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January 14, 2008

VIA FAX AND FIRST CLASS MAIL
FAX NO.: 717-787-3188

Janice Staloski, Director
Bureau of Community Program Licensure & Certification
Department of Health
132 Kline Plaza, Suite A
Harrisburg, PA 17104-1579

Re: Department of Health
Proposed Amendments
4 Pa. Code § 255.5
Our File No. 9942

Dear Ms. Staloski:

The purpose of this letter is to provide comment to the Department of Health's ("DOH") proposed amendments ("Proposed Amendments") to 4 Pa. Code § 255.5, regarding the confidentiality of records and information pertaining to patients seeking, receiving or having received addiction services from certain programs. The Proposed Amendments were published in the Pennsylvania Register on December 15, 2007.

Kelley & Murphy, LLP, provides legal representation to, among other clients, behavioral healthcare providers throughout our Commonwealth and in other states. Among its clients are several addiction treatment programs to which the Proposed Amendments would apply and substantially affect.

Summary of Comments

The Proposed Amendments do take important steps in removing "impediment[s] to service delivery and the coordination of care for individuals with substance abuse" by permitting parties essential to the patients' care to communicate necessary information to each other regarding treatment. *See* Preface at "Purpose of the Proposed Amendments".[1] However, in doing so they eviscerate the indispensable confidentiality protections afforded under the existing rule. Addiction is a unique form of illness because of the cultural attitudes and stigma that it can engender. Accordingly, in order to encourage individuals suffering from addiction to seek

[1] The expanded patient access rights under the Proposed Amendments are a welcome improvement.

treatment and communicate freely with their treatment providers, ensuring confidentiality is paramount. It is for this reason that legal protection of information regarding addiction treatment information must be more muscular and robust than that afforded to other types of health care information.

The Proposed Amendments undo a regulatory scheme that clearly defined the scope of information that could be released and the parties permitted to receive it. The Proposed Amendments, meanwhile, create vague and expansive categories of information to be disclosed and parties permitted to receive it. In doing so, the Proposed Amendments fail to: (1) limit and clearly define the category of third parties (not involved in treatment) entitled to receive the information; (2) limit and clearly define the scope of the information that programs may disclose to these non-treating third parties; (3) limit and clearly define the purpose for which these non-treating third parties may have access to the information; (4) provide a mechanism to resolve disputes over questions of access that will inevitably arise due to the vague terminology used; (5) prohibit retaliation by third parties where patients and programs raise good faith challenges to particular demands of access to information.

Moreover, the Proposed Amendments claim to prohibit third parties, over whom the DOH has no apparent authority, from making subsequent disclosures of information they receive from programs. It will create the false impression among patients and programs that confidential information will remain so after disclosures are made to third parties.

Third Party Payers and their Agents.

Although Subsection(c)(2) of the Proposed Amendments purports to limit the amount of information that a third party payer may receive, Subsection (d)(6) is dangerously vague and, even under a narrow construction, permits such extensive access to so many third parties so as to vastly undo any limitations afforded by Subsection (c)(2).

Broad authority to payers. Subsection (d)(6) extends virtually unfettered access to "third party payers". It states that a "program may disclose information to persons reviewing records on program premises in the course of performing audits or evaluations . . . on behalf of any third-party payer providing financial assistance or reimbursement to the program or performing utilization or quality control reviews." This power, in essence, permits payers and their agents to enter the premises of a provider and review the patients' entire confidential record on demand. This places payers beyond accountability in this regard as no checks are placed upon their right of access in this regard. The only limitation is the theoretical "relevant and necessary" requirement set forth under Subsection (d)(7).

Overreaching by payers. In practice, even under the current regulatory scheme, payers tend to have a broad view of their authority to review patient records. They frequently demand to review entire patient records while articulating little or no reason or purpose. Overreaching by payers in this regard is well precedented. *See Shrager v. Magellan Behavioral Health, et al.*, No. G.D. 00-015809 (Ct. Com. Pl. Alleghany County, Pa., Mar. 10, 2003), available at http://www.managedcareandpatientprivacy.com/court_opinion.doc .

Under the Proposed Amendments, a payer or its agent would only need to state that their request is for "utilization or quality review". Unfortunately, the Proposed Amendments define neither "utilization review" nor "quality review" leaving the matter for stakeholders to sort out.

Lack of dispute resolution mechanism. Moreover, if there is a dispute over how these terms should be applied or whether certain information is "relevant and necessary" as part of such a review, there is no resolution mechanism. This is particularly troubling given that payers are inclined to respond to providers' concerns of client confidentiality with threats of provider-contract termination. *See, e.g., Shrager.*

Regarding the "actual practice" of audits and reviews. In the Preface, the DOH points out that "[i]n 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." To the extent that this practice does indeed occur it is for one of two reasons. First, some programs are unaware that these reviews contravene the existing § 255.5. While the DOH conducts training on confidentiality, it does not routinely inform program personnel that these reviews are impermissible. Such programs simply rely upon the DOH's own training. Second, other, more educated programs, who are aware that these reviews violate the existing § 255.5, accede to the demands of payers because they fear retaliation if they raise concerns and they have no confidence that the DOH will enforce the rule in this regard.

Anti-retaliation provision. Accordingly, in addition to providing a mechanism to resolve disputes arising under the rule, it should also expressly prohibit payers and other third parties from retaliating against clients and programs who raise good-faith concerns in response to demands for access to patient information. Specifically, the rule should prohibit payers from threatening to terminate a provider contract where a provider raises an honest dispute.

Lack of Protection for Privileged Information

The Preface to the Proposed Amendments (at p.4) states that "[u]nder 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." Such "highly personal" information can often be in the form of direct communications between a patient and members of the patient's treatment team made in confidence. Depending upon the circumstances, such communications can be covered by a privilege, such as the Pennsylvania Psychotherapist-Patient Privilege, 42 P.S. § 5944 or the federal social-worker privilege, *Jaffee v. Redmond*, 518 U. S. 1 (1996). It is important that patients and providers know that such communications are off-limits to any third party. The Pennsylvania Psychotherapist-Patient Privilege, for example, is an absolute privilege that prohibits a provider from disclosing covered information to any third parties (not participating in treatment) absent the waiver of the patient, except under certain narrow circumstances. However, a single disclosure of privileged information, if construed to be with the express or implicit consent of the patient, could constitute a waiver of the privilege. *See Doe v. Ensey*, 220 F.R.D. 422 (D. Pa. 2004). Such waiver would expose the privileged information to disclosure in subsequent matters, such as civil and criminal litigation. *Id.*

The rule should expressly state that such information is not subject to disclosure to third parties under any circumstances. This should include disclosures for the purpose of obtaining governmental health benefits, such as SSA disability proceedings. There is no need for any third party not involved in the treatment of the patient to have access to such intimate, privileged communications.

Vague Authority Given to Governmental Entities

Subsection (d)(6) of the Proposed Amendments also contains a vague reference to governmental authority that should be clarified. It states that 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 . . . is authorized by law to regulate its activities." The term "regulates" here should be defined. Clearly, the DOH would be included as such an agency, but would the term also include any agency that may have reason to request patient records?

Misstatement of Conflict with Federal Law

The Preface of the Proposed Amendments (at p.6) states that disclosure under Subsection (d)(6) to third parties "would be required to be in accordance with 42 C.F.R. § 2.53 (relating to audit and evaluation activities)." 42 C.F.R. § 2.53 by no means requires programs to grant such

access pursuant to (d)(6). While § 2.53 does authorize such disclosures, it does so permissively rather than compulsorily. (The phrase used is that "patient identifying information *may* be disclosed . . . ." § 2.53 (a), *emphasis supplied.*) Accordingly, the federal rule certainly permits states to impose greater restrictions on disclosures and there is no conflict in this regard with the existing § 255.5. The Proposed Amendments, in all likelihood, will cause confusion with the federal rule because the two rules are similar but not identical.

In fact, the Pennsylvania Drug and Alcohol Abuse Control Act ("Act 63"), 71 P.S. §§ 1690.101, 1690.108, is much more restrictive than the federal rule (42 C.F.R. § 2.53). In this regard, it should be noted that the enforceability of the Proposed Amendments, to the extent that they permit disclosures that Act 63 prohibits, remains in doubt. While the Preface indicates that the Proposed Amendments are intended to "clarify certain terms used" in Act 63, it appears patently clear that certain disclosures, such as those permitted under Subsection (d)(6) of the Proposed Amendments, would be impermissible under Act 63.

False Assurance of Prohibition Against Subsequent Disclosures

Section (b) of the Proposed Amendments sets forth in pertinent part:

> (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.

It remains questionable whether the DOH has authority to prohibit third parties who have received patient information, but are not providers licensed or regulated by the DOH, from making subsequent disclosures. The DOH could have, but did not, include a "Business Associate Agreement" requirement such as that found in the HIPAA Privacy Rule, 45 C.F.R. Parts 160 and 164. Rather, the only thing that the above statements likely accomplish is to instill in providers and patients a false sense that information will remain confidential after it is disclosed to a third party. Patients should be warned that if they consent to disclose their information to third parties, that third party might not have any duty thereafter to maintain it as confidential.

Clarification of Law Enforcement Authority

The Preface appears to indicate that the term "incident" in Subsection (d)(3)(ii) refers exclusively to an "incident" as described in (d)(3)(i). This should be clarified in the text of the

regulation of the Proposed Amendments, or else the term "incidents" in (d)(3)(ii) might be interpreted as more inclusive. Otherwise, all law enforcement should be required to obtain a court order or patient consent prior to accessing patient information.

Conclusion

The Proposed Amendments are vague and permit excessive disclosure without providing important safeguards to protect the confidentiality of patients' substance abuse treatment information. If the DOH makes these Proposed Amendments effective without making significant modifications, it will usher in a new era in which patients seeking treatment for addiction cannot be secure in knowing that information regarding their treatment will remain confidential.

Thank you for your attention in this regard and please do not hesitate to contact me with any questions.

Very truly yours,

JOSEPH T. KELLEY, III

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