AMA
AMERICAN MEDICAL ASSOCIATION

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The Honorable Orrin G. Hatch
Chairman
Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member
Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Hatch and Ranking Member Wyden:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to express concern over efforts to remove patient privacy rights under 42 CFR Part 2 (Part 2). We applaud Congressional efforts to address the country's opioid crisis and understand why many stakeholders believe that aligning Part 2 with the Health Insurance Portability and Accountability Act (HIPAA) in the interest of information sharing is a critical component of those efforts. However, considering the current opioid epidemic, we believe it is important to not lose sight of the purpose of Part 2: to encourage patients to seek treatment for addiction knowing that their health information will not be shared, thereby easing fears of discrimination and negative legal consequences resulting from their substance use.

We believe that there is a fundamental misunderstanding on the part of many stakeholders of how Part 2 allows information to be shared among clinicians. **We do not believe that aligning Part 2 with HIPAA is the answer to the concern Congress intends to address.** We agree with the Medicaid and CHIP Payment and Access Commission's (MACPAC) statement in its June 2018 Report to Congress on Substance Use Disorder Confidentiality in Regulation and Care Integration in Medicaid and Chip (MACPAC Report) that "Additional clarifying guidance on the existing regulations…would be a meaningful step to help providers, payers, and patients understand rights and obligations under the current law as well as existing opportunities for information sharing."[1]

Proponents of alignment state that a patient struggling with substance use disorder (SUD) will still have the "same consent requirements" when his or her information is used and disclosed for treatment, payment, and operations (TPO) purposes as any other patient whose information is covered by HIPAA does. However, while covered entities *may ask* for a patient's consent to share patient information for TPO purposes under HIPAA, *consent is not required*.[2] Aligning Part 2 with HIPAA would effectively remove privacy rights from a particular patient population—the very rights that were created to encourage SUD treatment. As noted by 113 patient advocacy groups, aligning Part 2 and HIPAA will discourage

[1] https://www.aclum.org/en/publications/victory-police-massachusetts-must-now-get-warrant-access-sensitive-patient-data, p. 23.
[2] 45 CFR 164.506(b)(1).

individuals struggling with addiction from seeking treatment if they know that their information will not be protected.[3]

As you work to reconcile House and Senate opioid legislation, we urge you to not include language eliminating privacy rights under Part 2 without additional consideration of Part 2 and whether alignment is needed, who Part 2 applies to, how information may be disclosed under it, and how the potential unintended consequences of aligning it with HIPAA would impact both the medical profession and, most importantly, patients.

To Which Facilities and Individuals Does Part 2 Apply?

Part 2 applies to a (1) federally assisted (2) program that (3) holds itself out as providing and provides diagnosis, treatment, or referral for treatment for an SUD—all three elements must be met.[4] As of 2016, there were only about 12,000 such entities across the country, according to the Substance Abuse and Mental Health Services Administration (SAMHSA).[5]

A "program" is an individual, entity (other than a general medical facility), or an identified unit in a general medical facility. Medical personnel or other staff in a general medical facility who are federally assisted and identified as providers whose primary function is to provide diagnosis, treatment, or referral for SUD treatment are also considered "programs." For example, a physician who is registered with the Drug Enforcement Agency (DEA) to prescribe controlled substances for detox or maintenance treatment of an SUD and whose primary function is SUD diagnosis, treatment, or referral is considered a program for purposes of Part 2.

Part 2 does not apply to any practices or facilities that do not fit squarely into this definition. For example, Part 2 is irrelevant to emergency room personnel who refer a patient to the intensive care unit for an apparent overdose, unless the primary function of such personnel is the provision of SUD diagnosis, treatment, or referral for treatment and they are identified as providing such services or the emergency room has promoted itself to the community as a provider of such services.[6] Similarly, just because a physician is registered with the DEA to prescribe controlled substances for the treatment of opioid dependency does not mean he or she is covered by Part 2 if his or her primary function is not SUD diagnosis, treatment, or referral. In both instances, a physician can disclose information about SUD diagnosis, treatment, or referral in the same way he or she would disclose any other medical information, bearing in mind HIPAA and any relevant state privacy laws.

How Can Part 2 Information be Disclosed?

Part 2 information can be disclosed with written or electronic patient consent including several specific elements. **The information can be sent to an individual or an individual employed by a facility; or to a care team comprised of past, present, or future providers of treatment for any condition; or to an**

[3] https://lac.org/112-nations-leading-patient-advocacy-health-care-organizations-launch-campaign-protect-patient-privacy-rights/
[4] 42 CFR 2.11 and 2.12.
[5] Department of Health and Human Services: 42 CFR Part 2: confidentiality of substance use disorder patient records; proposed rule. Federal Register 81:6988–7024, 2016.
[6] 42 CFR 2.12(e)(1).

Accountable Care Organization (ACO) where the patient has past, present, or future providers of treatment for any condition.[7] As the MACPAC Report notes, if a care manager secures a patient's consent that "uses a general designation to share information with all of the patient's future treating providers…no new consents would be required to share information with a solo practice physician who is a new addition to the care team."[8]

Part 2 information can also be disclosed—without consent—to medical personnel to the extent necessary to meet a bona fide medical emergency in which the patient's prior informed consent cannot be obtained.[9] There are additional circumstances in which information can be disclosed in compliance with regulation, including for audit and evaluation, disclosures made to qualified service organizations, and for research.

Potential Unintended Consequences of Alignment

As the MACPAC Report states, "Disclosure of SUD-related information can have serious consequences" and notes that SUDs are "widely stigmatized."[10]

- **Part 2 Protects More Than Opioid Use Disorder:** Many proponents of alignment claim that alignment is necessary to reduce the number of patients who receive opioids because their primary care physicians or other specialists will not know that the patient has struggled or still struggles with opioid addiction. However, Part 2 covers all SUDs—not just opioid addiction. Alignment would remove the privacy rights of *all* patients who seek treatment at a Part 2 program for any SUD and could discourage patients from seeking treatment not only for opioid dependency, but for other addictions as well.
- **The Myth of Information Availability:** Supporters of alignment envision a patient's SUD records being available to all of the patient's providers at any given time. However, given the current state of interoperability, alignment simply will not result in on-demand information. A clinician cannot go to his or her electronic health record (EHR) and "pull" a patient's SUD information upon request—in other words, regardless of whether Part 2 has been aligned with HIPAA, a clinician cannot simply search a patient's name in his or her EHR and obtain all of the patient's information.[11] This problem exists even now with information covered by HIPAA and

[7] See https://www.aclum.org/en/publications/victory-police-massachusetts-must-now-get-warrant-access-sensitive-patient-data, p. 34, stating, "To provide greater flexibility in sharing information, including through intermediaries such as [health information exchanges] HIEs and ACOs, the 2017 Part 2 update now allows patients to make a 'general designation' of an individual or entity to whom information can be disclosed, so long as that person or entity has a 'treating provider relationship with the patient." Further, "[t]he 2018 rule made changes to permit Medicaid and CHIP agencies and MCOs [managed care organizations] to redisclose information without additional patient consent to contractors and subcontractors for payment and health care operations activities…" at p. 35.

[8] https://www.aclum.org/en/publications/victory-police-massachusetts-must-now-get-warrant-access-sensitive-patient-data, p. 31.

[9] 42 CFR 2.51(a).

[10] https://www.aclum.org/en/publications/victory-police-massachusetts-must-now-get-warrant-access-sensitive-patient-data, p. 25

[11] This issue persists even if the physician is part of a regional or EHR-based HIE. For example, just as is the case currently in healthcare, there may be 40 different "John Smith"s in an EHR and patient-matching is notoriously difficult.

would still exist with Part 2 information that is shared for TPO purposes. As you are likely aware, most clinicians cannot obtain a patient's health information from other clinicians electronically, often resorting to fax or having the patient bring copies of his or her record to the treating provider from the rendering provider. Of course, the AMA is trying to advance the state of interoperability such that this type of search could occur, but that is likely years away. This lack of interoperability impacts records currently shareable under HIPAA, so changing the law about patient consent for TPO purposes will not solve the problem of data availability. Changes in technology must occur first; such changes would be a much more effective way to address both consent and privacy, not only for SUD, but also for other types of sensitive information such as minor health, sexual health, mental health, and HIV-status.

- **The Burden of Data Segmentation:** Some proponents of alignment note that they simply want to permit sharing of Part 2 data by and between Part 2 providers and covered entities for only TPO purposes. They have aimed to ensure that Part 2 data will not be disclosed for other purposes (including redisclosure for any purpose permitted under HIPAA other than TPO). However, this means that physicians must always redact Part 2 data from a patient's record when they send information to any entity other than covered entities for TPO purposes. This constraint exists now, of course, but an influx of Part 2 data will only increase the amount of information a physician will need to manage. Currently, many EHRs do not include data segmentation functionality (at least not without significant cost to a physician), which means that Part 2 (and other types of sensitive) information is either integrated into the patient's main medical record or buried in free-text portions of the record. In either case, attempts to remove all mentions of SUD information before sending a patient's complete medical record will be highly burdensome and time-consuming for a physician, likely needing to be done by hand. Relatedly, under HIPAA, once SUD information is included in a patient's medical record, it is extremely difficult to remove.
- **Physician-Patient Relationship:** In many cases, if a patient wants to share SUD information, he or she will tell the clinician where he or she has received treatment and the physician can obtain those records with the patient's consent. If a patient does not want to share SUD information with his or her clinician (and given the lack of interoperability described above), it is very unlikely that the clinician would be able to locate the patient electronically even if the law is changed. Further, if a clinician *is* able to locate the correct patient's SUD record, the patient may not be aware of the clinician's access to such information. Surprising a patient with his or her SUD records when the patient has not provided consent for the clinician to receive them may erode trust in his or her relationship with his or her physician, both on the SUD treatment provider side and the treating clinician side.
- **State Law:** Some alignment advocates note that HIV and behavioral health do not enjoy a higher level of privacy under federal law, which they state has helped to reduce stigma related to those health issues. While it is true that there are no such federal laws, many states have adopted their own laws restricting disclosure of sensitive medical information. In fact, as of 2013, 20 states have more restrictive laws related to SUD information.[12] Another 18 states have incorporated Part 2 by reference or have requirements identical to Part 2.[13] Alignment will not pre-empt these more

[12] http://www.healthinfolaw.org/comparative-analysis/disclosure-substance-abuse-records-without-patient-consent-50-state-comparison

[13] http://www.healthinfolaw.org/comparative-analysis/disclosure-substance-abuse-records-without-patient-consent-50-state-comparison

restrictive laws, which will further confuse patients and clinicians about how SUD information can be shared.

- **Legal consequences:** While important work is being done to remove stigma and regard SUD as a medical issue like any other medical issue, the fact remains that most substance abuse is illegal, which is decidedly unlike any other medical issue.[14] Additionally, while HIPAA indeed protects patient privacy, HIPAA breaches also occur all the time and are increasing every day. Increasing the exchange of SUD data increases the risk of inappropriate disclosure of such data, the consequences of which could be exponentially more harmful to the patient than the improper disclosure of one's hypertension might cause (examples include loss of housing,[15] loss of child custody,[16] discrimination from medical professionals,[17] loss of benefits,[18] or loss of employment,[19] among others[20]). In fact, before enacting a law requiring that police and prosecutors obtain warrants before searching in sensitive patient information in the state's prescription monitoring database, Massachusetts allowed police and prosecutors to view patient medical records without warrants nearly 11,000 times—or about 20 times per day—between August 2016 and March 2018.[21]

We continue to stand ready to assist with efforts—at both the legislative and regulatory levels—to arrive at a solution that balances the need for health professionals to have the information they need to provide appropriate medical services to patients with SUD, while ensuring appropriate privacy protections for patients. **We urge Congress to refrain from removing rights from a specific, already-at-risk population, and exercise its discretion to thoroughly consider the range of issues related to alignment of Part 2 and HIPAA.**

Sincerely,

James L. Madara, MD

[14] https://www.wkbn.com/ohio-news/overdose-victims-cited-in-one-ohio-city/1067863977
[15] https://www.huduser.gov/portal/periodicals/cityscpe/vol15num3/ch2.pdf
[16] https://www.childwelfare.gov/pubPDFs/drugexposed.pdf
[17] https://www.ncbi.nlm.nih.gov/pubmed/23490450
[18] https://www.ssa.gov/policy/docs/rsnotes/rsn2001-02.html
[19] https://corporate.findlaw.com/litigation-disputes/the-americans-with-disabilities-act-and-current-illegal-drug.html
[20] https://www.healthaffairs.org/do/10.1377/hblog20170413.059618/full/; see also https://www.aclum.org/en/publications/victory-police-massachusetts-must-now-get-warrant-access-sensitive-patient-data, p. 25.
[21] https://www.aclum.org/en/publications/victory-police-massachusetts-must-now-get-warrant-access-sensitive-patient-data