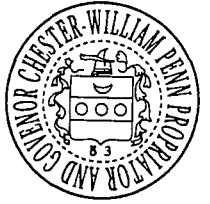




THE COUNTY OF CHESTER



COMMISSIONERS
Carol Aichele
Terence Farrell
Kathi Cozzone

DEPARTMENT OF DRUG AND ALCOHOL SERVICES
Government Services Center, Suite 325
601 Westtown Road
P.O. Box 2747
West Chester, PA 19380-0990
ADMINISTRATION:
Phone: 610-344-6620 Fax: 610-344-5743
CASE MANAGEMENT:
Phone: 610-344-5630 Fax: 610-344-5436

KIM P. BOWMAN, M.S.
Executive Director

#2654

June 27, 2008

Ms. Janice Staloski, Director
Bureau of Community Program Licensure
and Certification
Department of Health
132 Kline Plaza, Suite A
Harrisburg, PA 17104

RECEIVED
2008 JUL 1 AM 9:03
INDEPENDENT REGULATORY
REVIEW COMMISSION

**RE: Department of Health
Proposed Regulations 10-186
Changes to Drug and Alcohol Confidentiality of Patient Records and Information**

Dear Ms. Staloski:

I am writing to express my opposition to the Department of Health's April 25, 2008 Draft Final Rulemaking No. 10-186 regarding the state confidentiality protections of drug and alcohol treatment records. Despite the overwhelming amount of concern expressed about the first draft, especially the information allowed to be released to insurers, the changes made in this draft have not addressed the significant concerns that were raised.

Additionally, the revised version contains some changes that require comment and/or clarification. This includes confusing definitions, conflicts with federal regulations, concern about the information to be released to insurers, increased administrative burden and increased cost.

Currently, there is nothing in existing regulations that limits the amount of information that can be shared between agencies providing services to clients or preventing the reporting of child abuse. Therefore, these changes are not needed for client protection and care.

It appears that these regulatory changes are solely for the benefit of insurers who are not required to comply with them anyway. In contrast, individuals and families seeking treatment and the providers who serve them have much at risk, and are the only ones who can lose under these proposed regulations.

Under both the current and proposed regulations, there are consequences to the provider if they violate these regulations. The most current version of the proposed changes even added language regarding provider consequences and penalties. Clients and families also face a high price if they don't want to consent to the amount of information wanted by their insurer; they are denied payment for their care.

In contrast, third party payers are not held accountable for compliance with the existing standards and there is no consequence to them if they demand more information than the regulations allow. This consistently happens now.

The Department's FAQs state: *"But if a patient does want to receive insurance benefits or coverage, under the proposed changes, he or she can consent to the release of **limited** (emphasis added) information to the insurer."* How can the Department assert that the client would only need to release limited information?

The reality is that, just as it is now, if the patient does not agree to whatever the insurer wants they will not have access to care and no one holds the insurer accountable. Why would we not expect the insurers to continue to routinely ask, as they do now, for more than the regulations allow and then deny payment when those additional details are not provided?

It seems clear that the only party who has no consequence associated with these regulations is the insurer. Given this situation, it seems that the first step that should be considered in regulatory change would be to establish a mechanism to hold insurers accountable to the law. Only after that is done should consideration be given to whether any changes in the confidentiality regulations are needed.

Following are specific comments on the proposed regulations:

a. Definitions:

Government Officials:

This definition is confusing and much too broad. It appears that non-government officials can be government officials under this definition. Who and what determines this?

Also, this includes only those "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." There may be other government officials not related to benefits/services specific to drug and alcohol and information to these entities would need to be limited.

Whoever this definition is intended to include should be clearly articulated. The definition should not stray so far from plain language, as it does at present, that clients and families cannot easily understand the meaning.

Treatment:

This definition is confusing and also much too broad. Although these regulations relate to drug and alcohol treatment, the definition seems to include drug and alcohol treatment as an afterthought and goes well beyond the scope of treatment through the inclusion of coordination or management of services, including with a third party payer.

The federal regulations include a definition of Treatment. Why would we have a different definition? This creates a conflict.

Program:

Again, there is a definition of Program in the federal regulations. Why is a different one being created? This will be confusing and creates a conflict.

Third Party Payer:

There is a definition for this in the federal regulations; the same definition should be used to avoid confusion. Having a different definition than the federal regulations creates a conflict.

b. Scope and Policy:

(1).

Indicates it applies to records of patients who have received services. This could be construed to mean it applies retroactively to records/consents prior to any changes to the regulations. How can a patient give informed consent when the rules have changed from when they provided the information?

c. Consensual Release of Information:

(2)(i).

There is nothing that states that this subsection has any relation to any other section or sub-section. As written, it appears that you could use (2) (i) **or** (2)(ii) in releasing information to Government Officials and Third Party Payers. Why is the first sentence in this subsection necessary?

As written, this also seems to leave the door open to violate Act 106 of 1989. While there is a sentence stating that information for Act 106 cases is limited to the certification and referral, it is not clear how this relates to the first sentence of the subsection. It also seems to leave the use of (2)(ii) available to insurers for Act 106.

(2)(ii).

I continue to have serious concerns about the proposed regulations in this section. These concerns were raised in numerous comments from the initial version; not only have these concerns not been addressed, but new types of information have been added to this version (e.g. (c)(2)(D)).

The Department has indicated that the information reflects the domains of widely accepted patient placement criteria. Currently, the regulations allow insurers to be told the specific criteria the individual meets in all domains of the patient placement criteria to determine appropriate level of care.

However, the proposed regulations move beyond the criteria an individual meets and crosses the boundary to the clinical information behind the criteria. This is needed by the therapist to provide treatment but is not needed by or appropriate information for insurers.

For example, a program can currently provide diagnosis and the specific criteria an individual meets within the Emotional Behavioral dimension of the Pennsylvania Client Placement Criteria. The proposed changes now include, as information that can be released to insurers, the following? "...emotional or behavioral problems requiring treatment or negatively impacting responses to emotional or environmental stressors." Given that the insurer can already have the diagnosis and the criteria the individual meets, it can only be assumed that this would expand it to the detail of these emotional or behavioral problems. This is information that is usually very personal and difficult to disclose. Part of the challenge of treatment is an individual being able to acknowledge, understand and work through their behaviors and emotional responses, yet we want to disclose them to an insurance company?

Another simpler example is in Dimension 2, Biomedical Conditions and Complications in both the American Society of Addiction Medicine and Pennsylvania Client Placement Criteria. In this dimension, the level of care indicated is impacted by current or chronic medical conditions that may complicate treatment. Current regulations allow for disclosure of diagnosis; however, the proposed regulations go beyond diagnosis and also include things like vital signs and laboratory test results, information needed by the treating physician, not the insurance company.

Finally, and a very important consideration, is that there is no protection to insure that the information will be used by the insurance company within the intended frameworks. As stated previously, based on current experience, there appears to be no ability to enforce existing regulations with insurers, so why would these be any different?

Issues such as prior treatment history, motivation... are routinely used by insurers to deny treatment - despite the fact that the level of care criteria would actually call for higher levels of care if criteria were truly being utilized. There is a lack of client protections to guarantee that insurers appropriately utilize the criteria; therefore, it is unclear why we would sacrifice privacy rights.

(4). Information to Probation and Parole

(4)(iii)(D).

Services Plan should be defined.

(4)(iii)(F).

Medical Information - Why is this included for the drug and alcohol treatment provider?

(4)(iii)(H).

Aftercare Plan – This should be recommended aftercare services and should not be limited to inpatient discharges.

d. **Non-Consensual Release of Information from Patient Records:**

(d)(7).

This is new and would create extensive new administrative burden for providers. As written (7), which requires notification to patients of non-consensual release of information, applies to the full section (a) which includes (d)(6) regarding audits and evaluations.

There are multiple entities that routinely inspect provider records including but not limited to licensing bodies, funding entities and certification bodies. In the federal regulations there are specific requirements that must be followed to insure confidentiality is protected when records are reviewed on the premises and nothing is removed from the record. This proposed new requirement would add notification to patients of the review of their record. These are often records of patients that are long out of treatment. Given the protections that already exist, the extensive additional administrative burden and cost that this would create is not needed.

(f) Consent Form

(f) (8)

This again creates conflict with the federal regulations, The Department's draft allows for oral consent. Under the federal regulations, a signature is specifically required for consent and there is no provision for oral consent.

Even with deceased or incompetent patients, an authorized signature is specifically required.

Federal regulation specifically state: §2.31(a)... "A written consent to disclosure under these regulations must include: ... (6) The signature of the patient and, when required for a patient who is a minor, the signature of a person authorized to give consent under §2.14 or, when required for a patient who is incompetent or deceased, the signature of a person who is authorized to sign under §2.15 in lieu of the patient." (§2.14 relates to minor patients and §2.15 relates to incompetent and deceased patients.)

Cost to Implement

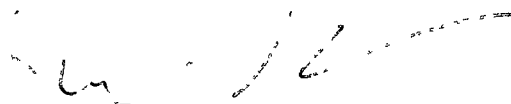
Finally, not only are there concerns with the lessening of privacy protections, but these regulations would create significant cost. The complexity of these proposed changes would require extensive training in the treatment community, and there would be a significant cost for the training alone.

In Chester County, we have approximately 111 clinical staff that would need this training. If the training were conservatively estimated at 9 hours, the cost would exceed \$50,000 in Chester County alone. This uses a conservative figure to include the training cost, as well as the cost for 50% of the staff that would need to be covered by substitutes and for lost revenue to providers for services not provided during these training hours for the other 50%.

A non-monetary cost is also the time this takes away from clients. We are experiencing tremendous workforce issues in the drug and alcohol field that impact on client access; this only adds to the problem.

For all of the reasons outlined above, I oppose the proposed changes and would urge the Department to maintain the existing privacy protections. Thank you for the opportunity to comment.

Sincerely,



Kim P. Bowman

KPB/gja