Testimony for the Record
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"Combatting the Opioid Crisis: Prevention and Public Health Strategies"

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Chairman Burgess, Ranking Member Green and members of the Subcommittee, thank you for inviting me to participate in today's hearing and thank you for devoting two full days to legislative solutions to end the opioid crisis and address the scourge of addiction in our communities, a topic which has been the focus of my professional career.

My name is Eric Strain. I am a psychiatrist and have spent over 30 years at Johns Hopkins, where I direct the Center for Substance Abuse Treatment and Research and serve as medical director of the Behavioral Pharmacology Research Unit.

In my practice and as a clinician leader at Johns Hopkins Medicine, I have seen the detrimental impacts of the current federal regulations 42 CFR Part 2 that limit the use and disclosure of patients' substance abuse treatment records and I am pleased that this Congress is taking a proactive step to update the law to be more in keeping with modern-day, multidisciplinary medical practice and the best patient care.

The amendment in the nature of a substitute to H.R. 3545 as offered by Representative Mullin goes a long way toward enhancing physicians' ability to share vital health information in a timely manner, while protecting patient confidentiality consistent with the Health Insurance Portability and Accountability Act (HIPAA).

Though well-intentioned at its enactment more than 40 years ago, 42 CFR Part 2 is outdated and, worse, it can result in harm to patients and inhibit new delivery system models, such as Accountable Care Organizations (ACOs) and bundled payments.

Full alignment of federal privacy rules with HIPAA for the purposes of treatment, payment and health care operations will ensure that patients with substance use disorder (SUD) receive accurate diagnoses, integrated and coordinated treatment, and appropriate patient-centered care.

42 CFR Part 2 poses a serious safety threat resulting from possible drug interactions.

Adverse drug interactions are one of the leading causes of morbidity and mortality in the United States and one of the greatest risks associated with 42 CFR Part 2 and its prohibition on sharing

SUD information with other medical professionals for treatment purposes. For example, if a patient is suffering from depression while in SUD treatment, he or she may be prescribed a sedating antidepressant by a psychiatrist who is unaware of the patient's SUD. This could lead to a severe adverse drug reaction if the patient is also taking methadone or buprenorphine to address his/her SUD. Such an adverse effect would otherwise be completely avoidable and preventable if the psychiatrist were aware of the patient's methadone prescription.

Another example involves treatment for HIV. Some common medications that are prescribed to treat HIV may hasten the metabolism of methadone and undercut the benefits of that drug. Several prescription medications that may otherwise be benign, actually slow the metabolism of methadone, causing adverse side effects. Finally, there are medications that essentially negate the benefit of methadone, undercutting the entire purpose of controlled methadone maintenance therapy.

Without legislative changes to 42 CFR Part 2, we will continue to see patients suffer as the result of these avoidable and often significant adverse drug interactions simply because non-SUD providers lack vital information about the patient's treatment.

PDMPs are prevalent, but patients do not fully benefit from them.

States, in partnership with the federal government, have spent hundreds of millions of dollars to set up prescription drug monitoring programs (PDMPs) and health information exchanges (HIE) to prevent avoidable, dangerous and potentially deadly drug interactions by permitting providers real-time medication history information on patients they are treating. However, because of 42 CFR Part 2, SUD records must remain separate and segmented from any other medical record and cannot be shared with a patient's primary care physician, psychiatrist or other specialist without the express, written consent of the patient, so the benefit to PDMPs and HIEs is undercut for patients suffering from SUD.

In dire situations, patient consent may not be possible.

Patients brought into the hospital emergency department (ED) after a serious accident, may be unconscious and therefore unable to communicate to the treating provider that they are in treatment for, or have a history of SUD. Without this important information, the ED provider may prescribe an opioid to alleviate pain and the patient may relapse as a result.

The "emergency" exception is insufficient and confounds early intervention.

We recognize that there <u>is</u> an "emergency" exception under 42 CFR Part 2 that would permit an SUD program to provide information to the ED physician without the patient's consent in a bona fide emergency, but there are limitations to this exception. Most importantly, the ED provider would have to know there was SUD information to request and would have to know from which SUD provider to request the information, which is rarely the case. Additionally, even if the ED provider were aware that there was SUD information to be requested, the SUD provider would have to be available and willing to provide the requested information, which is not always possible in an emergency.

With the advent of HIEs, PDMPs and electronic medical records (EMRs), most information is readily available to ED physicians 24 hours a day, and it has become the standard of care to check

these systems for evidence of past medical histories that guide a provider in delivering appropriate care. Unfortunately, due to 42 CFR Part 2's consent requirement, SUD information often is not available in these systems and is therefore not available to ED staff, a factor that has real and significant consequences for patients.

Additionally, most providers prepare for a patient encounter by reviewing the patient's medical records in advance. If the non-SUD physician must wait until the actual encounter to learn the patient has a history of SUD, it is too late for the physician to get a consent and obtain the records from the SUD program even if the patient is willing to share the information. As a result, the physician must rely on the patient to accurately disclose their medical regimen, dosage information, and plan of care, which may lead to inaccurate information in the patient's record.

Lack of transparency shortchanges patients who could benefit from additional care at the time of service.

Many patients undergoing SUD treatment have co-occurring conditions that may have come about as a result of, or are otherwise related to, their SUD, such as cardiovascular disease, HIV/AIDS, STDs, hepatitis C, depression, injuries and other illnesses. Segregating care and disorders into silos without sharing the information with other treating providers does a disservice to the patient and those providers who do not have the benefit of the SUD-related information.

42 CFR Part 2 tends to focus upon the "program" as the level of service delivery unit, and 42 CFR Part 2's privacy restrictions are limited to care rendered within the four walls of these programs. The development and approval of a variety of pharmacotherapies for SUDs (e.g., acamprosate, buprenorphine, naltrexone) has resulted in treatment occurring in primary care provider offices, as well as other general clinical settings. This expansion of treatment into other integrated care settings has been successful in getting patients the SUD care they need while also treating their other medical conditions.

Relying on consent is often not practicable in these contexts, and it may diminish the value of the integrated care programs. While our experience has been that a majority of patients will sign a consent form because they understand the benefits of the program communicating to the physician and trust their providers to do what is in their best interest, there is no mechanism for effectively treating patients in these interdisciplinary programs if they do not consent to sharing the information with other specialists involved in their treatment. Following are three examples:

- Johns Hopkins Bayview Medical Center (Bayview) offers an outpatient program through the Center for Addiction and Pregnancy (CAP) that helps mothers and infants deal with the physical, emotional and social problems caused by SUDs. This program offers coordinated and multidisciplinary care to drug-dependent mothers and their drug-affected babies. The program is less effective and patients lose the benefits of coordinated care when information is not freely shared between the CAP program and the Bayview Ob/Gyn Department, the Pediatrics Department, the Psychiatry Department and hospital social workers and case managers. In addition, when a drug-affected baby is treated in the Neonatal Intensive Care Unit (NICU), the NICU clinical staff may not have access to the mother's full SUD history, including what drugs may be affecting the newborn baby. Because 42 CFR Part 2 requires CAP to obtain written consent to share SUD information with the other departments, a

pregnant patient who requires SUD treatment but who is unwilling to sign a consent neither she nor her baby will receive the comprehensive care and treatment they need. The effectiveness of the Bayview program depends on the clinicians' ability to share relevant clinical information with all who are involved in patient care.

- Johns Hopkins' inpatient Chemical Dependence Unit (CDU) provides safe, medically supervised withdrawal in a monitored environment for individuals dependent upon alcohol, benzodiazepines and opioids. In addition to the SUD providers at the CDU, the patient benefits from consultations from other specialists outside the program. Because of the requirements of 42 CFR Part 2, the patient will not receive the full benefit of these other consultations if he or she is unwilling to provide the legally required consent.

- The buprenorphine component of Johns Hopkins' Bartlett Clinic -an HIV treatment site- relies on other departments within Johns Hopkins — but outside of the SUD program — to treat patients and meet their medical needs. The departments of medicine and psychiatry and SUD providers work together to holistically treat the patient within the same facility and health system, but outside the legally identified SUD program.

The foregoing examples illustrate how the limitations imposed by 42 CFR Part 2 are hindering effective care in an integrated care setting where our patients could benefit from multidisciplinary care in one place and during the same encounter.

42 CFR Part 2 hides the successes of treatment and perpetuates stigma.

Continuing to segregate SUD information from other medical information perpetuates stigma associated with SUD treatment. Ideal patient care occurs in a comprehensive manner. Systems and regulations that dissect and localize a particular treatment or illness are ultimately flawed in that they fail to appreciate and care for the whole person and create barriers to providing effective lasting treatment.

Those who would be permitted to receive SUD information under this amendment would be only those who are already subject to strict confidentiality restrictions pursuant to the regulations issued under HIPAA, which offers relevant privacy protections. These regulatory restrictions, coupled with the existing requirement to secure a specialty court order before SUD information could be introduced in litigation or a criminal proceeding, would enable providers to share potentially lifesaving information while still giving patients the confidence that their SUD information would remain protected and not used for purposes outside the treatment context.

Additionally, the Mullin amendment includes language to protect against loss of employment, housing, child custody, criminal arrest, prosecution and incarceration in the event SUD treatment becomes known to third parties. The proposed amendment includes strong anti-discrimination provisions that offer additional protections. We strongly support keeping the specialty restrictions available under 42 CFR Part 2 to keep SUD information from law enforcement professionals, employers and divorce attorneys.

Alignment with HIPAA for health care operations and payment should be included.

Health care delivery is moving from volume to value, and the value added by organizations such as health plans and ACOs should be considered in any attempt to amend 42 CFR Part 2. Health plans and other organizations, such as ACOs, have filled in gaps left by resource-strapped SUD programs by offering comprehensive care management programs to patients. But to do so, they must have a mechanism to identify who those patients are, and this can be best achieved by free communication between health plans, ACOs and SUD programs.

When ACOs cannot receive full data on all attributed patients, either from CMS or from relevant SUD programs, due to 42 CFR Part 2,the ACO then has an incomplete picture of their attributed patient population and what conditions may need to be addressed. Such data could allow the ACO to institute programmatic initiatives to more effectively address particular SUDs in its population. We are losing an opportunity for the ACOs to further help in this crisis. ACOs have been unable to focus on SUD interventions because they lack population-wide information about the incidence of SUD in their attributed beneficiary populations.

Additionally, SUD providers need to be able to share SUD information with a patient's health plan for payment purposes. As groups work to increase access to SUD care to address the current epidemic, treatment programs must be properly reimbursed for their services so that they can remain financially viable and open. Patients could retain the ability to keep their SUD treatment from their health plans by choosing to pay out-of-pocket for services, which is a right granted under HIPAA. However, SUD programs risk insolvency if they are not able to bill for their services in all other scenarios.

It is time to bring appropriate sharing of substance use records into the 21st century.

The current system of separate sets of rules and regulations for SUD information and general medical information no longer reflects the contemporary state of care for, or management of, patients. Optimal patient care occurs in a comprehensive and integrated manner, with information in a patient's entire medical record, including their SUD history shared across all specialties and providers.

We are in the midst of an epidemic. My training tells me we need to respond accordingly, with the broadest possible intersectional collaboration, with initiatives for both patients and populations, and with mapping and deployment of all possible resources. And most importantly, we need strategic and thoughtful information management. Providers on the front lines of treating substance use disorders. They are uniquely positioned to be a resource, but they cannot do so without an unobstructed view of their patients' medical records. I urge the committee to report out legislation amending 42 CFR Part 2 that allows the responsible sharing of patient records for the purposes of treatment, payment, and health care operations.

Thank you and I would be pleased to answer any questions you may have.

The opinions expressed herein are my own and do not necessarily reflect the views of The Johns Hopkins University.