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Now, on 4/25/08 the Department of Health has released a third version of the proposed draft final rule. This new rule leaves the issues raised at the Advisory Council unaddressed and creates new, additional problems as well.

Let me reiterate, we share the concerns raised at the Advisory Council meeting about the following sections: Definition of Government Officials, Definition of Program, Definition of Patient Records, Enforcement and Penalties for Violations, Act 106 of 1989 and Information to be Released With Consent. (See attached *Section-by-Section Review, 4/25/08 version.*)

The additional new problems include: a new definition of treatment (page 2, (a)), the new language on emotional/behavioral or environmental stressors (page 5, (c)(2)(ii)(D)) and the reinsertion of the oral consent provision (page 10, (f)(8)). (See attached *Section-by-Section Review, 4/25/08 version.*)

We are also concerned about the responses provided in the Frequently Asked Questions (FAQ) section. (See attached *Comments on the Frequently Asked Questions.*)

Currently under Act 106 of 1989, information regarding commercial patients is limited to the certification and referral to treatment by a licensed physician or psychologist. For the non-Act 106 patient and for the publicly-funded patient, Pennsylvania's highly regarded Pennsylvania Client Placement Criteria (PCPC) provides for communication with the payers while simultaneously protecting the privacy of the patient through use of the PCPC Summary Sheet.

These two instruments limit information to be shared with payers with consent of the patient to specific information about the illness itself and information about diagnosis, prognosis, progress, relapse and form of treatment.

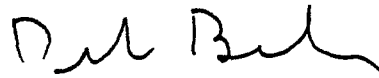
Under the new proposed rule, definitions are so broad that the role of government and payer is confused with the role of those providing hands-on treatment thus inviting the payer to intervene with treatment and to substitute his/her judgment for that of the treating professional.

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In summary, the changes proposed in the draft will significantly weaken, confuse and complicate the issue of confidentiality protections of sensitive patient information and allow insurers and payers to delve into the personal information of the most vulnerable patients.

For all of the reasons delineated above and in the attachments, we strenuously object to the Department of Health's Proposed Regulation No. 10-186.

Sincerely,



Deb Beck, MSW
President/DASPOP

Please see the attached:

Section-by-Section Review of the Proposed Draft Final Rulemaking
Comments on the Frequently Asked Questions (FAQ) Section

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SECTION-BY-SECTION REVIEW
DEPARTMENT OF HEALTH, REGULATION No. 10-186,
DRAFT FINAL RULEMAKING
(Version April 25, 2008)

Note: Most of the proposed draft final rule incorporates already existing federal or state rules. These provisions – long in effect in Pennsylvania – include: requirements to report child abuse, the ability to do audits and evaluations, the ability to do scientific research, the ability to report crime on the premises, the ability to disclose information to the patient’s lawyer, the entire section on patient access to records, provisions for employers, rules for emergencies, prohibitions against using information to initiate criminal charges and specifications regarding court orders and the proper format for consent forms.

These existing federal and state rules appear throughout the draft final rule and should not be mistaken for a new proposal.

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

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, Congress?) and officers and employees of non-governmental entities and their subcontractors.

As drafted, for the purpose of receiving sensitive patient information – what is the difference here between governmental and non-governmental entities? This draft rule will throw open the window to sensitive patient files and allow private information to be exposed to numerous unspecified individuals, unnamed subcontractors and their vendors.

In addition, according to this section, non-governmental entities and their employees are to be treated “because of their status or other reasons” (what “other reasons”?) as government officials under applicable federal, state or local law. We join the Advisory Council in questioning the appropriateness of this definition and would also like to know 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.

In summary, there are no clear limits here on who or what entity can receive records.

2) DEFINITION OF PROGRAM – see Page 2, (a).

The definition of the term “program” includes licensed treatment programs and also unlicensed governmental agencies. “. . . or 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 is the governmental agency 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 these unlicensed agencies.

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.

As we know, licensure provides for oversight, accountability and protection of patients. Where is the consumer of service protected here from the practice of an unlicensed agency or an unlicensed private contractor?

3) DEFINITION OF TREATMENT – Page 2, (a).

A new definition of treatment has been added here that we have been unable to locate in any of the Department of Health’s licensure standards. “The provision, coordination, or management of health care and related services, . . .” are of course, helpful and important but are not the same as treatment services for the addicted individual.

Drug and alcohol addiction treatment programs are specifically licensed to provide treatment for the primary illness of addictive diseases. The programs are also already, and properly, required to assist patients in identifying and addressing other health care and other issues uncovered during treatment.

In this remarkable new definition of treatment, drug and alcohol addiction treatment services appear secondary to “The provision, coordination, or management of health care and related services . . .”. This definition appears to open the door to activities more typically associated with managed care entities. These activities are not treatment under the meaning of the term as defined by the Division of Drug and Alcohol Program Licensure.

In fact, we are puzzled to see a definition of treatment here that differs so widely from the definition in the General Provisions of the Licensure Standards for Drug and Alcohol Services.

Once again, the definitions of Government Officials, Program and Treatment confuse the role of government and payer with the role of those providing hands-on treatment thus inviting the payer to intervene with treatment and to substitute his/her judgment for that of the treating professional.

4) SCOPE AND POLICY - Page 2, (b)(1).

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 certainly pertinent to the treating facility and to the hands-on treating professional, this information is frequently used by the payer to downcode or deny services all together – regardless of the determination of the treating physician.

We also question why the records of patients that have received treatment are included here as well. Is there intent here by payers to do retrospective data gathering as well?

We note that former patients, or patients who have already received treatment in the past entered treatment and signed consents for release of information in good faith reliance on the current confidentiality protections – not this proposal.

5) ENFORCEMENT AND PENALTIES FOR VIOLATIONS 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 here for insurers and payers that violate the rules or that solicit and sometimes demand the breaking of the rules as they

currently do. Despite claims to the contrary in the narrative, we see no provision in this regulation that will protect patients and programs from coercion of this sort and from having payment for treatment held hostage and leveraged to force release of sensitive information.

Why are no penalties proposed here 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? (Centralized databases are not permitted under federal rules except for methadone.)

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

The immediate past version failed to clearly exempt Act 106 by listing only non-hospital residential and outpatient and failing to include detoxification, partial hospitalization and the additional treatment section. In this new version, it is not clear that the physician or psychologist's certification and referral is all that is being required here. In fact, the construction of the section could be used by insurers/payers to argue that additional information can be requested under the first sentence of (c)(2)(i) and that medical necessity procedures (c)(2)(ii) could also be used in addition to the certification and referral of the physician and psychologist.

This flies in the face of the plain requirements of the statute.

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

Some have argued that the new rules empower clients and that, after all, information will only be shared with client consent. However, any notion that client consent safeguards privacy is illusory, belied by shameful and desperate patients forced into treatment by frightened friends and families – sometimes coming directly from prison and handcuffs. In the context of addiction, “consent” to release private information to obtain payment for treatment is by its nature, coercive and cries out for the protection of the current rules.

Under the federal confidentiality rules alone and now under this new proposal, it is not clear what kind of information could ever be withheld from payers – even where that information is personally embarrassing, detrimental and of no relevance to the diagnosis of addiction. Yet, our guilt-filled population is quite vulnerable when entering treatment and likely to give consent and sign away almost any right mediated through a helper.

Section (c)(2)(ii)(A-G) of the new rules expands the information that can be released – and that the programs are sure to be pressured to release – to government officials and third-party payers making medical necessity admission determinations, continued stay reviews, etc.

The proposed new section (c)(2)(ii)(A-G) requires a lengthy inventory of information to be provided to the payer. Almost all of the items listed have been used unfairly by third-party payers to deny treatment. Some of these items have been used to downcode the level of treatment provided when they are in fact, indicators of a need for more intensive care. (For example, wavering motivation.) In the past, even desperately ill patients have been

penalized for not being mentally ill or on the other hand, have been penalized for having a stable home – and therefore, denied treatment.

Many of the items are also quite variable in nature. For example, levels of detoxification fluctuate constantly, there is the matter of primary and secondary withdrawal from a multitude of different drugs, information on the drugs used is generally not reliable and social supports and stressors, relapse triggers and motivation also vary widely over time.

Drug and alcohol addiction treatment facilities are required under licensure by the Department of Health to obtain detailed psycho-social histories. During these interviews, we learn about family relationships, delve into difficult experiences and explore many issues that are sensitive and embarrassing to our patients and their families – and frankly, would be for the rest of us as well.

Currently under Act 106 of 1989, information regarding commercial patients is limited to the certification and referral to treatment by a licensed physician or psychologist. For the non-Act 106 patient and for the publicly-funded patient, Pennsylvania's highly regarded Pennsylvania Client Placement Criteria (PCPC) provides for communication with the payers while simultaneously protecting the privacy of the patient through use of the PCPC Summary Sheet. Information provided with patient consent includes information on admission to treatment, diagnosis including the names of the drugs of addiction, mental health diagnosis (if appropriate), 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.

In summary, these two instruments limit information to be shared with payers with consent of the patient to specific information about the illness itself and information about diagnosis, prognosis, progress, relapse and form of treatment.

What more does a payer need?

8) CONSENT FORM – page 10, (f)(8).

A provision to do oral consent to allow information to be released has been reinserted here. This provision was in the original draft proposal distributed for comments in November of 2007 and was eliminated from the draft provided for the 4/16/08 meeting of the Advisory Council. We are disturbed to see oral consent reinserted in the proposal. Some patients under the influence of drugs and alcohol will be “physically unable to provide a signature” and thus, this section could be utilized to exploit them at a vulnerable time to obtain consent. We could find no provision allowing “oral consent” in the federal rules.

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COMMENTS ON THE FREQUENTLY ASKED QUESTIONS
(FAQ-BDAP, April 25, 2008)
DEPARTMENT OF HEALTH, REGULATION No. 10-186,
DRAFT FINAL RULEMAKING

Note: Most of the proposed draft final rule incorporates already existing federal or state rules. These provisions – long in effect in Pennsylvania – include: requirements to report child abuse, the ability to do audits and evaluations, the ability to do scientific research, the ability to report crime on the premises, the ability to disclose information to the patient's lawyer, the entire section on patient access to records, provisions for employers, rules for emergencies, prohibitions against using information to initiate criminal charges and specifications regarding court orders and the proper format for consent forms.

These existing federal and state rules appear throughout the draft final rule and should not be mistaken for a new proposal.

The FAQ/BDAP explanation of the draft final rule includes many statements that concern us.

The FAQ implies that updating of the current rules is necessary because of recognition that people with addictions may also have mental health problems. Interestingly, the current rules anticipated this issue and have long included provisions that allow sharing of records between treatment professionals, including mental health professionals with the patient's consent.

The FAQ also claims that health insurers deny care when they cannot get the "basic information" that they need. However, the rules of engagement are quite clear. Under Act 106 of 1989, information regarding commercial

patients is limited to the certification and referral to treatment by a licensed physician or psychologist. For the non-Act 106 patient and for the publicly-funded patient, Pennsylvania's highly regarded Pennsylvania Client Placement Criteria (PCPC) provides for communication with the payers while simultaneously protecting the privacy of the patient through use of the PCPC Summary Sheet.

These two instruments limit information to be shared with payers with consent of the patient to specific information about the illness itself and information about diagnosis, prognosis, progress, relapse and form of treatment.

The FAQ also fails to recognize that Act 106 of 1989, PA's law requiring provision of addiction treatment through commercial insurance, applies to the Children's Health Insurance Program and to the health insurance of the state employees. And of course, the FAQ writer is correct – states cannot draft defined benefit plans for commercial insurance laws for other states or for that matter, for federal Medicare or for self-insured plans (federal rules apply) which are generally outside the province of state law. Given the limits of state jurisdiction in this matter, Act 106 covers a healthy number of residents of Pennsylvania.

The FAQ provides a telling list of things that treatment programs will not be allowed to turn over to payers under the new proposed rule.

According to the FAQ, the new rules:

- do not allow - treatment providers to turn over the entire patient medical record to an insurer
- do not allow – treatment providers to share treatment notes

- do not allow – treatment providers to turn over the names of friends, family, or colleagues that may be using illegal drugs or otherwise abusing drugs or alcohol
- do not allow – providers to release the names of people that may have committed crimes or harmed the patient, unless the patient is the victim of child abuse in which the case reporting of the alleged abuse to the proper authorities is required, even without the patient's consent

These are some of the very items that fall under the protection of the Summary Sheet of the Pennsylvania Client Placement Criteria.

It is interesting to note that these do nots or prohibitions against sharing information appear nowhere in the proposed regulation itself.

The FAQ specifies that the payers do not need the entire patient chart, yet it remains unclear in the proposed regulation how the program could stop them from asking for or coercing release of every element. What does the FAQ consider off-limits to the payer? How is that reflected in the proposed regulation and what steps is the Department prepared to take to stop payers from holding programs and patients hostage to force release of intrusive information?

Addiction treatment programs need and do review past treatment history and deal actively with issues of denial, treatment acceptance and resistance to assist patients with recovery but information of this type is often illogically used by payers to deny and downcode treatment when in fact, relapses are often indicators of the need for more intensive treatment at higher levels of care and for longer lengths of stay.

Information provided with patient consent includes information on admission to treatment, diagnosis including the names of the drugs of addiction, mental health diagnosis (if appropriate), 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.

FAQ#20 states that the "Third party payers do not provide services" but instead, "they cover services". However, the new definitions in the actual proposed regulation contradict this statement and confuse the role of government and payer with the addiction treatment program thus allowing the government and payers access to private information and inviting the payer to substitute his/her judgment for the judgment of the treating professional.

According to FAQ#24, the new draft regulation adds "emotional or behavioral problems requiring treatment or negatively impacting responses to emotional or environmental stressors" to the inventory of information to be shared with the payer. The FAQ writer seems unaware that although drug and alcohol addiction treatment programs are specifically licensed to provide treatment for drug and alcohol addiction, licensure of facilities also requires the programs to assist patients in identifying and addressing other health care and other issues uncovered during treatment.

Once again, under this new language in (c)(2)(ii)(D), it is not clear what kind of information could ever be withheld from payers – even where that information is personally embarrassing, detrimental and of utterly no relevance to the treatment of the addiction.

We expect that this language will be utilized by payers and insurers to continue to press for more sensitive information beyond mental health diagnoses and for intensely personal information.

Throughout the Frequently Asked Questions document, the terms “minimal” information and “limits” on information are repeated. Yet, the regulation itself provides no limit and no shield (such as the PCPC Summary Sheet) from ever more intrusive requests for information.

Finally, it has been argued that most of the information discussed here goes out only with the consent of the patient – i.e. – the patient has control and therefore is protected. This notion fails to grasp the inherently unequal relationship between the patient and the treating professional – an inequality, ratcheted up to painfully high levels for people with untreated addictions.

Not well enough to make a truly informed consent, scared and deeply ashamed – our patients will sign anything and sign away almost any right.

What choice does a patient really have here? Do you want treatment? Then you must release this information. This dynamic is coercive in its nature.