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By federal express
Janice Staloski, Director
Bureau of Community Program Licensure
and Certification
132 Kline Plaza, Suite A
Harrisburg, PA 17104

Re: Department of Health Proposed Regulation No. 10-186
Regarding Confidentiality of Addiction Treatment Records

Dear Ms. Staloski:

I write to register my objections to the most recent (April 25, 2008) proposed revisions to the confidentiality regulations that apply to addiction treatment. (These revisions are hereinafter referred to as the "Draft Final Regulations".) These regulations would dramatically expand the information that managed care companies can demand from treating clinicians, and would result in significant reductions in needed addiction treatment services for those most in need. The Draft Final Regulations would also grant new, quasi-governmental powers to employees of private managed care companies entrusted with public dollars. These are extremely significant policy shifts that are not only harmful to Pennsylvania citizens, but are also far beyond the permissible scope of regulatory activity.

The Draft Final Regulations do not address the many concerns and objections that were raised in response to the regulations as initially proposed in November, 2007 (hereinafter the "First Proposed Regulations"), and do not address the many concerns and objections that were raised in response to the second version of the proposed regulations, which were submitted to the Pennsylvania Advisory Council on Drug and Abuse in April, 2008 (hereinafter the "Second Proposed Regulations"). It is not my intention, however, to simply repeat those concerns here. Those general issues have been, and will doubtless continue to be, forcefully and ably covered by other voices.

Instead, I would like to place the Draft Final Regulations, and the two versions of proposed rules that preceded them, in a broader context. The proposed changes are part of an effort to dramatically expand the powers and prerogatives of managed care companies, both with

respect to private insurance and with respect to managed care companies that control, and seek to control, public addiction treatment funds.

I. The Draft Final Regulations Would Discard Settled Rules, Grant New Powers To Managed Care Companies, And Harm Pennsylvania Citizens.

A. Current Settled Rules Provide Clear and Necessary Privacy Protection for Patients.

Today, addiction treatment is governed by clear and settled rules that establish what information payers and managed care companies are, and are not, entitled to receive. 4 Pa. Code § 255.5. These rules are applied by treatment programs, payers, and managed care companies every day in this Commonwealth.

For the medical assistance population, the patient-specific clinical information that managed care companies are entitled to receive is defined by the Pennsylvania Client Placement Criteria guidelines, which were developed by the Department of Health's Bureau of Drug and Alcohol Programs ("BDAP"). *See* 55 Pennsylvania Code § 1163.59a, 55 Pennsylvania Code § 1163.455a. These have been in use since 1998. The PCPC guidelines include and make use of a "PCPC Summary Sheet"; that sheet sets forth, and defines, the information that treatment programs are permitted to share and that managed care companies are therefore entitled to receive and demand. *See* Pennsylvania Department of Health Information Bulletin 13-98 ("The PCPC Summary Sheet has been determined by the Bureau of Drug and Alcohol Programs (BDAP) and the Bureau of Community Program Licensure and Certification to fall within the parameters of the state confidentiality regulation"). The PCPC summary sheet permits certain limited, clearly defined categories of information to be disclosed by programs.

For those with private insurance, the majority of treatment days and sessions are covered by and subject to Act 106 of 1989, 40 Pa. Stat. §§ 908-1 to 908-6, and are subject to the regulatory guidance regarding Act 106 set forth in the Insurance Department's Notice 2003-06, titled *Drug and Alcohol Use and Dependency Coverage*, 33 Pa. Bulletin 4041 (August 9, 2003). The Insurance Department's enforcement efforts are the subject of a lawsuit that is currently before the Pennsylvania Supreme Court – the case has been fully briefed, and was argued on May 14, 2008. (The Draft Final Regulations do not adequately protect Act 106; this is addressed in a separate section below.)

For those treatment days and sessions not covered by the PCPC or Act 106, the current regulations clearly define the limited information that managed care companies are permitted to demand. Thanks to enormous efforts on the part of legislators, regulators, law enforcement, and

facilities, the confidentiality rules are now settled and clear to all. Violations of these rules by managed care companies raise obvious enforcement issues, but these violations are not and cannot be a justification for ratifying this misconduct through regulatory changes.

B. The Proposed Regulations Grant A Significant Victory To Managed Care Companies That Have Long Sought Broader Access To Treatment Records.

Managed care has long chafed against Pennsylvania's strong and clear confidentiality protections, arguing that they need greater access to information in order to make "medical necessity" determinations for patients.

These demands for information are part of efforts by managed care employees sitting in a distant call center to second-guess decisions made by the clinicians who are actually treating the patient. Inevitably, this kind of involvement means that patients receive less care, or less intensive care. Experience teaches that the very ability to demand information – even the limited information permissible under current law – places a powerful tool in the hands of managed care, as new information is demanded every one or two days. If the information is not provided, or is not provided promptly enough, coverage is denied. If the information is provided, it is all too often used a pretext to deny needed care.

Allowing managed care companies to make ever more intrusive demands for information would strengthen considerably the power of managed care companies, as they use information demands to intrude upon the treatment process and second-guess decisions made by treating clinicians. There can be no dispute that strengthening the hand of managed care companies in this way means less addiction treatment, and treatment at less intensive levels of care, for those most in need. There is a vast body of evidence confirming and establishing this point. The Draft Final Regulations appear to assume exactly the opposite – that broader information sharing with managed care companies would somehow result in more effective care or greater access to care. There is no basis, other than hopeless naivete, wilful ignorance, or Stockholm syndrome, for this bold departure from known facts.

There is also a considerable body of evidence establishing that the more addiction treatment is provided, the greater the chance of a successful outcome. The new powers granted to managed care companies in the Draft Final Regulations would result in patients receiving less treatment and less effective treatment, and more untreated and undertreated addicts and alcoholics. Given the uncontroverted direct link between addiction and crime, it seems clear that one effect of the Draft Final Regulations would be more drug-related crime, more drunk drivers on our roads, and more ruined lives.

It is telling that as the regulations have progressed through various drafts, the scope of information to be disclosed – already too broad even in the First Proposed Regulations, which were published in November, 2007 – has become more broad, not less so. *Compare* Section 255.5(c)(2)(ii)(D) in the First Proposed Regulations *with* Section 255.5(c)(2)(ii)(D) in the Draft Final Regulations. In response to the First Proposed Regulations, the drafters of the regulations received over 160 letters opposing broader disclosure. Remarkably, the drafters responded to this input by making the disclosure permitted under the regulations broader still. In a sense, that tells you all you need to know about the intentions of the drafters.

The Department of Health has taken sides on this substantial policy question, and has sided with the managed care industry.

II. The Proposed Changes Advance Broader Agendas of Those Who Seek To Increase The Role of Private Managed Care Companies In The Management of Public Funds.

The fact that the proposed regulations grant broad new powers to the managed care industry, without any legislative action or other appropriate warrant for doing so, is more than sufficient, standing alone, to strongly counsel against the proposed regulations. Those observations, however, do not fully capture either the breadth or the real significance of what the proposed regulations would do.

To fully understand their scope, the regulations must be viewed against the backdrop of two broader policy agendas currently being pursued by the Department of Health over the objections of the treatment community and many others in government.

A. The Regulations Help Expand The Role of Private Managed Care Companies in the Management of Public Treatment Dollars.

The lines between private managed care companies and government entities is increasingly becoming blurred. Recent years have seen a significant expansion of managed care in the management of public treatment dollars. Private management of public treatment dollars is growing and will continue to grow.

This expansion has taken a number of different forms. Sometimes, public treatment dollars are simply handed over to a private managed care company. One example of this is the Community Behavioral HealthCare Network of Pennsylvania ("CBHNP"). CBHNP is a subsidiary of Amerihealth Mercy, which is in turn a partnership of Independence Blue Cross and Mercy Health System. Sometimes, private companies can be handed control over public

treatment dollars, in ways that are not at all transparent and that are extremely difficult to spot. In another common arrangement, private managed care companies and government entities can create public-private partnerships. Whatever the precise arrangement, they are all manifestations of the same underlying phenomenon: a ceding of control over public dollars from public officials to private companies.

When the government in a democracy spends the public's money, it can be held accountable in many different ways. There are extensive laws and procedures that are designed to bring transparency to the process, and there is an extensive system of checks and balances. In exchange, government actors often have privileges (for example, immunity from suit) that private actors do not.

The accountability tools that apply to government actors do not necessarily apply once public dollars are handed over to private companies. While there is nothing intrinsically wrong with these relationships, stewards of public dollars and the public trust must embark on these relationships with great care. Transparency and oversight are absolutely critical.

The Draft Final Regulations contain radical new definitions of "government officials" and treatment that would grant significant new prerogatives to private managed care companies handling public treatment dollars. These new powers are not, however, accompanied by any tools that would provide any accountability or oversight to accompany these new powers. This would be unwise under any scenario. That the Department of Health is attempting to materially advance this goal through the regulatory process, without any of the checks and balances that accompany the legislative process, and without even announcing these important intentions, is more troubling still.

As commonly understood and under current Pennsylvania law the employees of private managed care companies are not government officials, and their activities are not "treatment". The Draft Final Regulations change that. This change is not announced in the proposed regulations or in any of the accompanying materials from the Department of Health, and in order to understand them it is necessary to walk through a series of interconnected definitions.

The regulations define "government officials" as follows.

> *Government officials* – Elected or appointed representatives 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. *Government officials includes officers, directors, or employees of non-governmental entities whose employees are treated, because of their status or other reasons, as government officials under applicable federal, state or local law.*

Draft Final Regulations at 1 (emphasis added). This language explicitly includes employees of "non-governmental entities" as "government officials," and is clearly designed to sweep broadly. If a managed care company is treated as a governmental official under *any* applicable federal, state or local law, then the managed care company can argue that its employees should be treated as "government officials" for confidentiality purposes.

This change becomes even more apparent when the context of the term as it appears in the Draft Final Regulations is considered. Every time the phrase "government official" appears in the Draft Final Regulations, it appears as part of the phrase "government officials and third-party payers" or the phrase "government official or third-party payer". For the purpose of these regulations any particular person or entity is either one (government official) or the other (third-party payer). That makes the term "third-party payer" a pivotal term.

The definition of "third-party payer" in the Draft Final regulations is quite narrow, and includes only entities that "pay[] for diagnosis, treatment, or referral for treatment." Draft Final Regulations at 2. Many managed care companies do not directly pay for treatment themselves. Instead, they are often paid for managing, coordinating, and controlling care, with programs paid from another source. A managed care company in this common role does not fall within the regulation's narrow definition of "third-party payer." Those seeking government-like status for private managed care companies will doubtless argue that under these regulations a managed care company must be either a "government official" or a "third-party payer," and if they are not a "third-party payer," then they must be a "government official".

Conferring government status on managed care companies could dramatically expand the scope of people and groups that have access to addiction treatment records. Government status could also have significant implications for the accountability of these organizations, and might allow them to argue that they are entitled to the legal immunities that are typically afforded governments, even though these private companies are often beyond the reach of many of the oversight and accountability mechanisms that apply to government agencies and officials.

Whatever one's views on the merits or wisdom of such an approach, there can be no dispute that these are substantial changes and substantial policy questions that are more appropriately left to the legislative process.

The Draft Final regulations also include a radical new definition of "treatment". Under current law, and under any common sense understanding of the term, the coordination and utilization review activities of managed care companies cannot plausibly be called "treatment". The Draft Final regulations would change that:

> *Treatment* – The provision, coordination, or management of health care and related services, including drug and alcohol abuse services, by one or more medical personnel or programs, including coordination or management of health care by medical personnel or programs with a third party; consultation between medical personnel or programs relating to a patient, or the referral of a patient for health care from one medical personnel or program to another.

Draft Final Regulations at 2. Thus, this regulatory definition now includes "coordination or management . . . with a third party", and also includes the referral of a patient for health care from one "medical personnel or program to another." None of these activities are treatment under current law. *See, e.g.*, 28 Pa. Code § 157.2; 28 Pa. Code § 701.1; 28 Pa. Code § 709.123.

The expansion of "treatment" to include managed care activities matters. Section 255.5(c)(1) of the Draft Final regulations grants essentially unlimited access rights to "medical personnel" "for the purpose of diagnosis, treatment or referral for treatment." Once treatment is extended to include managed care activities, the only remaining question is whether managed care personnel are "medical personnel".

Under existing law, of course, and under any plain meaning of the term, managed care employees are not, and cannot reasonably claim to be, medical personnel. But on this front, also, the Draft Final Regulations effect a radical change.

> *Medical personnel* – A physician, nurse, emergency medical technician or other person licensed, certified, or otherwise authorized by the laws of the jurisdiction where the person is located, to provide medical, mental health or addiction *treatment* to a patient. Medical personnel does not include a health care practitioner who is an employee or agent of a third-party payer.

Draft Final Regulations at 1 (emphasis added). This circular definition provides that anyone authorized to provide "treatment" can deem themselves medical personnel. Since we know that "treatment" now includes managed care activities, managed care employees who are authorized to carry out managed care activities can now argue that they are "medical personnel" for the purposes of this regulation.

The final sentence of the definition of "medical personnel" on its face appears to exclude employees or agents of "third-party payers", but on careful reading the last sentence is really no limitation at all, because as set forth above under these regulations many managed care companies are not "third-party payers" at all.

It should be noted that this expansive new definition of "treatment" does not appear in either the First Proposed Regulations or the Second Proposed Regulations; it appears for the first time in the Draft Final Regulations. This suggests that required input from the Pennsylvania Advisory Council on Drug and Alcohol Abuse, *see* 71 Pa. Stat. § 1690.101 *et seq.*, for this important change has not been sought or obtained.

B. The Proposed Regulations Advance The Agendas of A Few Seeking Broader Information Sharing.

Some have argued that more extensive information sharing made possible by technology would lead to better, more cost-effective addiction treatment. (It is important to stress that this is very much a minority view; most policymakers and many in government acknowledge that maintaining privacy, not disregarding it, is the better policy by far.) This minority view is obviously inconsistent with the patient-protective confidentiality regulations that are currently the law in Pennsylvania.

A recent example from Philadelphia provides a powerful illustration of the tension between technology and confidentiality. Philadelphia's Department of Social Services recently spent years, and millions of dollars, creating a database known as DSS Cares. This database was designed to include comprehensive, detailed patient-specific information about patients who had contact with Philadelphia's Department of Social Services. If implemented as envisioned, the database would have allowed over 3,700 public and private employees, vendors, and contractors to access these records. This level of access would have made many privacy guarantees effectively meaningless.

This approach clearly ran afoul of existing confidentiality laws. According to an article published in the Philadelphia Inquirer on August 13, 2007, the database is now little used, at least in part because of privacy concerns and because of the procedural complexities engendered by

privacy laws. Marcia Gelbart, *Costly Social Services Database is Little Used – Mayor Street Pushed the Idea to Coordinate Aid from Various Agencies; Privacy Limitations Have Been a Barrier*, Philadelphia Inquirer, August 13, 2007, at B1.

As set forth above, the proposed regulations would grant broad new rights of access, to basically everyone involved in "coordination or management of health care" for those suffering from addiction. That's a lot of people. In a sense the regulations may be in part an effort to ratify what DSS tried to do with its DSS Cares system.

The current law in Pennsylvania reflects and embodies the view that more confidentiality means more treatment. If the Department of Health wants to change that, it should proceed through the legislative process. It is not appropriate to pursue such significant policy changes through the regulatory process – particularly a regulatory drafting process that fails to candidly or openly discuss all the goals of the changes and all their intended effects.

II. The Draft Final Regulations Do Not Adequately Protect Act 106 of 1989.

I join those who believe that this section does not adequately protect Act 106 of 1989. I am concerned that managed care companies will argue that the broader disclosure of section (c)(2)(ii) is in addition to (or an alternative to) the certification and referral referred to in section (c)(2)(i). Clarifying this would be a simple matter, and it is disappointing that this has not been done.

My concern on this point is heightened, and not allayed, by the fact that the Department of Health has attempted to unfairly minimize the significance of Act 106 in a set of "Frequently Asked Questions" that accompanied the Draft Final regulations. The Department of Health states, in bold print, that "Act 106 does not cover roughly two thirds of the people in Pennsylvania with health insurance." This statement is not consistent with the data that I am aware of regarding the scope of Act 106, and it would be interesting to learn the basis for this statement by the Department.

Also, the statement does not mention (a) the CHIP program or the PEBTF, two insurance programs that are subject to the requirements of Act 106 and are vitally important to large numbers of Pennsylvanians, or (b) the essential leadership role that Act 106 has played, and continues to play, in this Commonwealth and throughout the nation. By requiring that treating decisions be made by treating professionals and not by a managed care reviewer in a distant call center, Act 106 raises the bar for all.

Finally, even if the Department of Health's efforts to minimize the reach of Act 106 were accurate in some narrow sense (they would still be misleading), why is the Department of Health writing FAQs – which are not required as part of the regulatory drafting process – that contain a gratuitous swipe at a statute that was enacted by the General Assembly, and that is so important to so many of our most vulnerable citizens?

Once again the Department of Health has taken sides, and it has sided with the managed care industry.

For all these reasons, I object to the Draft Final Regulations.

Very truly yours,

GREGORY B. HELLER

GBH/ld

cc: Independent Regulatory Review Commission (by Federal Express)
Senator Edwin Erickson (by fax)
Senator Vincent Hughes (by fax)
Representative Frank Oliver (by fax)
Representative George Kenney (by fax)