way. What is the Department's statutory authority for proceeding with the rulemaking without first seeking the written advice and consultation of the Council?

We recommend that the Department consider withdrawing this proposed regulation to provide the Council to an opportunity to review it as required by § 1690.103(e)(2). In the alternative, we recommend that the Department issue an advanced notice of final rulemaking. This would allow the regulated community, including the Council, an opportunity to resolve as many remaining concerns as possible prior to the submittal of the final-form regulation.

**2. Possible conflict with statutes.**

Commentators have stated that the proposed regulation conflicts with Act 106 of 1989 (40 P.S. § 908-1 et. seq.) (Act 106) and a related Commonwealth Court case, *The Insurance Federation of PA v. Commonwealth,* 929 A.2d 1243 (2007) (*Insurance Federation of PA).* As noted by the Court in that case, "Act 106 plainly provides for mandatory benefits and...nothing solely on its face, apart from certification and referral [from a licensed physician or psychologist], limits the availability of mandatory benefits by any extraneous procedures."

We believe that certain sections of this proposed regulation conflict with Act 106 because they appear to allow third-party payers to deny addiction treatment benefits to insureds who have been certified and referred by a licensed physician or psychologist. The specific provisions that conflict with Act 106 are addressed in more detail below. However, as a general comment, we recommend that the final-form regulation include provisions that clearly state that third-party payers may not deny treatment to insureds covered by Act 106 who have the necessary certification and referral from a licensed physician or psychologist, regardless of what patient information is obtained via consensual or nonconsensual release of the patient record.

**3. Need for the regulation.**

According to the Regulatory Analysis Form, the compelling public interest that justifies this rulemaking is twofold. First, it will correct a conflict with federal confidentiality regulations "thereby reducing any perceived complexities in the regulations that drug and alcohol treatment facilities must comply with." Second, the Department states that some of the provisions of the existing regulation that are being replaced by this proposal are "outdated and impede service delivery and the coordination of care for individuals with substance abuse problems."

We have two concerns. First, the Department has failed to identify the specific sections of the federal regulations that conflict with the existing regulations. We request the specific sections that are in conflict be identified.

Second, the Department has failed to explain why the regulations are outdated and how they impede service delivery and coordination of care. The final-form regulation should provide a more detailed explanation on why this regulation is needed. In addition, the Department should quantify how many people a year do not receive treatment because the existing regulation is inadequate.

**4. Protection of the public health, safety and welfare.**

The Department has stated that the risks associated with not making the proposed amendments are "increased regulatory obstacles to drug and alcohol treatment facilities in the delivery of treatment services to the individuals they serve." Representative Frank Oliver, Chairman of the Health and Human Services Committee, Representatives George Kenney and Gene DiGirolamo and Senators Michael Stack, Roger Madigan and Mike Folmer, along with a large segment of the regulated community, disagree with this statement. They believe the proposed regulation will *increase* obstacles in the delivery of treatment services because the client and counselor relationship, which relies on trust and the expectation of confidentiality, will be undermined.

They note addiction is a unique form of illness because of cultural attitudes and stigmas associated with it. In order for individuals suffering from addiction to seek treatment and communicate freely with counselors, ensuring confidentiality is paramount.

We agree with the commentators that an unintended consequence of the proposal could be fewer people seeking and receiving treatment for their drug and alcohol addiction problems for fear that personal and potentially embarrassing information could be released to others. In the Preamble to the final-form regulation, the Department should explain why this proposal will not discourage people who need help with their drug or alcohol problems from seeking the necessary treatment, and how it adequately protects the public health, safety and welfare of the citizens of this Commonwealth.

**5. Economic or fiscal impact of the regulation.**

The Department has indicated that the proposal will not impose any costs on the regulated community. Commentators, including Representative Oliver, disagree with that statement. They note the proposal will increase the administrative burden of treatment service providers, including extensive training that will be needed to implement the regulations. How did the Department determine that the regulated community will not experience a negative fiscal impact when the proposal is implemented?

**6. Implementation procedures and timetables for compliance by the public and the regulated community.**

As noted above, the regulated community believes extensive training will be needed to implement this regulation. Accordingly, we recommend that the effective date of the regulation be six to 12 months after it is published as a final rule in the *Pennsylvania Bulletin.* This would provide the Department and the regulated community time to develop the necessary procedures for administering the rule and train those that will be implementing it.

**Section 255.5. Confidentiality of patient records and information.**

**7. Section 255.5(a) *Definitions.* – Need; Clarity and lack of ambiguity.**

*Government officials*

This definition reads as follows:

> 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.

We have four concerns. First, § 1.7(e) of the *Pennsylvania Code and Bulletin Style Manual* states that a term being defined may not be included as part of the definition. Accordingly, this definition needs to be amended. Second, what is meant by the following terms or phrases:

"assisting a patient," "benefits" and "services"? We recommend that these terms or phrases be defined so that it is clear which individuals will have access to patient information. Third, is there a difference between "abuse" and "dependence"? This should be explained in the final-form regulation. Finally, would the defined term include probation and parole officers?

*Medical authorities and medical personnel*

Physicians, nurses, emergency medical technicians and other persons employed, licensed, certified or otherwise authorized by law to provide medical, mental health or addiction treatment to a patient fall under this definition. We have four concerns. First, the definition does not specify what licensing or certifying authorities would be acceptable. Would a physician or nurse licensed or certified by another state or country fall under this definition? Second, the phrase "otherwise authorized by law" is vague. What laws would apply? Third, the inclusion of the word "employed" in this definition would open the scope of this definition to any employee of an entity that provides medical, mental health or addiction treatment services. We suggest that only people licensed or certified in a particular medical field directly related to addiction treatment be included in this definition. Finally, we recommend that the terms "mental health" and "addiction treatment" be defined.

*Patient record*

This definition may include information such as "medical, psychological, social, occupational, financial and other data prepared or obtained as part of the diagnosis, classification and treatment of a patients." We raise three issues. First, Representative Dennis O'Brien, Speaker of the House, wrote to express his concern with "provisions that provide for the dissemination of drug and alcohol addiction treatment records and **other personal information** to third party payers." (Emphasis added.) We are also concerned about the release of personal information to third-party payers and others that would have access to it under this proposal, and the potential for misuse or abuse of that information, either intentional or unintentional. What is the need for including the "social, occupation, financial and other data" of the patient in this definition?

Second, what is meant by the phrase "patient's treatment"? This should be defined in the final-form regulation.

Finally, the term "other data" is vague and should be deleted.

*Program*

Similar to our concerns with the definition of "medical authorities and medical personnel," we believe this definition is vague. In particular, the terms "institution," "practitioner," "project" and "other entity" should be defined. Also, the inclusion of the phrase "or holding itself out to provide treatment for drug or alcohol abuse or dependence" is problematic because it could apply to entities not properly licensed or certified. We recommend that the definition be narrowed to treatment facilities licensed by the Department.

**8. Section 255.5(b) *Scope and policy.* – Need; Reasonableness; Clarity and lack of ambiguity.**

*Paragraph (1)*

This paragraph states that this section of the regulation applies to the record of a patient "seeking, receiving or having received" treatment. Why are records of patients that have received treatment included? How long will the records be available for consensual and nonconsensual release?

*Paragraph (2)*

Under this paragraph, patients are to expect that their information will be treated with respect and confidentiality by those providing services. Does the phrase "those providing services" mean the same thing as the defined term "program"? If so, we recommend that the defined term be used. In addition, we recommend that the expectation of privacy be extended to any entity that may have access to patient information or a patient's record. What are the consequences for a program or other entity that violates the confidentiality of patient information or a patient's record? How will the Department determine if programs are in compliance with the regulation? We have similar concerns with Paragraph (4).

*Paragraph (3)*

This paragraph states the record of a patient receiving addiction treatment services is the property of the program providing services. Who owns the record of a patient that has already received addiction treatment services and how can that record be released? This should be explained in the final-form regulation.

*Paragraph (5)*

Redisclosure of patient information is prohibited under Paragraph (5), unless otherwise noted. We have two concerns. First, we agree with Speaker O'Brien's concern that "the proposed regulations do not provide sufficient safeguards against subsequent intentional and unintentional dissemination by third party payers." What protects the confidentiality of the patient record after it leaves the program? We recommend that the final-form regulation list the specific federal and state laws and regulations that prohibit any entity or individual from redisclosing any information contained in the patient record and the penalties associated with violating the regulations and statutes. If no laws or regulations exist that protect the patient record once it is released by the program, how can the Department ensure the confidentiality of these records?

Second, what does the phrase "unless otherwise noted" refer to? If redisclosure is permitted under this regulation, the sections that address redisclosure should be cross-referenced.

*Paragraph (6)*

Under this paragraph, disclosure of patient information from a patient record may not be used to initiate or substantiate criminal charges "against the patient." We have two questions. First, can information obtained from a patient's record be used to initiate or substantiate criminal charges against other people?

Second, if a patient is on probation or parole, can information obtained from that patient's record be used to revoke the probation or parole?

**9. Section 255.5(c) *Consensual release of patient records and information.* – Statutory authority; Need; Reasonableness; Implementation procedures; Clarity and lack of ambiguity.**

*Paragraph (2)*

This paragraph states that a program can release information to government officials and third-party payers "to obtain benefits due the patient as a result of his drug or alcohol abuse or dependence." The Department should clarify whether "benefits due the patient as a result of his or her drug or alcohol abuse or dependence" means addiction treatment or treatment for other conditions (for instance, cirrhosis of the liver) that may develop as a result of drug or alcohol dependence. We note that defining the terms "benefits" and "services" as recommended above would aid in the clarification of this paragraph.

In addition, to be consistent with the definition of "government officials," we recommend that the phrase "or services" be added after the word "benefits."

*Paragraph (2)(i)*

This paragraph reads as follows: "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." We have two concerns. First, who determines what information is necessary? Is the program responsible for this decision or do government officials and third-party payers make the determination? If a dispute arises between the program and government officials or third-party payers as to what information is necessary, how will it be resolved? Will a patient be able to receive treatment while the dispute is being resolved? We recommend that the final-form regulation specify which party is responsible for making this determination and how disputes will be resolved.

Second, the phrase "to the information necessary to accomplish the specific purpose for the disclosure" is vague. It is our understanding that the specific purpose of the disclosure can only be to obtain benefits that are due the patient. If that is the case, Paragraph (2)(i) should be amended to explicitly state that fact.

*Paragraph (2)(ii)*

This paragraph limits information that can be released to a government official or a third-party payer. We have three concerns. First, the following terms are used in this paragraph, but are not defined: "medical necessity," "concurrent review," "coordination of care" and "entitled service benefits." We recommend that these terms be defined.

Second, the Department should clarify whether third-party payers accessing patient records under this provision may use them to determine "medical necessity" and to deny addiction treatment benefits to a patient who is covered by Act 106 and has been certified and referred by a licensed physician or psychologist. Pursuant to *Insurance Federation of PA*, a third-party payer covered by Act 106 is obligated to pay for specified addiction treatment services whenever an insured is certified and referred by a licensed physician or psychologist. If a determination of medical necessity could result in such a denial, the Department should explain its statutory authority for promulgating this provision, in light of Act 106 and Commonwealth Court's ruling in *Insurance Federation of PA.*

Third, the Department should explain the need for third-party payers to access patient records under this provision. Since third-party payers covered by Act 106 must provide addiction treatment benefits to certified and referred patients, what need might they have for this information?

*Paragraph (4)*

Under Paragraph (4), a program may disclose patient information to a patient's probation or parole officer. Unlike paragraph (2), which limits the information from a patient's record that can be released to government official and third-party payers, this paragraph appears to allow the officer to review the entire patient record. What is the need for allowing a probation or parole officer access to the entire patient record? How often do probation or parole officers request to see patient records?

*Paragraph (4)(ii)*

Similar to our concern on Paragraph (2)(i) on who determines what information is necessary, who will determine if a probation or parole officer has a need for the patient record? Is the program responsible for this decision or do the officers make the determination? If a dispute arises between the program and the officers as to actual need, how will it be resolved? We recommend that the final-form regulation specify which party is responsible for making this determination and how disputes will be resolved.

**10. Section 255.5 (d) *Nonconsensual release of patient records and information.* – Statutory authority; Need; Reasonableness; Implementation procedures; Clarity and lack of ambiguity.**

This subsection pertains to the nonconsensual release of patient records and information. If patient records and information are released under this subsection, we recommend that the

patient be informed of the release, what information was released, who the information was released to and why the information was released. We also recommend that any information released without the consent of the patient be released at the same time to the patient.

*Paragraph (3)*

Paragraph (3) and Subparagraphs (3)(i) and (ii) use the undefined term "communications." We recommend that it be defined in the final-form regulation.

*Paragraph (5)*

Under this paragraph, nonconsensual release of a patient record is permitted for the purpose of conducting scientific research if there is written agreement that patient names and identifying information will not be disclosed. The final-form regulation should specify who must be parties to the written agreement.

*Paragraph (6)*

This paragraph reads as follows:

> 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.

We have four concerns. First, the phrase "to regulate its activities" is vague. Many government agencies regulate the activities of programs, for example, taxing authorities and building inspectors. The scope of Federal, State or local agencies that could have access to a patient's record should be amended to mirror the definition of "government officials" found in Subsection (a).

Second, the Department should define the following terms: "audit," "evaluation," "utilization review" and "quality control review." The final-form regulation should also explain what is being audited, evaluated or reviewed and what standards are being used to quantify the results of the audits, evaluations or reviews.

Third, the Department should explain whether disclosure of information under this provision could result in denial of addiction treatment benefits to insureds who are covered by Act 106 and have been certified and referred by a licensed physician or psychologist. If so, the Department should explain its statutory authority for promulgating this provision, in light of Act 106 and *Insurance Federation of PA.*

Fourth, the Department should provide further information as to the intended use by third-party payers of information released under this subsection. Since third-party payers covered by Act 106 must provide addiction treatment benefits to certified and referred patients, what need might they have for this information?

*Paragraph (7)*

This paragraph states the following: "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." We have two concerns. First, the phrase "relevant and necessary" is subjective and open to interpretation. It does not establish a binding norm that is clear to the regulated community. What a program believes is "relevant and necessary" can be different than what law enforcement personnel, those conducting scientific research, federal, state or local agencies and third-party payers believe is "relevant and necessary." Similar to our concern on Paragraph (c)(2)(i), who determines what information is necessary? Is the program responsible for this decision or do others make the determination? If a dispute arises between the program and those requesting the information as to what information is necessary, how will it be resolved? Will a patient be able to receive treatment while the dispute is being resolved? We recommend that the final-form regulation specify which party is responsible for making this determination and how disputes will be resolved.

Second, this provision applies to "this section," which is all of § 255.5. We suggest that the paragraph be amended to state "this subsection," which could be § 255.5(d).

**11. Section 255.5 (e) *Patient's access to records.* – Implementation procedures; Clarity and lack of ambiguity.**

Under this subsection, patients have a right to inspect their own records. If a program removes portions of a patient's records before the inspection occurs, that program must document the reasons for it and keep them on file. Patients also have a right to appeal a decision limiting access to their records. We have two recommendations. First, the final-form regulation should specify how long a program must keep the reason for denying access on file.

Second, the details of how a patient can appeal a decision of a program to limit access to their records should also be included in the final-form regulation.

# Facsimile Cover Sheet

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INDEPENDENT REGULATORY REVIEW COMMISSION
333 MARKET STREET, 14TH FLOOR, HARRISBURG, PA 17101

**To:** Yvette Kostelac
Regulatory Coordinator
**Agency:** Department of Health
**Phone:** 3-2500
**Fax:** 5-6042 3-3794 or 2-6959
**Date:** February 13, 2008
**Pages:** 11

**Comments:** We are submitting the Independent Regulatory Review Commission's comments on the Health Department's regulation #10-186 (IRRC #2654). Upon receipt, please sign below and return to me immediately at our fax number 783-2664. We have sent the original through interdepartmental mail. You should expect delivery in a few days. Thank you.

**Accepted by:** Pam Getz **Date:** 2/13/08

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