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Congress of the United States House of Representatives
Committee on Energy and Commerce, Subcommittee on Health
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Washington, D.C. 20515
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Re: Confidentiality of Substance Use Disorder Patient Records, Combatting the Opioid Crisis, Prevention and Public Health Solutions

We appreciate the opportunity to provide the requested clarification to the Committee on Energy and Commerce, Subcommittee on Health. As discussed in the Committee, virtually all of the cases I have seen can be addressed effectively while respecting the balancing concern of confidentiality protections. An understanding of the reasons for confidentiality as well as the desired coordination can lead to an effective and balanced solution that protects the individual seeking care. Focus should remain on the impact to the majority of those affected, rather than rare or very uncommon situations.

In your followup request, you asked:

- So if the providers cannot see methadone in the PDMP and the patient does not disclose this information to them, how can they know if a patient is getting prescriptions for controlled substances and methadone and is potentially at risk for a dangerous drug interaction?

Context: Every change to the confidentiality regulation has unintended consequences, since it affects multiple types of patients. Based on the limited details provided, an adverse impact caused by unknown multiple prescriptions as described is quite uncommon. When offering a new prescription, this limited risk of unknown interactions must be weighed against the known risks as noted on the FDA label change for all long-lasting opioids stating:

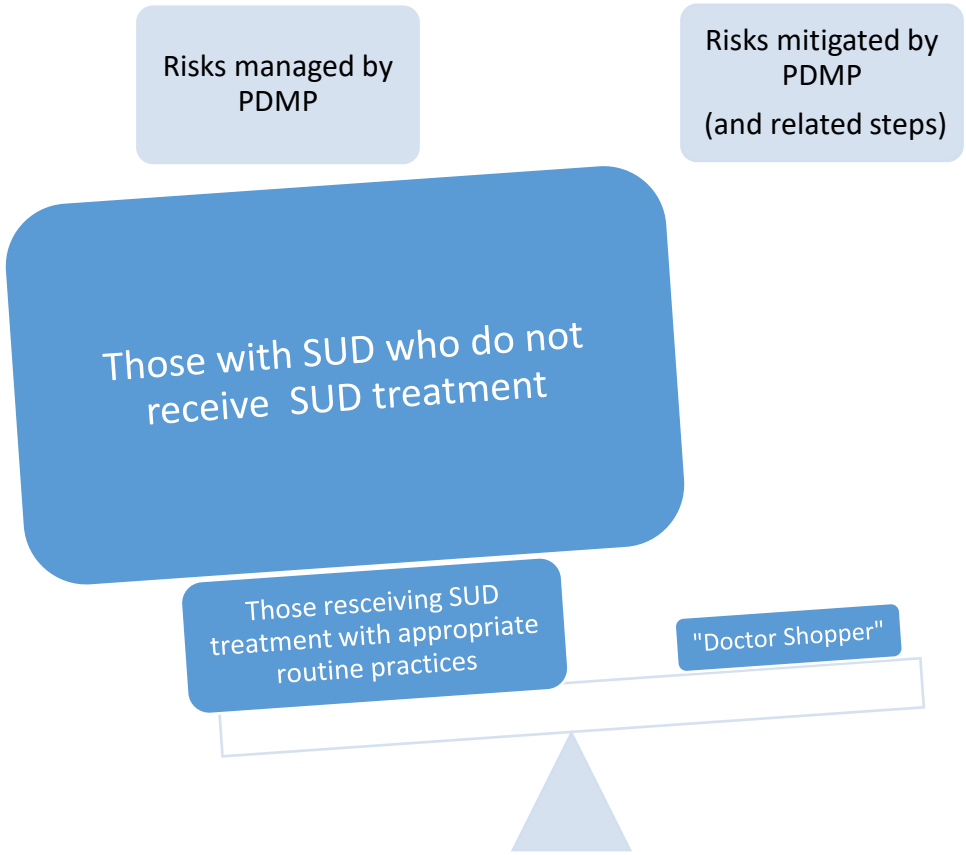
> "Because of the risks of addiction, abuse and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve [Trade name] for use in patients for whom alternative

treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain." (2013)

Scenario to explain the use of PDMP:

The follow-up question does not provide a sufficient detail of the concerning situation that is driving this particular effort. Therefore, accurately answer, I will describe a scenario in which an individual who is on methadone and seeks an additional prescription for opioids from another provider. This situation highlights the importance of the PDMP which may be used as an effective, although imperfect tool.

The illustration below demonstrates where this situation fits in the context of SUD.



Group 1) Majority scenario: Those with SUD who do not receive SUD treatment

The vast majority of those with SUD receive no SUD treatment whatsoever. Consequently, the PDMP accurately describes their medication history. Given the widespread

use and efforts at interstate sharing of data in this system it is perhaps the most complete source of information of this nature, although it is imperfect (it will not describe illicit use history).

Remember that SAMSHA reviewed and published two final rules in the past year and a half, after considering hundreds of detailed comments of information from the field over multiple revisions and review periods. They reiterated that 42CFR Part 2 would remain, and that its original purpose of "intended to insure that an alcohol or drug abuse patient in a federally assisted alcohol or drug abuse program is not made more vulnerable by reason of the availability of his or her patient record than an individual who has an alcohol or drug problem and who does not seek treatment.(42 CFR Part 2, §4.3 Purpose and Effect)". This conclusion is supported by their signature study; the annual National Survey of Drug Use and Health (NSDUH) that surveys over 90,000 Americans (the most recent was published September, 2017). The NSDUH study continues to find that two of the top reasons why individuals do not seek treatment are related to the fear of stigma. Specifically, they report concern of what others will think of them and fear of impacts on employment. They also find that among those who need treatment, approximately 90% do not receive it. Any considered changes to the system are weighed against the adverse impact to this majority.

While sharing of this confidential personal medical information is illegal under both HIPPA and 42 CFR, we know that adverse impact, and related discrimination is more common when personal data is more widely available. The current Cambridge Analytica situation has highlighted these risks, as well as the concern that disclosures today can lead to other unforeseen risks in the future. It is noteworthy that 42 CFR Part 2 is specific to the release of information from a Part 2 covered program. So despite its reputation, confidentiality does not impact sharing of personal data shared in other non-42 CFR settings (the majority of hospitals, doctor's offices etc.). One other key difference between 42 CFR and HIPPA is that 42 CFR requires the direct release of information from the patient, who thereby remains in control of the disclosure of their most personal guilt, fear, shame and trauma, while HIPPA permits sharing more broadly with a general release. These are the specific concerns of the majority of individuals with SUD, as illustrated by the NSDUH survey, and consequently must be central to any consideration since we can't help individuals who are so afraid of harm that they do not ever seek treatment.

Group 2: Those with SUD who are engaged in appropriate routine practice.

With routine practice, any physician asks the patient about their medical history, orders various lab tests, and seeks follow-up information from other treating physicians with a release from the patient. Similarly, it is routine that treatment providers in a Part 2 covered program monitor for changes in the medical history, check the PDMP, orders drug testing, and obtain signed releases for a variety of collaborators for coordination of care. The specific releases help to engage the patient in the treatment process. With these routine practices, there is coordinated care to prevent aberrant prescribing requests or associated drug interactions.

Group 3: "Doctor Shopping"

The third group of individuals include two subsets: those with a prior relationship with the prescribing physician and those without. In this scenario where both a general practitioner

and methadone clinic are working with a patient, there is already a release in place, as well as detailed information in the general practitioner's medical record due to the history. If a patient seeks additional prescriptions from this provider, the existing history will be glaring red flag, and simple follow-up phone call can maintain coordinated care. Even if a medication were prescribed, the methadone clinic could see the prescription change made by the general practitioner in the PDMP.

In the scenario of this patient going to a new general practitioner, what would they find when they check the PDMP? The Center for Disease Control finds that among those prescribed opioids, **there are an average of 3.5 opioid prescriptions per individual user** (CDC, 2017). Consequently, the prescriber would likely have reason to prescribe with caution (as indicated by the FDA warning label). When in any doubt (such as presenting risk factors or history), in the current environment of the opioid epidemic, it is good practice to order a drug screen prior to a new prescription of a controlled substance. This would help not only to protect against a drug interaction of prescribed medications, but also protect against interactions with other drugs obtained illicitly, which would be an expected risk in this subset.

Alternate Solution:

Rather than reducing confidentiality for millions of Americans, to potentially correct a concern in a serious but uncommon situation, emphasis should be placed on:

- The methadone provider offering adequate treatment and referring to more intensive care when the outpatient medication assisted treatment is inadequate to stabilize a patient.
- The methadone provider engaging in continued monitoring of PDMP to adjust the treatment plan.
- Insurance or other funders authorize and pay for adequate intensity and duration of SUD treatment, just like offering the proper dose and duration of an antibiotic.
- For some individuals, outpatient treatment is not adequate stabilization, so the removal of the Institute for Mental Disease (IMD) barrier to residential care is critical for these patients.
- The prescribing community use due caution with opioid prescribing, which would include checking the PDMP as well as drug testing prior to offering new prescriptions in patients that demonstrate risks.
- Use of effective best practices including routine releases of information and direct coordination of care rather than "access" to a record.
- Remembering that there is a struggling patient at the center of this. If we stop them from obtaining a prescription, they will go illicit sources instead. Therefore, the emphasis must be on improving their clinical care, rather than trying to simply "catch" a unique situation.

As discussed, the best solutions invariably are grounded in the effective relationship building with a patient directly, who will always know more than we will, since they know what was used illicitly.

In terms of outlining the context, there is one other group to consider, which is larger than any of those mentioned above; the recovery community. There are an estimated 23.5 million Americans in recovery from SUD. While some may have the financial means, and recovery support to share their personal information, many continue to avoid disclosing these past behaviors for fear of impact on their employment, housing, or other situations, years later. At the recent SAMHSA listening session on confidentiality, a testifier discussed how he continued to face challenges for a heart condition and pain management, many years after being labeled with SUD following a severe spinal cord injury. A recent New York Time exposé entitled *"Injecting Drugs Can Ruin a Heart. How Many Second Chances Should a User Get?"* discusses offering SUD treatment as a rationale to deny surgery:

> "Dr. Pollard has been lobbying hospital systems in Knoxville to provide addiction treatment for willing endocarditis patients, at least on a trial basis, after their surgery. If the hospitals offered it, he reasons, doctors would have more justification for turning away patients who refused and in the long run, hospitals would save money."

Taken together, the PDMP offers a means to mitigate the risk of drug interactions, identify aberrant drug seeking, and engage a patient in the proper SUD treatment, while protecting the civil rights of personally protected information from being spread unnecessarily.

If you have additional questions as they relate to the critical nature of confidentiality on the SUD treatment relationship, please let me know. Since the question posed relates directly to methadone, you might also seek input from the American Association for the Treatment of Opioid Disorders, the national association specializing in this area.

Again, thank you for your careful consideration in this complex issue that is so sensitive in the context of the current epidemic.

Sincerely,

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