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June 23, 2014

Substance Abuse and Mental Health Services Administration

1 Choke Cherry Road

Room 5-1011

Rockville, MD 20857

Re: Docket # 2014-10913

To Whom It May Concern:

I am writing on behalf of the American Association for the Treatment of Opioid Dependence, which represents more than 950 Opioid Treatment Programs in the United States through 30 state member association chapters and individual programs in non-member states. We are specifically writing with regard to the above-referenced docket concerning recommended changes/modifications to 42 CFR Part 2 Confidentiality Protections.

We participated in the SAMHSA "Listening Session" of June 11, 2014. Some of the comments that follow reflect a number of topics, which were raised during the listening session. We understand that the confidentiality protections were put in place more than 40 years ago and could not have anticipated changes in electronic record keeping, Health Care Reform, or the increased abuse of prescription opioids which would lead to the use of Prescription Monitoring Programs. We also understand the arguments that were put forward, indicating that the confidentiality protections need to be reevaluated in light of these new policy initiatives and the interest of integrating the medical care for patients who receive treatment for their substance use.

Stigma

Unfortunately, we are still living in a society that actively stigmatizes people with substance use disorders, especially those with opioid addiction. The confidentiality regulations, while written 40 years ago, understood this reality. We agree with the perspective of the Legal Action Center that "people with substance use disorders still face loss of employment, housing, child custody; insurance and health care discrimination; criminal arrest, prosecution, and incarceration; and a host of other negative consequences." This reality is reflected in many reports, which we continue to receive from Opioid Treatment Programs throughout the United States and through concerns expressed by patient advocates.

Employment Discrimination

Studies that AATOD has been involved in since 2005 (RADARS™ System as managed by the Denver Health and Hospital Authority) have indicated that

approximately 41% of patients in OTPs are employed. Many of these patients actively discuss with OTP counselors whether they should inform their employers about their involvement with methadone maintenance treatment. This continues to be a sensitive topic since many patients are of the judgment that informing their employers of their involvement with methadone treatment will have negative consequences and potentially result in the loss of their job.

Criminal Justice

The Criminal Justice System has not had a favorable view in understanding why patients continue to receive maintenance treatment for opioid addiction whether it is the use of methadone or buprenorphine. Very few correctional facilities provide continued access to these medications although recent policy initiatives and published reports are intent on changing this reality. Patients who are maintained on methadone and buprenorphine are frequently told by judges in various jurisdictions that they cannot continue to receive their maintenance treatment if they want to recover custody of their children (Family Court) or face jail time if they continue their treatment in various Drug Courts. Once again, this reality depends on the particular jurisdiction but this is a widespread practice at the present time. This condition does not exist in the treatment of any other chronic disease in the U.S. where medications are used to treat the patient effectively and to preserve continued health.

Pregnancy

Another important topic came to surface during the listening session and that involves the protections that pregnant women require when they are receiving methadone or buprenorphine maintenance treatment. Tennessee has recently passed legislation which could endanger the continuity of such patients in treatment depending on who is making the determination. While the intent of the Tennessee legislation is allegedly not to end the treatment for such people in maintenance care, it could be used that way by various parts of the Criminal Justice system. Many pregnant methadone maintained women are extremely fearful of having anyone know of their involvement in treatment, including other medical professionals and other family members. They have reason for such fear when speaking with representatives from Child Protective Services in different states and Family Court Judges.

Medical Professionals

We also agree with the correspondence which the National Alliance for Medication Assisted Recovery submitted on June 9, 2014. "Medical professionals do not get their information about methadone treatment in medical schools or from the scientific literature. Rather it comes from the media and they believe the myths and misunderstandings about methadone treatment and opioid addiction." This is why many patients are apprehensive about disclosing their

involvement in treatment to medical professionals. We have been advised by many of the patients who are treated in OTPs about the change in attitude demonstrated by medical professionals once they disclose that they are involved in opioid treatment programs. This includes misunderstandings about how patients should get access to pain management medications when there is a legitimate need to provide analgesic relief for chronic pain.

NAMA Recovery makes an extremely important point in the aforementioned correspondence. "Until the medical professional is educated about methadone and addiction, methadone patients need the right to first develop a relationship with the physician or medical professional before they tell them they are a methadone patient in addiction treatment." The Legal Action Center has made this point in their public comments and we support the premise. "The Legal Action Center continues to believe that patients in alcohol and drug programs should retain the power to decide when and to whom their records are disclosed, even for treatment and payment purposes, given the continued prevalence of discrimination in our society. This includes disclosures to the general health care system, HIEs, health homes, ACOs, and CCOs. The best way for patients to retain that power is by requiring patient consent for most disclosures, together with a strong prohibition on re-disclosure".

HIPAA Protections

We listened with interest to the comments that were made by a number of parties during the SAMHSA June 11, 2014 listening session. A number of representatives who presented are of the judgment that the protections afforded to patients under HIPAA are sufficient. In our judgment, such individuals have not carefully read the confidentiality protections with regard to prohibition on re-disclosure. If they had, they could not arrive at the conclusion that HIPAA protections are equally strong. The patient needs to be in control of who knows about their treatment, which is the point that has also been made by NAMA Recovery and the Legal Action Center.

It is also important to point out that one of the speakers at the listening session indicated that we should pay attention to the ultimate consumers of this treatment system. NAMA Recovery is the preeminent patient advocacy group in the United States with regard to the use of medications for opioid addiction treatment. Their correspondence has already been referenced in this communication and AATOD supports their point of view. Many administrators and clinicians, who work in OTPs, understand that we are simply custodians of the individual patient's care. It is the patient who takes on the risk of entering and remaining in treatment. Research has proven repeatedly that such patients benefit from ongoing care as long as they achieve therapeutic outcomes. This was certainly the cornerstone of the SAMHSA Treatment Improvement Protocol #43, "Medication Assisted Treatment for Opioid Addiction in Opioid Treatment Programs". While patients continue to get benefit from remaining in treatment,

they still take on the risk of discrimination if that treatment is improperly disclosed to other parties.

Preserving Core Protections

We also agree with the Legal Action Center perspective in updating the mechanics of the federal Alcohol and Drug Abuse Confidentiality Regulations to facilitate better integration of care and communication in an age of electronic health care records. We also support the Legal Action Center's position that the "core privacy protections must be maintained". If not, we believe that there will be tragic consequences with regard to admitting people to treatment programs and for stable patients to continue their treatment. NAMA Recovery makes this point succinctly in their submitted comments. "First and foremost is the fact that prospective patients will be wary to seek treatment if they know that this knowledge will be disseminated, and through that distribution possibly become known by friends, family, employers, insurers, and other providers of medical services to them". The patients who participate in NAMA Recovery know all too well about the stigma and discrimination that they routinely suffer throughout their treatment experience. It is not a policy question for them, or a philosophical point. It is a bedrock reality that shapes what they disclose to medical professionals, and what they disclose to their closest family members. While we have made strides in developing electronic records and in an interest in ensuring that patients get the most comprehensive and coordinated care possible, the reality of stigma persists in the society towards opioid addiction and people entering such treatment.

Prescription Opioid Abuse

We are in an age where prescription opioid abuse has increased the need for treatment interventions including methadone and buprenorphine maintenance in addition to the more recently approved medication, Naltrexone/Vivitrol. All three federally approved medications need to be used throughout the nation as we provide increased access to care for the millions of Americans who need such treatment interventions, both in the general health care setting and in the Criminal Justice setting. We also know that providing access to such services and reimbursing such services continues to be a major struggle.

Most states have now adopted the use of Prescription Monitoring Programs in order to better track who is getting access to prescription opioids and other psychoactive substances. AATOD has supported the expansion of PMPs and have encouraged our members to access data from such programs in order to provide more therapeutic care for our patients. We have also discouraged all OTPs from disclosing confidential patient information into PMPs. This issue was raised during the June 11, 2014 listening session. A representative indicated that 18 PMPs provide data access to enforcement organizations. In some cases, the PMP is under the direct aegis of a state narcotic enforcement agency. One

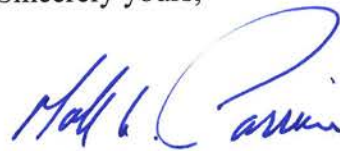
such agency informed AATOD that they wanted access to confidential patient data for individuals participating in OTPs so they could cross match such data against outstanding warrants. This is clearly not the purpose of establishing PMPs and indicates what can happen if patient information is disclosed.

Summary

In summary, we are urging the Substance Abuse and Mental Health Services Administration to exercise every caution in redrafting the protections afforded to patients in substance abuse treatment as it relates to current political and policy initiatives. While our society has moved to a greater degree in understanding the value of treating addiction, there is still major stigma concerning the use of medications to treat opioid addiction. This point cannot be emphasized enough. We are of the judgment that any loosening of the privacy standards afforded to patients under 42 CFR Part 2 will have terrible consequences on patients' interest in seeking care for their addiction and in their interest in remaining in treatment.

The decision to enter and remain in treatment is a deeply personal challenge to each and every patient. They struggle with the public perceptions of why they decide to enter treatment and why they decide to remain in treatment. We must do everything we can to assist them in their decision to enter and remain in care, and in preserving the core elements of the existing confidentiality protections. Thank you for taking these comments into account.

Sincerely yours,



Mark W. Parrino
President