Patient Safety
MOVEMENT
zero preventable deaths by 2020

August 19, 2015

The Honorable Fred Upton
Chairman
Energy & Commerce Committee
2183 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
Energy & Commerce Committee
237 Cannon House Office Building
Washington, DC 20515

RE: Reforming 42 CFR Part 2

Dear Chairman Upton and Ranking Member Pallone:

The PSMF is committed to the elimination of the more than 400,000 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, particularly those with substance abuse or mental health problems.

In order to bring the full benefits of interoperable electronic health records 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.

Individuals with mental health or 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 adverse events, particularly when mental health and substance abuse patients are unable to benefit from the modern tools that coordinate other patients' care such as health information exchanges (HIEs). Today, there are three FDA-approved treatments for opioid addiction (methadone, buprenorphine and

VIVITROL and three for alcohol dependence (disulfiram, acamprosate and naltrexone). With approximately two million individuals currently receiving these addiction treatment medications there is a significant risk for drug interactions.

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.[2] Annually, there are more that 2 million adverse drug events,[3] which lead to more than 100,000 preventable deaths,[4] 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.

As a result, PSMF strongly supported the interoperability provisions in 21st Century Cures Act (Title III, Subtitle A), which have significant potential to propel the US healthcare system into the modern era. We believe, however, that it should be the goal that these improvements benefit all Americans. 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."**[5] This means that substance abuse and mental health 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.

At a minimum, this problem should be addressed by streamlining the consent process for the sharing medical records in integrated care settings. By simplifying Part 2 patient/consumer consents in Health Information Exchanges, Medicare Accountable Care Organizations and Medicaid Health Homes, the sharing of addiction medical records could make an enormous contribution to the integration of addiction treatment, primary care and medical specialty services.

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