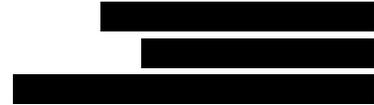




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May 18, 2015

Attn: Subcommittee on Oversight and Investigations, Committee on Energy and Commerce

Re: Questions regarding the hearings on “Combating the Opioid Abuse Epidemic”

Dear Members of the Committee,

Thank-you for giving me the opportunity to respond to these questions. My answers follow below in the format requested.

**The Honorable Tim Murphy:**

**The Committee has received a variety of reports on the impact of 42 CFR Part 2 both on the fight against the new epidemic of opioid abuse in the United States as well as efforts to integrate mental health and addiction services into the larger health care system.**

**Specifically we’ve heard reports that the stringent consent requirements associated with Part 2 aid and abet illicit doctor shopping for prescription opioid medications. Further, we understand that this federal regulation – based upon law passed in the early 1970’s – interferes with the ability to coordinate care for people with major substance use disorders. For example, most Health Information Exchanges refuse to accept addiction medical records and CMS must redact all data containing addiction medical information before sharing it with Medicare ACOs, State Medicaid agencies and Medicaid Health Homes.**

- 1. Can you give us your assessment of the interaction between Part 2 and efforts to reduce prescription drug abuse through efforts like Prescription Drug Monitoring Programs (PDMPs)?**
- 2. Do you think the time has arrived for new statutory exceptions to Part 2? For example, would it be appropriate to create new exceptions for PDMPs, Health Information Exchanges, Medicare Accountable Care Organizations, Medicaid Health Homes and other programs designed to**

**coordinate care for people with serious behavioral health conditions and comorbid medical/surgical chronic diseases?**

I wholeheartedly believe that 42 CFR Part 2 needs to be amended for the following two reasons: 1.) Patient privacy is adequately protected by HIPAA, the federal Health Insurance Portability and Accountability Act of 1996; 2.) 42 CFR Part 2 interferes with doctors' ability to provide safe and effective treatment to patients with substance use disorders, and therefore represents a form of discrimination against this sub-population of patients within the health care system.

- a. A basic quality measure of good health care is "medication reconciliation", which means assessing and documenting all the medications a patient is taking, to make sure drug-drug interactions are avoided, and the best treatment is achieved. As a result of 42 CFR Part 2, a doctor's ability to complete medication reconciliation is compromised. For example, a patient who is getting methadone from a methadone maintenance clinic, who fails to inform the doctor of this medication, is at increased risk for iatrogenic (doctor caused) harm if the doctor prescribes opioid pain relievers (e.c. Oxycontin) and/or benzodiazepines (e.g. Valium) on top of the methadone, thus increasing the chances of death due to accidental overdose, cardiac arrhythmia, etc. Attempts to reconcile medications using the Prescription Drug Monitoring Databases (PDMDs) will be of no help, because many states' PDMDs exclude methadone, as required by 42 CFR Part 2.
- b. 42 CFR Part 2 limits what medical records can be exchanged between health care organization, and even between certain departments within health care organizations. Although these records can in theory be acquired at the time of a medical emergency, in reality, 42 CFR Part 2 limits urgent access to a vital part of the patient's medical history, thus limiting the doctor's ability to provide the best care. For example, a patient who presents to the emergency department in life-threatening alcohol withdrawal, unable to verbally communicate, no longer with a detectable alcohol level in his or her blood (hence no data to suggest an alcohol use disorder), and no records of alcohol addiction in the electronic medical record database, is at increased risk of complication and even death as the doctors attempt to figure out what has rendered the patient delirious.
- c. Integrating substance use disorder treatment with other health care should be a national priority, yet 42 CFR Part 2 greatly hinders integration and coordination of care, for the very reasons you cite above, namely that Health Information Exchanges refuse to accept addiction medical records and CMS must redact all data containing addiction medical information before sharing it with Medicare ACOs, State Medicaid agencies and Medicaid Health Homes. Also Qualified Service Organization Agreements (QSOAs) cannot be signed between two treatment providers covered by 42 CFR Part 2, which prevents the use of QSOAs between an alcohol and drug program and a community mental health center, hospital or clinic that also provides covered alcohol and drug services.

Finally, on a more philosophical note, we cannot expect true parity reform for the treatment of substance use disorders, until we treat addiction as a disease, which means integrating it within mainstream health care and subjecting it to the same rules and regulations as other diseases.

### **The Honorable Markwayne Mullin**

**Dr. Lembke, Oklahoma has one of the nation's biggest problems when it comes to prescription drug abuse. Just yesterday, it was reported that last month there were more Oklahomans enrolled in Medicaid than there have ever been. We have over 830,000 people enrolled in SoonerCare. It is my understanding that most state Medicaid programs encourage doctors to prescribe methadone for pain, because it is cheap, even though the Food and Drug Administration (FDA), the CDC, and two pain medicine doctor groups recommend that methadone not be used as a first-line therapy for chronic pain. Do you think this is appropriate given the issues we've seen with Methadone being responsible for more than 30 percent of overdose deaths while accounting for just 2 percent of opioid prescriptions for pain?**

I agree that methadone should not be used as first line treatment for pain, given the high risk of accidental overdose death associated with the unique pharmacology of this drug. However, I would emphasize that opioid analgesics should not be first line treatment for any chronic pain condition, as data show they are not an effective treatment long-term for pain. Furthermore, although methadone in pill form for the treatment of pain accounts for a large share of accidental overdose deaths in this country, the same cannot be said for methadone in liquid form prescription for the treatment of opioid addiction. The latter has proven, over decades of accumulated data, to be one of the most safe and effective treatments for opioid addiction, and is not associated with high rates of accidental overdose.

Sincerely,

Anna Lembke, MD