

April 15, 2018

Chairman Michael C. Burgess, M.D. Energy & Commerce Health Subcommittee United States House of Representatives 2336 Rayburn House Office Building Washington, DC 20515

Dear Chairman Burgess:

Thank you for your continued leadership on the federal response to the opioid crisis. We are writing to express strong support for the **Overdose Prevention and Patient Safety Act, H.R. 3545**, in its original bipartisan form and to urge against the adoption of the "Amendment in the Nature of a Substitute" drafted by the bill's sponsor, Rep. Markwayne Mullin.

We deeply appreciate Rep. Mullin's leadership on this bill but believe his substitute proposal would fail to solve the significant problems the original legislation set out to address. The original, on the other hand, would be an essential piece of any opioid response package produced by the House this session.

As background, the Hazelden Betty Ford Foundation is the largest nonprofit provider of substance use treatment, education and prevention services in the world. We have provided leadership in the field of addiction treatment for nearly 70 years. In 2017 alone, our organization touched the lives of more than 21,000 people affected by addiction and other co-occurring medical and mental health conditions. We have 17 sites nationwide, serving children, adolescents, adults, families, schools and communities, and all of our treatment facilities are licensed or certified and have achieved accreditation by The Joint Commission.

To address the opioid overdose epidemic and the underlying addiction crisis in this country, we need your help to closely *integrate* addiction care within the broader health care system so patients have multiple *access* points and can get support for this chronic condition beyond the acute care stage. The original H.R. 3545 reforms the outdated 42 CFR Part 2 ("Part 2") privacy regulations, which have become a barrier to access and deprive patients of the full benefits of modern health care services. That's why we support this bill to align the Part 2 requirements with those of the Health Insurance Portability and Accountability Act ("HIPAA"), which apply to all health care providers and allow the use and disclosure of patient information when needed to facilitate optimal care.

Part 2 is outdated and onerous

Part 2 is a 45-year-old law that was created a quarter century before HIPAA specifically to protect the privacy of patients who sought care within the very young and largely un-professionalized addiction treatment industry of that time. When HIPAA was enacted in 1996, Part 2 was left in place, despite providing little to no extra privacy protections beyond those HIPAA began providing for all patients regarding all health conditions, and despite addiction care integrating more and more over time with the rest of health care.

Generally speaking, Part 2 requires many specific, written consents by the patient for his or her substance use-related health records to be shared among doctors, hospitals, specialty care providers like

the Hazelden Betty Ford Foundation, insurers and others who may support the patient's care. HIPPA, on the other hand, allows for streamlined blanket consents that better facilitate needed information sharing. Both laws provide protections for privacy violations, and the federal government regularly prosecutes HIPAA violators. But not a single enforcement case has ever arisen from Part 2, partly because full compliance is a practical impossibility that often poses risks to patient care, and also because legitimate infringements on patient privacy are already well covered by HIPAA.

Part 2 is not fairly and uniformly applied

It's also important to note that, unlike HIPAA, Part 2's unnecessary privacy regulations do not apply to all health care providers who serve patients seeking care for substance use disorder. Generally, Part 2 <u>only</u> applies to the patients of nonprofit specialty treatment providers and those that treat the poor and elderly through public insurance. Most for-profit treatment providers are not subject to the Part 2 regulations; nor are most primary care providers and independent mental health professionals, who increasingly are part of the care continuum for people with a substance use disorder; and nor is the Veterans Administration. As a result, thousands of patients receive treatment services at non-Part 2 providers throughout the country, and their information is protected by HIPAA and state law. The good news is that HIPAA is meeting the needs of those patients just fine, without the barriers that Part 2 poses for patients of Part 2 facilities.

Part 2 is largely unnecessary

Opponents of H.R. 3545 have testified it would create a framework by which, for example, a father in recovery could be denied visitation with his children because he was in addiction treatment, a mother could be threatened with eviction from a shelter because she was being treated with prescribed methadone for her opioid addiction, or a young man receiving worker's compensation could be cleared for work by a doctor but forbidden from returning due to the discovery of a previous treatment for addiction. The fact is that none of those scenarios plays out differently under HIPAA v. Part 2. All would involve disclosures made by the patients themselves, not providers – who would be equally bound under either law. Remedies in each of these situations would be best pursued under discrimination laws.

What is needed for substance use patients is legal protection from discrimination, not laws that impede information-sharing for legitimate treatment, payment and operational purposes. The idea that Part 2 provides extra protection against discrimination is, practically speaking, an illusion. While some have testified that harmonizing privacy laws would discourage people from seeking treatment, neither the law itself nor our experience as a frontline treatment provider supports that assertion.

Part 2 compromises care

In the end, Part 2's costly, onerous rules don't add meaningful protections for patients and, in fact, compromise care by forcing hospitals and doctor's offices to keep records from Part 2 providers on paper or in separate systems from all of the other electronic patient data maintained by their HIPAA-compliant systems. The result of the dual systems is that addiction treatment data are often not shared among doctors. This means doctors may not know if their patients have a history of drug or alcohol misuse or even if they've gotten treatment, and hospitals and doctors in integrated care models can miss crucial information to prevent misdiagnosis and harmful medical interactions for the patient. This separation of the data also makes it difficult for addiction treatment providers to participate in some integrated care models, for which they have to share their patient data. The reality is that the health care system is designed around HIPAA, and now that addiction care is integrating with mainstream medicine to serve patients better, Part 2 poses a dangerous disconnect. The dual policies are simply incompatible with health care today.

As it is, we are faced every day with balancing the impossible requirements of Part 2 with a sacred commitment to our patients, whose care is compromised by the letter of this outdated law.

One example: A recently discharged, hard-of-hearing patient used a relay service interpreter to contact us, a call we cannot legally take without a signed release from the patient for that interpreter. This type of scenario forces us to choose between two risks: breaking the law to help the patient, or abiding by the law and risking patient harm? It's an easy decision in the end, but a double-jeopardy with which we shouldn't even be confronted.

Another example: A patient was prescribed suboxone during residential treatment and returned to his home state. As part of his discharge plan, he was to engage a physician to continue his care. He delayed engaging a physician in his home area, which necessitated a call to the treatment center physician with a request to send his prescription to the local pharmacy. The patient was unable to immediately execute and deliver a written consent to the local pharmacy, however, meaning our physician at the treatment center could not legally call in the prescription refill or consult with the pharmacist.

Anything less than full alignment with HIPAA is problematic

Rep. Mullin's drafted amendment would dial back the scope of his original proposal by aligning Part 2 with HIPAA only for treatment purposes but not for payment or operations purposes. Unfortunately, this further bifurcation of health care records only complicates compliance further and keeps the requirement that dual systems be maintained. It also will hurt patients.

Part 2, as it relates to payment, creates access and quality care barriers, starting with patients' first call for help to determine if they have benefits and if the insurer will issue the necessary preauthorization. These barriers continue through the adjudication of the claim through the insurer as well as the peer review and utilization review processes, and on to any eventual application for disability benefits. The more patients are confronted by barriers like this, the less likely they are to follow through with their intent to access and complete treatment. In serving thousands of patients every year, we know financial impact is one of the most important factors for them – and can be a barrier to access.

Part 2, in fact, requires specific written consent for each person who touches a record within the insurance payment process, and each provider staff member who needs to touch the record as part of day-to-day operations. The average patient at the Hazelden Betty Ford Foundation, for example, is asked to sign about a dozen releases during the course of his or her care. Imagine people who have a heart attack being asked to provide consents to every person in the emergency room, hospital, insurance payment pipeline, and in their health care history who may have information pertinent to optimal care. It's unreasonable and an impossible requirement for Part 2 providers to meet in many cases, but still a federal criminal law. So, responsible organizations like ours do everything we can to comply, at great frustration, expense and harm to care.

Part 2 is a frustration to many patients, not a benefit. Payment alone takes, on average, three to five consents. Having to revisit those conversations throughout the treatment process is a barrier between patients and their care, and often takes an emotional toll on patients. Worse, if mistakes are made at any point, or if anything changes in the process of insurance review, providers often cannot make even the simplest changes without the patient's express consent. And if providers are unable to locate the patient in a timely manner—due to the complicated logistics of obtaining written consents from patients not physically on site, a barrier that does not exist for the rest of healthcare or for non-Part 2 treatment providers—bills end up becoming the patient's responsibility, the stress of which can significantly impact recovery in a negative way. Under HIPAA, on the other hand, presenting your insurance card at the outset provides consent for the whole payment process, a much more patient-friendly policy.

Part 2 institutionalizes stigma

Repeated consents also send patients the signal that the illness for which they're getting care is one that requires unusual secrecy. In that way, Part 2 institutionalizes and exacerbates the very stigma it purports to protect against. We have fought for decades to have addiction viewed and treated as a healthcare condition, and yet Part 2 validates—even if unintentionally so—the stigmatized view that it is instead a moral failing, worthy of hiding.

Part 2 also needs to be aligned with HIPAA for operations purposes. Part 2 programs need to be able to utilize patient information for administrative, regulatory financial, and quality programs. It is impossible for a Part 2 program to obtain consent for every activity and person within the organization that may need to touch patient information for operations activities like fulfilling our licensing and accreditation requirements and performing quality assurance. Some specific examples of operations-related needs include (but are not limited to) utilizing patient information to: examine the most effective treatment options; improve documentation; defend the organization or its partners in a legal dispute; conduct training programs for students, trainees or practicing clinicians; review the competence or qualifications of our multi-disciplinary team of professionals; and evaluate clinical performance.

Alignment supports "parity"

By aligning Part 2 with HIPAA for "treatment," "payment," and "operations" purposes, the original H.R. 3545 would continue Congress's effort to bring much-needed parity between care for addiction and care for physical health conditions. At the same time, the bill would actually strengthen Part 2's protections against discrimination and other potential abuses of information in criminal and civil courts; we know how important this is because we get subpoenas every day for patient records, which our Legal Department fights strenuously.

When Part 2 was enacted in the 1970s, there was no insurance coverage for addiction treatment, few states regulated facilities or providers who delivered services, and there were no other federal or state privacy regulations of comparable scope. However, much has changed in the decades since. Thanks to the 2008 Mental Health Parity and Addiction Equity Act, millions of Americans are now able to utilize their insurance benefits. Many states also now regulate facilities and providers, and providers are subject to federal regulations as well – most notably, HIPAA. It's time to bring about the regulatory changes necessary for providers to meet the needs of our patients.

It is critical that the original H.R. 3545 be preserved to align Part 2 with HIPAA for "treatment," "payment," and "operations" and included in any opioid package enacted by this Congress.

We have led the way in advocating for the rights of people with addiction for decades. In this case, the concerns of those opposed to the original bill are not supported by facts or our frontline experience. We feel strongly that maintaining unnecessary barriers to care during the nation's worst addiction crisis ever would be a missed opportunity and potentially grave mistake.

Thank you very much for your consideration and leadership on this important topic.

Sincerely,

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