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April 16, 2018

The Honorable Greg Walden, Chairman
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone, Jr., Ranking Member
House Committee on Energy and Commerce
2322A Rayburn House Office Building
Washington, DC 20515

Cc: Kristen Shatynski
Caleb Graff
Waverly Gordon
Tiffany Guarascio

Re: Support for alignment of Part 2 with HIPAA for purposes of TPO

Dear Chairman Walden and Ranking Member Pallone,

We are very encouraged by Congress's dedication to reversing the opioid epidemic. Centerstone is grateful for all the efforts Congress has made, particularly in the past year, to find ways to better treat patients with substance use disorders. Specifically, Centerstone thanks you for all your work in drafting dozens of legislative proposals to become part of a larger CARA 2.0 package. We appreciate the Committee's continued leadership in working toward well-vetted, high-quality solutions to our nation's opioid challenge. Once again, we reiterate our support for a legislative vehicle to align Part 2 with HIPAA for the purposes of treatment, payment, and healthcare operations (TPO).

The Confidentiality of Substance Use Disorder Patient Records rule – 42 CFR Part 2 – is a stringent rule that prevents providers from systematically treating OUD/SUD patients in reliance on complete and accurate patient histories. **In moving towards more robust integrated care models where every member of a patient's treatment team needs to understand a patient's full medical/SUD history, Part 2 stands as a hindrance to whole-person care**. Part 2 has never been applied universally: only federally assisted alcohol and drug abuse programs providing SUD diagnosis or treatment are subject to the stringent Confidentiality of Substance Use Disorder Patient Records rule – 42 CFR Part 2.[1,2] Part 2 prevents these federally funded providers from accessing a patient's full substance use history without the patient's prior written consent. In contrast, non-federally assisted providers throughout the country are governed only by HIPAA. Re-disclosures of protected patient information occasionally cited by patient privacy groups are currently illegal. Thus, improper re-disclosures of information are not a reflection of a weak privacy law, but rather, are a reflection of improper on-the-ground practice, which can be challenged in court. Thus, we urge lawmakers to **align 42 CFR Part 2 with HIPAA for the purposes of treatment, payment, and health care operations**. Common sense legislation like **The Overdose and Patient Safety Act (H.R. 3545)**, would align Part 2 with HIPAA for the purposes of *treatment, payment, and health care operations*. The Amendment in the Nature of a Substitute to H.R. 3545 has strengthened language regarding penalties for improper re-disclosures. Centerstone supports that added language, but stresses the need for the statutory alignment to be for purposes of treatment, payment, and healthcare operations, and not solely for the purposes of treatment (as in the AINS).

[1] https://www.samhsa.gov/sites/default/files/faqs-applying-confidentiality-regulations-to-hie.pdf
[2] http://www.jhconnect.org/wp-content/uploads/2013/09/42-CFR-Part-2-final.pdf

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Substance use disorders can have complicated ripple effects on a patient's health that need to be carefully identified and coordinated.[3] The current outdated rule poses a serious safety threat to persons with substance use disorders due to risks from multiple drug interactions and co-existing medical problems. To illustrate this, an example from a Centerstone Indiana patient follows:

A young man was referred to Centerstone from a surgeon who had concerns about depression in his patient. The referred individual had complex medical needs due to an injury. Upon initial referral, it appeared as though the young man had some mental health concerns that were being treated with an anti-depressant and a benzodiazepine, as prescribed by the surgeon. When assessing the young man at our community mental health center for mental health and addiction services, we developed serious concerns about the possibility of overlapping addictive disorders including opiate, benzodiazepine, and alcohol addiction, in addition to a depressive disorder. Due to the severity and combination of drugs the man was using, there were major safety concerns. The young man's support system was shallow - he was not from the area and had no friends or family that lived locally. He had concerns about signing releases of information for any of his family that lived out of town or for any other health care provider because he feared he would no longer be able to hide his addiction from them, or obtain medication from other providers to support his addiction. **Due to the complexity of his medical condition, he was able to easily obtain both opiates and benzodiazepines from separate medical providers. Being honest about his addiction would have resulted in him no longer having access to the drugs that were being legally prescribed to him – ones that were threatening his wellbeing and posing high levels of lethal risk of overdose.**

After consulting with psychiatric staff, we determined he was in need of an additional psychiatric assessment before potentially starting him on Suboxone to aid in staving off his addiction to opiates. The fear remained, though, that he would continue to access benzodiazepines, which, if combined with Suboxone, could be dangerous. As part of the terms of his Suboxone treatment, he had to agree to sign releases of information to his other medical providers so that his psychiatrist could inform them of his full condition, which, if ignored, could be more lethal than any of the other complex conditions he was being treated for. After several months, the young man agreed to be more open about his opioid use, and agreed to involve more and more individuals in his care by signing additional releases of information. Shortly after he signed a release for his mother, he had a significant relapse. Thanks to the ability to correspond with his mother, the treatment team intervened to get him immediate medical attention and follow-up inpatient treatment that led to a longer term residential placement. If the young man had not signed the ROIs for his mother or his other health care providers, his providers would have been extremely limited in how to proactively respond to his needs. **Without an ability to share the young man's full medical history, he would have been at high risk of death.**

SAMHSA recently released two final rules which take some steps to modernize Part 2, but they do not go far enough. Legislative action through **The Overdose and Patient Safety Act (H.R. 3545)** is necessary to modify Part 2 to the full TPO extent. We hope you will consider examples like these in finalizing a CARA 2.0 package to make care safer for all those who seek it. Thank you for your continued attention to these matters.

Sincerely,

David C. Guth, Jr.
Chief Executive Officer
Centerstone

[3] http://www.helpendopioidcrisis.org/