Patient Safety
MOVEMENT

October 8, 2015

The Honorable Lamar Alexander
Chairman
Senate Health, Education, Labor & Pensions (HELP) Committee
SD-455 Dirksen Senate Office Bldg.
Washington, D.C. 20510

The Honorable Patty Murray
Ranking Member
Senate Health, Education, Labor & Pensions (HELP) Committee
SR-154 Russell Senate Office Bldg.
Washington, D.C. 20510

RE: Reforming 42 CFR Part 2

Dear Chairman Alexander and Sen. Murray:

The Patient Safety Movement Foundation is committed to the elimination of the more than 200,000 preventable deaths that occur annually in US hospitals by 2020.[1] We work with healthcare organizations, medical technology companies, patient advocates, and policymakers to identify the leading causes of preventable death in hospitals and develop solutions that can be rapidly implemented to address those issues. We believe that interoperable health technologies will be central in eliminating these preventable deaths but we know that we will fall short of our goal if we cannot develop a technology-enabled healthcare system that treats all patients equally, including those with substance abuse conditions.

In order to bring the full benefits of interoperable electronic health records (EHRs) to people living with serious substance abuse disorders, we encourage you to investigate the benefits of statutory changes that would update 42 CFR Part 2 for the era of digital medicine – with the goal of enhancing patient safety while saving lives and reducing costs through improved care coordination.

We believe that EHRs and health information exchanges (HIEs) are key to bringing healthcare into the modern era. Under current law (42 CFR Part 2), however, if addiction data is accessible via an HIE, the patient must re-sign a consent form every time a new healthcare professional is given access to the system *even if that provider will never treat them*. The value proposition of HIEs is to ensure that doctors are able to securely access their patients' appropriate health information in order to deliver high quality, coordinated care in a timely manner. In short, to realize this value all healthcare

professionals need to be leveraging HIEs and HIE networks; this means we still have a long way to go and many providers to bring on line, which is going to equate to an onerous number of consent forms for patients with addiction disorders.

As the *New England Journal of Medicine* (NEJM) noted in a recent commentary: "These regulations [42 CFR Part 2 rules], which are overseen by the Substance Abuse and Mental Health Services Administration (SAMHSA), already frustrate accountable care organizations and health-information exchanges, since their elaborate consent requirements make it difficult or impossible to share patient data related to substance-use disorders. As a result, **many organizations exclude such information from their systems, undercutting efforts to improve care and efficiency."**[2] This means that substance abuse patients will not benefit in the same ways as other patients from these care coordination models and therefore will remain at higher risk for adverse events that would otherwise have been caught by health information technologies.

Individuals with substance abuse disorders often suffer from comorbidities and may be prescribed different medications by several different providers. Without a way to effectively manage these individuals care they are at a significantly higher risk for patient safety issues such as adverse drug events. For example, there are currently three FDA-approved treatments for opioid addiction (methadone, buprenorphine and VIVITROL) and three for alcohol dependence (disulfiram, acamprosate and naltrexone), all of which have documented adverse interactions with other therapeutic drugs that are not indicated for these disorders and would likely be prescribed by a different provider. Even the most rudimentary, Meaningful Use Stage 1 certified EHR system must be able to alert providers if there is a potential for an adverse drug interaction. However, if a provider only has access to part of a patient's clinical information, there will not be sufficient data to trigger this safeguard.

As you know, adverse drug interactions are a significant patient safety issue, are extremely costly to the US healthcare system, and are completely preventable. Adverse drug events are the fourth leading cause of death in the United States ahead of pulmonary disease, diabetes, AIDS, pneumonia, accidents and automobile deaths.[3] Annually, there are more that 2 million adverse drug events,[4] which lead to more than 100,000 preventable deaths,[5] and cost the US healthcare system $136 Billion.[2] These tragedies and this costs can be eliminated but that will not happen unless all patients have equal access to interoperable electronic health information technologies.

We believe that this issue can be addressed with the addition of a new section to 42 CFR that would create a one-time opt-in process to HIEs for patients with addiction

disorders. Specifically, the consent could be structured so that addiction data "*can only be accessed by a patient's healthcare practitioner for the purposes of providing an episode of care.*"

We believe that this streamlines the consent process while guaranteeing the additional layers of privacy protection afforded to patients with addiction disorders by leveraging existing law. Access to the data would remain restricted to a patient's provider(s), with whom they have already signed a HIPAA consent form, and it would similarly limit a provider's access to that data to the length of an episode of care–which is already defined in the law for payment bundling [42 USCS § 1395cc-4(a)(2)(D)]–to stop unauthorized future access. We believe this policy approach aligns well with the Mental Health Reform Act (S. 1945) introduced by Sens. Cassidy and Murphy, which contains reforms to 42 CFR Part 2 reforms.

It is not often that such simple changes to the law can have such a significant impact on the quality of care delivered to an at risk population while generating billions of dollars in savings.

Thank you for your attention to this important issue and we hope to continue to work with your offices and with the Committee.

Sincerely,

Jim Bialick
President
Patient Safety Movement Foundation | Patient Safety Movement Coalition

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[1] James J. J Patient Safety 2013; 9(3):122-128
[2] Frakt et al. N Engl J Med 2015; 372:1879-1881 (emphasis added)
[3] Institute of Medicine, National Academy Press, 2000
[4] Lazarou J et al. JAMA 1998;279(15):1200–1205; Gurwitz JH et al. Am J Med 2000;109(2):87–94
[5] Johnson JA et al. Arch Intern Med 1995;155(18):1949–1956

Suboxone (buprenorphine / naloxone) Drug Interactions

Check for interactions with Suboxone (buprenorphine / naloxone)

Type in a drug name and select a drug from the list.

Top of Form
Bottom of Form

Common medications checked in combination with Suboxone (buprenorphine / naloxone)

- Adderall (amphetamine / dextroamphetamine)
- Adderall XR (amphetamine / dextroamphetamine)
- alprazolam
- Ambien (zolpidem)
- Celexa (citalopram)
- clonazepam
- clonidine
- Cymbalta (duloxetine)
- gabapentin
- Klonopin (clonazepam)
- Lamictal (lamotrigine)
- Lexapro (escitalopram)
- Lyrica (pregabalin)
- Neurontin (gabapentin)
- omeprazole
- Prozac (fluoxetine)
- Seroquel (quetiapine)

- trazodone
- Xanax (alprazolam)
- Zoloft (sertraline)

You should also know about...

Suboxone (buprenorphine / naloxone) disease Interactions

There are 14 disease interactions with Suboxone (buprenorphine / naloxone) which include:

- Impaired Gi Motility
- Infectious Diarrhea
- Liver Disease
- Prematurity
- Renal Dysfunction
- Acute Mi
- Drug Dependence
- Intracranial Pressure
- Respiratory Depression
- Adrenal Insufficiency
- Biliary Spasm
- Hypothyroidism
- Seizure Disorders