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President and Chief Executive Officer

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

Dear Ms. Staloski:

Thank you for taking time to share the latest version of the Department of Health's Proposed Draft Final Regulation No. 10-186 more broadly, and now with all of the groups affected. Thank you also for extending the time for review of the draft to July 23, 2008.

Policy discussions of this sort must be held to the highest standards of openness and transparency. Providing such openness ensures that those actually impacted by the regulations have the opportunity to be heard.

With this said, I am surprised and disappointed to see that none of the concerns raised by myself and others at the April 16, 2008 meeting of the Pennsylvania Advisory Council on Drug and Abuse or specified in my letter of April 25, 2008 were addressed.

In fact, the April 25, 2008 version of the Draft Final Rule deepens these concerns and appears to open the door for payers to argue the ability to overrule clinical decisions of the treating medical professionals.

As per my comments at the meeting and prior letter, the definitions of Government Officials and Program set no clear limits on who or what entity can receive sensitive patient information and appear to allow unlicensed entities to provide treatment and referral services. The Patient Record section is drafted in a way that could reach into the records of patients who have received treatment in the past (and entered treatment under protection of the current confidentiality rules) and the section on enforcement and penalties for violations fails to address the problem of payers withholding payment to

force release of information beyond the confidentiality protections. Let me re-state – none of these concerns have been addressed in the current version.

Now further compounding these problems, the new draft includes a new definition of Treatment that severely blurs the roles of government, payers and treatment programs and a provision allowing for "oral consent" to release information – something not permitted under federal rules.

The section on Act 106 of 1989 has been altered but still is drafted in a disturbingly ambiguous fashion that is sure to cause problems in implementation. Finally, the regulation adds still more sensitive elements to the already troubling section regarding Information to be Released with Consent and goes far beyond the protection of the Pennsylvania Client Placement Criteria Summary Sheet.

In summary, consistent with previous versions, this draft regulation is ambiguous, confusing and sure to be costly and burdensome for treatment programs while endangering patient privacy.

I urge the Department of Health to withdraw Proposed Final Draft Rulemaking No.10-186.

Sincerely,

Kenneth S. Ramsey, Ph.D.
President and CEO
Member: The Pennsylvania Advisory Council on Drug and Alcohol Abuse

SECTION-BY-SECTION REVIEW

The current version (4/25/08) of the regulation fails to address any of concerns raised at the April meeting of the Pennsylvania Advisory Council on Drug and Alcohol Abuse and in my subsequent letter. Also, the current version of the Proposed Final Draft Rulemaking raises new and additional concerns. The following Section-by-Section Review reiterates our prior concerns and identifies the new and additional problems as well.

1) DEFINITION OF GOVERNMENT OFFICIALS - see Page 1, (a).

This section is unclear and requires more specific detail via examples and references to the particular "applicable federal, state, or local laws".

For example, this section defines the term government officials for the purpose of receiving patient information to assist in obtaining benefits or services for the patient. This definition provides essentially no limits on who can access the patient's private information including "elected representatives" (the House of Representatives?) and officers and employees of non-governmental entities, their subcontractors and their subcontractors.

In fact, there appears to be no difference here between governmental and non-governmental entities for the purpose of receiving sensitive patient information. This draft rule will throw open the window to sensitive patient files and allow private information to be exposed to numerous unspecified individuals, subcontractors and their subcontractors.

In addition, according to this section, non-governmental entities and their employees are to be treated "because of their status or other reasons", as government officials under applicable federal, state or local law. Which local, state and federal laws are applicable here? Workman's comp? Tax law? Minimally, this section could confer immunity from liability for misdeeds to private managed care entities.

Again, this definition sets no limits on who or what entity can receive records.

2) DEFINITION OF PATIENT RECORDS - Page 1, (a).

For purposes of disclosure of sensitive information, the draft rule applies to the records of patients " . . . seeking, receiving or having received addiction treatment..." Although past treatment history is pertinent to the treating facility, this information is frequently used by the payer to down code or deny services all together - regardless of the determination of the treating physician. I question why the records of patients that have received treatment are included here at all.

3) DEFINITION OF PROGRAM - see Page 2, (a).

The definition of the term program includes licensed treatment programs and also unlicensed governmental agencies. ". . . any government agency authorized to provide diagnosis, treatment, or referral for treatment for drug or alcohol abuse or dependence."

Under this definition, a governmental agency will be able to provide diagnosis, treatment and referral WITHOUT A LICENSE. (How and which governmental agency is authorized to provide this service and how will competency be determined?) This language as drafted will grossly undermine licensure standards and remove all oversight of the treatment of addicted individuals.

In the prior section, governmental agency is defined to include non-governmental agencies. These two sections combined could allow non-governmental agencies including managed care entities to do diagnosis and become addiction treatment programs - without being required to obtain a license.

4) DEFINITION OF TREATMENT – see Page 2, (a).

Treatment of addiction is carefully defined by Department of Health, Division of Drug and Alcohol Program Licensure. The definition proposed in this draft regulation includes an array of items that simply fail to meet the definition of treatment and will water down both its meaning and effectiveness.

"Provision" and "coordination" and "management of health care" are important activities in their own right but they are certainly not treatment. The definition of Treatment provided here is yet another example on how this regulation blurs and entangles the roles of government, payer and treatment program.

In addition to the definitions of Government Officials and Program, this new section appears to open the door for payers to argue the ability to overrule clinical decisions of the treating medical professionals.

5) <u>ENFORCEMENT AND PENALTIES FOR VIOLATIONS</u> of the state and federal confidentiality regulations - see Page 3, (b)(4).

This section re-states the existing penalty provisions for violations of the confidentiality rules by licensed addiction treatment programs. No similar penalties or rules are proposed for insurers and payers that violate the rules or that solicit and demand the breaking of the rules as they currently do.

What penalties can be utilized to enforce the rules with payers?

In addition, what is the penalty for unauthorized disclosure and re-disclosure as may be reflected in Philadelphia's centralized database (DSS-Cares) that combines and seeks to combine records from mental health, mental retardation, housing, criminal justice, drug and alcohol addiction treatment and HIV status?

6) <u>ACT 106 of 1989,</u> requiring all group health plans to provide treatment for addiction - see Page 4, (c)(2)(i) and (ii).

The prior draft failed to protect ALL of Act 106 from the provisions of this section and listed only outpatient and non-hospital residential services. We asked for the inclusion of detoxification and partial hospitalization.

Now, this new draft is written in a fashion that could be used by insurers to argue the ability to do medical necessity gatekeeping in addition to the certification and referral of the treating physician.

7) <u>INFORMATION TO BE RELEASED WITH CONSENT</u>. Pages 4 and 5 (c)(2)(ii)(A-G).

This section continues to mix up items of information already provided to payers under 255.5(b) and the Summary Sheet of the Pennsylvania Client Placement Criteria with requests for additional, unnecessary information. Privacy of the patient and other is his/her life is currently protected by handling much of

this information in a more general way through the Summary Sheet of the Pennsylvania Client Placement Criteria.

All versions of the proposed regulations ask for information not pertinent to the diagnosis and at the same time, include items of information commonly used to deny or minimize the need for addiction treatment. For example, section (c)(2)(ii)(E) "motivation to change". Do insurers ask about motivation to change regarding heart attack patients? The language relative to motivation to change should be deleted.

Although we currently can share mental health diagnoses, the latest version now adds this ambiguous, impossible to define category – ". . . emotional or behavioral problems requiring treatment or negatively impacting responses to emotional or environmental stressors."

Under the current rules, we already provide information on admission to treatment, diagnosis including the names of the drugs of addiction, mental health diagnosis, related biomedical complications and addiction related illnesses, summaries of progress in treatment, prognosis for recovery including general information on the patient's recovery environment and information on relapse. This seems to us to be comprehensive and adequate to meet payer needs. I suggest that the current rules remain without modification or expansion.

8) <u>CONSENT FORM – page 10, (f)(8).</u>

Why has "oral consent" been added to this draft? This provision was in the original draft proposal distributed for comments in November of 2007 and <u>was eliminated</u> from the draft provided for the 4/16/08 meeting of the Advisory Council. This is disturbing, opens the door to exploitation of the ill and I believe, is in violation of the federal confidentiality rules. I suggest that "oral consent" be deleted.