SUBMITTED VIA E-RULEMAKING PORTAL

January 31, 2023

U.S. Department of Health and Human Services
Office for Civil Rights
Attention: SUD Patient Records
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue, S.W.
Washington, DC 20201

Re: Confidentiality of Substance Use Disorder Patient Records
RIN 09-45-AA16, Docket No. HHS-OCR-0945-AA16

To Whom It May Concern:

The Legal Action Center (LAC) is a national non-profit organization that uses legal and policy strategies to fight discrimination, build health equity, and restore opportunity for people with arrest and conviction records, substance use disorders, and HIV or AIDS. LAC appreciates the opportunity to comment on the U.S. Department of Health and Human Services' (HHS) Notice of Proposed Rulemaking (NPRM) to implement section 3221 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act by amending 42 CFR Part 2 (Part 2). **LAC writes in support of individuals' rights to privacy and autonomy** – cornerstone elements of treatment and recovery – and with concerns about several of the proposed modifications to weaken established confidentiality protections and expose patients to greater risk of prosecution, discrimination, or stigma.

Executive Summary

Part 2 safeguards patients against the all-too-common harms that result from the disclosure of one's treatment records, including targeted investigation and prosecution by law enforcement, discriminatory or stigmatizing treatment in healthcare settings, and discriminatory barriers to housing, employment, and benefits. As HHS acknowledges in this rulemaking, weaker patient privacy protections "result in a greater likelihood of harm to [patients'] reputation, relationships, and livelihood," and also discourage people

from entering treatment.[1] In the National Survey on Drug Use & Health, individuals' concerns about confidentiality, stigma, and discrimination consistently rank among the top barriers to treatment.[2] Information in substance use disorder (SUD) treatment records is particularly sensitive due to the criminalization of people who use drugs and the persistent stigma and discrimination against people who use or have used drugs. Indeed, the Part 2 privacy protections have served as a model for many other privacy laws for sensitive, stigmatized, or criminalized health information, including states' SUD privacy laws, mental health privacy laws, and HIV privacy laws.[3] More recently, reproductive health and justice advocates have looked to Part 2 as a model for state or federal privacy laws to protect patients in states that have criminalized abortion and reproductive healthcare, since HIPAA is not sufficiently protective.[4]

Privacy protections for SUD treatment records bolster many of the Biden-Harris Administration's top public health priorities. Confidentiality safeguards help expand access to treatment – and expanding access to evidence-based treatment and recovery support services are both stated priorities for the Biden-Harris Administration's drug policy.[5] Moreover, privacy protections "advance recovery-ready workplaces" by protecting individuals against discrimination in the workplace – another stated goal of the Biden-Harris Administration's drug policy.[6] Given the national patterns and practices of racially targeted surveillance, policing, prosecution, and punishment, Part 2's strict prohibitions against using SUD treatment records to criminally investigate or prosecute a patient[7] help to advance racial equity issues in drug policy" – again, a stated priority for the current Administration.[8] Recognizing individuals' privacy rights means centering patients as decision-makers in their health and treatment, and ultimately enhances "patients' health and well-being."[9] Meanwhile, *there is no evidence* to support the claim that weakening Part 2 and patient privacy rights will improve treatment outcomes or address stigma in healthcare settings.[10]

LAC's comments on the NPRM include the following key points:

- HHS should withdraw the proposed changes that would allow law enforcement to obtain **patient consent to criminally investigate or prosecute a patient** (§ 2.12).

- HHS should introduce **additional safeguards for consent forms** authorizing disclosures for treatment, payment, and healthcare operations (TPO), in order to meaningfully preserve individuals' right to direct disclosures of their treatment records (§§ 2.31, 2.32, 2.33).

- Any changes to weaken the privacy protections for SUD treatment records should go into effect **at the same time as the corollary anti-discrimination protections** required by Section 3221(i) of the CARES Act.

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- HHS should **prioritize proven public health strategies that center individual rights and harm reduction** approaches to substance use disorder, rather than focusing on "investigating and prosecuting bad actors."

Throughout LAC's comments, we return to a central question for HHS in this rulemaking: given HHS's acknowledgement that privacy protections encourage individuals to enter treatment,[11] and promote patient confidence in treatment,[12] and protect patients from stigma, discrimination, and criminalization,[13] **why is HHS pursuing a rulemaking that weakens patient privacy any more than what is strictly required by the CARES Act?** Why is HHS not using *every tool at its disposal* to promote patient privacy rights and protect against harmful disclosures? In the NPRM's preamble, HHS references the well-funded lobbying efforts to minimize compliance costs and "align" Part 2 with HIPAA,[14] and references a letter from the National Association of Attorneys General in support of weakening patient privacy rights.[15] *But HHS does not appear to be taking into account the hundreds of advocacy groups and directly impacted individuals who have spoken in favor of patient privacy rights.*[16] Nor has HHS addressed the lack of evidence supporting the claims that weakening patient rights will improve patient outcomes or promote access to care or reduce stigma.[17]

We urge HHS to pay special attention to comments about this proposed rule from directly impacted stakeholders, including current and former patients at Part 2 programs, and the harm reduction and recovery organizations that represent patients, individuals in recovery, policy and legal advocates, and people who use harm reduction services.

Detailed Comments and Recommendations

A. Proposed effective and compliance dates should be tolled until HHS publishes corollary anti-discrimination protections required by CARES Act.

In passing the CARES Act, Congress weakened some aspects of patients' privacy rights but also introduced new anti-discrimination protections for individuals in healthcare, housing, employment, and more.[18] The current rulemaking, however, only addresses the CARES Act's privacy changes; HHS indicated that it would pursue the anti-discrimination protections in a separate rulemaking but did not indicate a timeline for the rulemaking or its effective date.[19]

HHS should time the effective date of the weaker privacy standards to coincide with the corollary anti-discrimination protections required by the CARES Act. It would be contrary to sound public policy and Congressional intent to remove patients' privacy protections without implementing the required anti-discrimination protections at the same time. Implementation of

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the NPRM's weaker privacy rules will inevitably lead to individuals' SUD treatment information being used and disclosed with greater frequency. The CARES Act's corollary anti-discrimination protections would safeguard individuals from discrimination on the basis of their SUD treatment records in healthcare, employment, housing, access to courts, access to benefits, and access to any services provided with federal funds.[20] Without these anti-discrimination protections in place at the same time, individuals are put at increased risk of the negative consequences that Congress intended to protect against with the anti-discrimination protections.

B. HHS's regulatory cost-benefit analysis fails to capture the true costs to patients of privacy violations.

HHS requests comments on the estimates, assumptions, and analyses in its cost-benefit analysis.[21] In two key respects, HHS has *underestimated* the costs and *overestimated* the benefits:

- **HHS *underestimates* the costs to patients, their family, and our society.**

HHS fleetingly acknowledges the costs of weakening privacy protections generally: "potential patients may avoid initiating treatment altogether, which would harm both patients and programs."[22] While it is true that the proposed rule will impact programs' bottom line by discouraging patients from entering treatment, the cost of untreated substance use disorder for patients, families, communities, and our society dwarf the economic impact on programs. The Centers for Disease Control and Prevention estimated that the economic cost of opioid use disorder and fatal opioid overdose surpassed $1 billion in 2017 alone.[23] Many other studies have attempted to quantify the individual and societal costs of untreated substance use disorder, including healthcare costs, mortality costs, criminal legal system costs, child and family assistance costs, education costs, productivity loss costs, and reductions in quality of life.[24] HHS should treat these costs seriously in the rulemaking's cost-benefit analysis, just as it should address the moral and policy implications of these costs seriously throughout the proposed rule.

HHS also acknowledges the following costs: a "sense of loss of control" when patients lose the opportunity to make specific decisions about which uses and disclosures they would permit; and a greater likelihood of harm to reputation, relationships and livelihood.[25] LAC agrees that these costs are likely outcomes of weakening the privacy protections, but urges HHS to consider them more fully: "harm to reputation, relationships and livelihood" encompasses serious and permanent harm, including loss of child custody, loss of housing, loss of employment, and more. Moreover, HHS does not appear to contemplate the harm to individuals who will be arrested, prosecuted, or denied probation or parole due to its proposed changes.

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Nor does HHS appear to contemplate the ways these changes will lead to more discrimination and stigma within the healthcare system, which will harm individuals when they are denied surgery, admission to skilled nursing facilities, home care services, or simply respectful treatment.[26]

- **HHS *overestimates* the "marked" benefit to covered entities and business associates.**

HHS estimates that covered entities and business associates will enjoy a "marked" benefit when they gain the ability "to follow only one set of federal regulations when making decisions about using and disclosing Part 2 records," and "no longer need to segregate SUD treatment data."[27] However, neither statement is accurate: covered entities and business associates will need to continue following Part 2 when using and disclosing Part 2 records that were received prior to the effective date of the new rule or pursuant to a standard Part 2 consent form (*i.e.*, not one of the new consent forms for treatment, payment, and health care operations (TPO)). Even for records received pursuant to a TPO consent form, the covered entity or business associate will need to continue segmenting or tagging Part 2 data in order to avoid releasing information "in any civil, criminal, administrative, or legislative proceedings by any Federal, State, or local authority, against the patient," unless authorized by patient consent or a court order.[28] Finally, even in the cases where the HIPAA Privacy Rule replaces Part 2 as the applicable standard for use and disclosure, it is not accurate to say that covered entities and business associates will be subject to "only one set of federal regulations;" in addition to the HIPAA Privacy Rule, covered entities and business associates must follow many other applicable federal and state privacy laws governing the uses and disclosures of minors' health records, mental health records, HIV information, reproductive health information, genetic information, and more.

C. Proposed changes to § 2.3 (Civil and Criminal Penalties) should withdraw the proposed "safe harbor" provision – or in the alternative, include more realistic requirements for determining whether a provider is a Part 2 program.

The proposed "safe harbor" provision is outside the scope of the CARES Act and unnecessary. In the NPRM, HHS discloses that it proposed this provision "after consultation with the Department of Justice,"[29] but does not explain why law enforcement merits special consideration for protection from liability, or why HHS omitted similar consultations with civil rights organizations, legal and policy advocates, providers, or patients.

In addition, the proposed "safe harbor" provision is inadequate. HHS proposes a very low standard of "reasonable diligence," and then provides examples that are not even barely sufficient to identify whether a provider offers substance use disorder treatment. In particular, checking a state's Prescription Drug Monitoring Program (PDMP) website should not be

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sufficient to establish reasonable diligence, since the *majority of Part 2 programs do not report any information to PDMPs.*[30] Nor should "driving by" a provider's physical location be sufficient to establish reasonable diligence, since many providers preserve their patients' privacy by avoiding overt street signage or advertisements. Better alternatives exist, such as checking SAMHSA's Locator or the state oversight agency's list of licensed and certified providers.[31]

There should also be a bar against using the "safe harbor" provision without inquiring directly with the provider about whether Part 2 applies. In the last 40 years, Legal Action Center attorneys have helped Part 2 programs respond to hundreds of law enforcement requests for SUD treatment records. Based on our experience, many Part 2 programs report that law enforcement officials are not familiar with 42 CFR Part 2 and do not listen to program staff about the heightened privacy protections for substance use disorder treatment records. Occasionally, program staff have even been arrested and charged with obstruction for attempting to explain the federal privacy law. The NPRM's suggestions to simply check a state's PDMP website or drive by a suspected Part 2 program to verify its existence should not entitle law enforcement entities to a shield of liability or provide an opportunity for law enforcement to force Part 2 programs to share records.

D. Proposed changes to § 2.4 (Complaints of Violations) should include explicit mechanism for patients to file complaints with HHS.

In the preamble to the rulemaking, HHS signals its intent to replace Part 2's existing provisions about directing reports of Part 2 violations to the U.S. Attorney's Office or SAMHSA with provisions about filing complaints with the individual's Part 2 program, the HHS Secretary, or SAMHSA.[32] The proposed changes to the notice of patient privacy rights also refers to the right to file complaints with the HHS Secretary or SAMHSA.[33] The actual proposed language of Section 2.4, however, only gives individuals the right to file complaints with the Part 2 program.[34]

The regulations should clearly identify the independent agencies – other than Part 2 programs – authorized to receive and investigate complaints from patients. It is not sufficient for patients to only have a right to file complaints with their Part 2 program. Not only is there an inherent conflict of interest for any entity tasked with investigating its own alleged violations, but there are also instances when a Part 2 program will not be able to meaningfully investigate a patient's complaint, including in the following cases:

- The violation arises out of the Part 2 program's misinterpretation of the federal privacy law and regulations. *Example*: a Part 2 program mistakenly believes that it can release patient records in response to a subpoena.

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- The violation arises out of the Part 2 program's misinterpretation of whether the federal privacy law and regulations apply to its records. *Example*: a SUD treatment provider falsely contends that it does not meet the definition of a "Part 2 program" because it only treats patients through telehealth. Such a provider may not have a complaint process for Part 2 violations, since it erroneously maintains that it is not a Part 2 program.

- The violation does not involve the Part 2 program at all. *Example*: a lawful holder receives Part 2-protected records and posts patient-identifying information on social media platforms.

In LAC's experience, an oblique reference to a complaint process in the *Federal Register* results in a confusing lack of transparency about where individuals can file complaints. Rather, Section 2.4 should be amended to include specific provisions about how and where patients can file their complaints with the HHS Secretary (or OCR) and SAMHSA, and those offices' responsibility to receive and investigate complaints. Lastly, all notices and complaint procedures for the public should also comply with federal guidance and best practices for individuals with limited English proficiency, and individuals with limited literacy or health literacy skills.[35]

LAC supports HHS's proposals in this section to protect patients from adverse action after they file a complaint, and to prohibit requiring individuals to waive the right to file a complaint as a condition of services.

E. Proposed changes to § 2.11 (Definitions) should clarify definitions of "breach" and "qualified service organization."

In general, LAC agrees with HHS's rationale for adding and modifying definitions in Section 2.11. We have questions, comments, and concerns about the following proposed changes to the following definitions:

▲ Breach

See our comments re: Section 2.16 (Security for Records and Notification of Breaches), below.

▲ Qualified service organization

HHS proposes to modify the definition of "qualified service organization" (QSO) to include the following paragraph: "A qualified service organization includes a person who meets the

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definition of Business associate in [the HIPAA Privacy Rule] with respect to the use and disclosure of protected health information that also constitutes a 'record' as defined by this section."[36] According to the preamble, this change will "clarify that [business associates] are QSOs in circumstances when Part 2 records also meet the definition of PHI . . . ."[37] This explanation is unclear. It is true that business associates are QSOs when they provide "qualified services" to Part 2 programs and receive Part 2 records pursuant to a Qualified Service Organization Agreement (QSOA) (§ 2.11). A business associate, however, may handle Part 2 records *without* being a QSO, if it receives Part 2 records pursuant to patient consent (§ 2.31), or during an audit or evaluation of a Part 2 program or lawful holder (§ 2.53), or in the course of providing payment or healthcare operations for a lawful holder of Part 2 records (§ 2.33(b)).

This proposed change is unnecessary and confusing; Part 2 has always applied to business associates that use or disclose Part 2-protected records, and the proposed change could be interpreted to mean that being a business associate is an *alternative* to paragraphs (1) and (2) of the QSO definition, which require QSOs to provide certain "qualified services" and to have a written QSOA in place. This is especially true when reading the proposed new paragraph together with Section 2.12(c)(4) ("The restrictions on disclosure in the regulations in this part do not apply to communications between a part 2 program and a qualified service organization of information needed by the qualified service organization to provide services to the program.").

Currently, Part 2 programs struggle to convince large vendors to enter a Qualified Service Organization Agreement in addition to a Business Associate Agreement. Vendors frequently point to their default Business Associate Agreement as a "take it or leave it" offer for Part 2 programs that want to use their services.[38] The proposed change could unintentionally bolster the misunderstanding that HIPAA compliance is sufficient for entities that use or receive Part 2 records when providing services to a Part 2 program.
HHS should consider removing the proposed new paragraph or amending it to clarify that a business associate must still meet all aspects of the QSO definition, including entering into a Qualified Service Organization Agreement. LAC attorneys have drafted sample contract provisions for a joint Qualified Service Organization Agreement and Business Associate Agreement; HHS should consider creating and publishing an official version of a similar resource and disseminating it to stakeholders. HHS should also work to improve major technology vendors' understanding of Part 2, so that Part 2 programs and their patients can benefit from services like email, cloud-based storage, and telehealth platforms, while maintaining confidentiality safeguards.

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F. Proposed changes to § 2.12 (Applicability) should preserve Part 2's longstanding prohibition on use of patient records to criminally investigate or prosecute patients.

HHS proposes to permit the use and disclosure of Part 2 records in a criminal investigation or prosecution of the patient, so long as the patient signs a written consent form.[39] HHS characterizes the change as "heighten[ing] protections against use or disclosure of records in proceedings against the patient,"[40] but instead this marks a major – and deeply troubling – departure from the long-standing privacy protections for individuals with substance use disorder treatment records. For the last 40 years, only a special court order could authorize the use or disclosure of patient records in a criminal investigation or prosecution.[41] Given the inherently coercive nature of the criminal legal system, it strains credulity to believe that many patients would voluntarily consent to the use of their SUD treatment records to be used against them in their own criminal investigation or prosecution. It is far likelier that many patients will feel they have no choice but to sign a consent form. Given the crucial role of patient privacy in encouraging people to seek SUD treatment and the important Constitutional protections at play, there should be no opportunity for law enforcement to force, coerce, or intimidate patients into signing consent forms authorizing their treatment records to be used against them in a criminal investigation or proceeding.

HHS should abandon this proposed change. Individuals should not be asked, encouraged, forced, or coerced to consent to their treatment records being used against them.[42] Expanding law enforcement's ability to access and use individuals' substance use disorder treatment records will cause harm to patients and exacerbate racial disparities in access to SUD treatment and treatment outcomes. **It is imperative to acknowledge the racial impact of any proposed change to increase criminalization of individuals who have used drugs**, particularly in light of the well-documented racist impact of enforcing criminal drug laws.[43] Black and brown communities already face disproportionate criminalization based on drug use *and* higher barriers to community-based treatment.[44]

This change will have a particularly chilling effect on patients seeking SUD treatment in jail or prison. Jails and prisons throughout the country are slowly[45] starting to expand access to treatment – and in particular, medication for opioid use disorder (MOUD) – in order to comply with their obligations under the U.S. Constitution, the Americans with Disabilities Act (ADA), various federal and state mandates, and recognized standards of healthcare.[46] It is particularly important to protect the treatment records of people receiving services in carceral settings so that patients can seek treatment without worrying that their records could subsequently be used against them in a pending criminal action, or used to bring new charges or disciplinary proceedings.

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In addition, this change will have a particularly harmful impact on pregnant people, who are at increased risk of prosecution in states with abortion prohibitions[47] and so-called "fetal assault" laws, many of which penalize pregnant people for using drugs while pregnant.[48] Pregnant people already face the threat of prosecution and child welfare investigations for using drugs or taking MOUD while pregnant,[49] even though MOUD is the standard of care for pregnant people with opioid use disorders.[50] But for the last 40 years, Part 2 protected patients' treatment records from being turned into accusatory evidence against them.

LAC recommends that HHS exercise its regulatory authority to "provide for such safeguards and procedures . . . as in the judgment of the Secretary are necessary or proper to effectuate the purposes of this section . . . "[51] and withdraw the consent provision for criminal investigations and prosecutions. Law enforcement should be required to obtain a Part 2 court order and judicial oversight before accessing or using a patient's Part 2-protected treatment records to criminally investigate or prosecute the patient.

If, however, HHS determines that the CARES Act requires the regulations to permit disclosures with consent for some uses and disclosures in the criminal legal system,[52] HHS should take every possible step to ensure that there will be safeguards against patients being coerced, misled, or forced into signing consent forms that can be used against them in a criminal case. There should also be limits on when law enforcement can use a patient's consent to criminally investigate or prosecute the patient. LAC urges HHS to delay the implementation of this requirement and work closely with legal advocates, including public defenders, to identify appropriate protections for patients.

At a minimum, HHS should address some of the key procedural and substantive questions raised by this new proposed provision, including:

- What will prevent law enforcement from routinely asking individuals to consent to overbroad disclosures of their current and past SUD treatment records? This will pose a particular threat to pregnant people, especially in states that criminalize abortion or substance use during pregnancy.

- What will prevent law enforcement from conducting "fishing" expeditions and looking through treatment records for additional evidence to substantiate charges, bring new charges, or simply prejudice the judge or jury against the patient?

- What will prevent law enforcement from conditioning a plea deal or sentencing on a patient signing a consent form authorizing uses and disclosures of their treatment records related to the pending allegations or new, yet-to-be-defined charges? This is already common practice in child welfare investigations, which

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may also use a patient's refusal to sign a consent form as evidence of "non-compliance" with the agency's investigation.[53]

- In settings where patients are already routinely required to sign consent forms or face negative consequences (such as disqualification from drug court or termination of parental rights), what will protect against these records being used to further criminalize, investigate, and prosecute a patient for new offenses?

We recommend that HHS consider the following safeguards *as a starting point* to address the concerns above:

- Patients should have the right to meet with their legal counsel prior to signing a consent form authorizing the use or disclosure of their Part 2 records that could be used against them in a criminal investigation or prosecution.

- The consent form should limit uses and disclosures to a particular pending criminal allegation, so that the records cannot be used in a fishing expedition to find additional charges against a patient.

- The consent form should limit the records to be disclosed to recent time periods – for example, 30 days; law enforcement should seek a court order pursuant to Part 2's Section 2.65 for records dating back further than 30 days.

- HHS should prohibit multi-purpose consent forms, so that a consent form authorizing uses and disclosures for criminal investigations and prosecutions cannot be combined with a consent form authorizing disclosures for treatment, payment, or any other purpose.

HHS should also include a mechanism in this provision for patients to enforce their rights if they are violated, and courts should be required to disregard records that were inappropriately used or shared in violation of the law. In the absence of an explicit suppression remedy in the regulations, some courts have refused to let patients suppress records entered against them in violation of Part 2. (*See* comments, below, re: proposed changes to Section 2.33.) HHS should add an explicit suppression remedy if it starts allowing patients to consent to their own records being used against them for the first time in 40 years.

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G. Proposed changes to § 2.16 (Security for Records and Notification of Breaches) should clarify that the applicable privacy standard is Part 2, not HIPAA.

LAC supports HHS's proposal to add a breach notification requirement to Section 2.16, so that patients are notified of a breach of their Part 2 records in the same manner as a breach of HIPAA-protected health information (PHI).[54] We agree with HHS that breach notification is an important patient right and permits affected individuals to protect themselves from harm that may arise as a result of the breach.

HHS should clarify that the breach notification requirement applies to disclosures that violate the Part 2 standard of confidentiality, and not just disclosures that violate the HIPAA Privacy Rule. The rulemaking proposes to define the term "breach" in Section 2.11 of 42 CFR Part 2 by reference to the definition in HIPAA, which incorporates the HIPAA Privacy Rule as the relevant standard for unauthorized uses and disclosures:

> *Breach* means the acquisition, access, use, or disclosure of protected health information in a manner *not permitted under subpart E of this part* which compromises the security or privacy of the protected health information. . . .
> 45 CFR § 164.402 (emphasis added)

HHS should amend the definition of "breach" in Section 2.11 or clarify in Section 2.16 that patients should be notified of any acquisition, access, use, or disclosure of Part 2 records in a manner *not permitted under 42 CFR Part 2* and that compromises the security or privacy of the Part 2 record.

H. Proposed changes to § 2.26 (Right to Request Privacy Protections for Records) should expand patients' right to *meaningfully* request a restriction on disclosures.

HHS proposes to add a new right for patients to request restrictions on uses and disclosures of their records for TPO purposes. Specifically, patients have a right to *request* the restriction, but providers are not obligated to acquiesce to the request unless the patient has paid in full and out-of-pocket and is requesting a restriction on disclosure to a third-party payer. **This proposed right is profoundly inequitable:** as HHS acknowledges in its cost-benefit analysis, *this right is only available to patients with the means to pay privately for SUD treatment*.[55] SUD treatment is prohibitively expensive for most people. The cost of SUD treatment can approach $60,000 for detoxification, inpatient rehabilitation, or outpatient rehabilitation services.[56] Moreover, individuals being released from carceral settings – who are likely to be indigent and uninsured, and more likely to be Black or brown – would never have access to this proposed right to restrict uses and disclosures of their SUD records.

HHS acknowledges that this proposed provision will benefit the patients who can afford to use it, by shielding them from potential harmful effects of restrictive coverage policies in some

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health plans and other potential negative consequences of having a SUD health record, including potential and actual employers learning of patients' SUD diagnosis and treatment. HHS also anticipates that this right will improve rates of access to SUD treatment" because of patients' increased trust that self-pay patients have the opportunity to ensure that their records will remain within the Part 2 program."[57] And HHS anticipates that this will benefit Part 2 programs by requiring more patients to pay in full and out-of-pocket.[58] But HHS fails to balance these costs against the larger costs of blocking access to treatment, and fails to explain why these rights and benefits should only accrue to the wealthy.

HHS should strengthen this provision so that providers comply with all patients' requests to restrict disclosures of this sensitive health information – not just those patients who are wealthy enough to pay in full and out-of-pocket. Not only should HHS address the transparent inequity of offering a right only to patients who can self-pay, but strengthening the provision is also consistent with the CARES Act's "Sense of Congress" in Section 3221(k)(3): "covered entities should make every reasonable effort to the extent feasible to comply with a patient's request for a restriction regarding such use or disclosure." When patients request a restriction on disclosure of their Part 2 records, the default answer should be "yes," subject to narrow exceptions such as disclosures to treat a medical emergency. In practice, however, providers' default answer is almost always "no," which is why HHS should provide a more enforceable right here.

Notice of this right to request limitations of disclosures of health records, and the process for doing so should again comply with federal guidance and best practices for individuals with limited English proficiency and individuals with limited literacy or health literacy skills.

I. Proposed changes to § 2.31 (Consent Requirements) should prioritize transparency, specificity, and preserve patients' right to maintain confidentiality safeguards following disclosure.

HHS proposes a number of changes to Section 2.31, describing the requirements for consent forms authorizing the disclosure of Part 2 records. LAC attorneys have helped hundreds of Part 2 programs, covered entities, patient advocates, court officials, public health agencies, and government officials comply with Part 2's consent form requirements. We have also created sample consent forms authorizing disclosure of Part 2 patient records.[59] Our comments are informed by our decades of experience reviewing and drafting consent forms, answering questions, and troubleshooting challenges to obtaining patient consent – including for patients in jail or prison, patients without capacity but without an appointed guardian, minor patients, patients experiencing homelessness, and more. We also hope HHS continues to support its stated goal of ensuring that patients with substance use disorders have the right to benefit from new, integrated healthcare models without fear of putting themselves at risk of adverse

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consequences.[60]

- **TPO consent requirements:**

HHS proposes to implement the CARES Act amendments to 42 USC § 290dd-2(b)(1)(B) – permitting an initial consent for TPO purposes to authorize future uses, disclosures, and redisclosures – by integrating the TPO consent form requirements into Section 2.31's description of general consent form requirements. We support HHS's efforts to provide patients with this option, while preserving patients' right to authorize more limited disclosures.[61] Based on our experience obtaining and interpreting consent forms, and drafting model consent forms, we caution HHS that additional safeguards are needed in order to meaningfully preserve patients' right to choose a more limited consent form and prevent the TPO consent from becoming a *de facto* default.

A TPO consent will dramatically expand the way that Part 2 records are used and shared without the patient's actual knowledge. Under HHS's proposed changes, a patient could be asked to sign a consent form that would never expire[62] and authorize unlimited disclosures to unnamed parties[63] for largely unspecified purposes[64] and with limited rights to revoke consent.[65] As HHS acknowledges, the TPO consent will undermine Part 2's longstanding patient right to revoke consent, since the "CARES Act redisclosure permission for [recipients] of Part 2 records limits the ability to 'pull back' Part 2 information from those entities once it is disclosed."[66] As HHS concedes, this new TPO consent will cause some patients to "experience a sense of loss of control over their records" and pose a "greater likelihood of harm to reputation, relationships, and livelihood."[67] In some states, the patient (or a provider) may be subject to criminal investigation on the basis of information contained in a Part 2 record.

Once a patient has signed a TPO consent and the Part 2 program starts sharing information with a covered entity, business associate, or another Part 2 program, the HIPAA Privacy Rule permits much greater uses and disclosures than permitted under Part 2. HHS notes throughout the rulemaking that these "disclosure pathways are permissive, not required,"[68] which is technically true under the HIPAA Privacy Rule but misleading, since the Information Blocking Rule *mandates* disclosures that were previously *permissive*, with limited exceptions.[69] In fact, a discussion of the impact of the Information Blocking Rule is strikingly absent from HHS's discussion and analysis in this rulemaking. Given the profound changes the Information Blocking Rule introduced to the general health data environment, and the ways HHS proposes in this rulemaking to inject Part 2 records into the general health data environment with less patient oversight than ever before, LAC urges HHS to directly address the reality of the Information Blocking Rule before finalizing its proposed changes.

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i. TPO consent requirements should be described in a separate section

TPO consent form requirements should be described in a separate section of Part 2, to avoid confusing cross-references in Section 2.34 (disclosures to central registries), Section 2.35 (disclosures to the criminal legal system), Section 2.36 (disclosures to prescription drug monitoring programs), and Section 2.66 (court orders to investigate or prosecute a Part 2 program). This is particularly important considering the simultaneous proposal in Section 2.12(d) to permit disclosures and uses with patient consent in criminal proceedings. (*See* our comments, above, re: changes to Section 2.12). LAC does not believe that HHS intends for TPO consent forms to be used, for example, when a patient authorizes an opioid treatment program (OTP) to share information with a central registry to prevent multiple enrollments, since patients are required to sign this consent form as a condition of treatment at many OTPs.

ii. TPO consent requirements should include the following precautions to promote transparency and protect patients' rights:

Prohibition on combining TPO consent forms; TPO consents should not be combined with any other authorizations to use or disclose records to other parties for other purposes. This will promote both patients' and providers' understanding of the consent form. In LAC's decades of experience reviewing consent forms, it is important that consent forms are easy to interpret both for patients and healthcare staff, given the high turnover in the field and the lack of widespread training about how to interpret and explain consent forms.

Prohibition on conditioning treatment; TPO consents should include a statement that the patient has a right to sign a more limited consent form, and that signing the TPO consent is not a condition of access to treatment, payment, enrollment in a health plan, or eligibility for benefits.[70] This would not affect a program's ability to condition treatment on having the patient sign a more limited consent form for third-party payers. Patients should not be forced to choose between their treatment and their privacy, particularly if they are seeking care during medically dangerous withdrawal from alcohol, opioids, methamphetamine, or other substances, or during an acute mental health crisis or suicidal ideation.

Description of recipients; TPO consents should include information about the recipients who may receive the information upon disclosure *and redisclosure.* HHS's proposed language to describe recipients – "my treating providers, health plans, third-party payers, and people helping to operate this program" – does not adequately inform patients of all the additional recipients entitled to receive the information upon redisclosure.

Explanation of limited right to revoke consent; TPO consents should advise patients that

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they have a right under Part 2 to revoke consent and stop future disclosures by the Part 2 program, but do not have a right to stop redisclosures of the information already shared. HHS should consider creating such a right under the HIPAA Privacy Rule.

Expiration upon ending treatment or after three years, whichever is sooner; TPO consents should expire upon the patient's discharge, completion, or end of treatment, or after three years from the date of signing, whichever is sooner. Once a patient is no longer receiving services from a Part 2 program, it no longer makes sense for the Part 2 program to have unlimited authority to share information expansively, including for "healthcare operations" purposes that will no longer benefit the patient. The alternative three-year expiration date, for patients who are receiving treatment for more than three years with the same provider, gives both the provider and the patient an opportunity to revisit the terms of the original consent form and confirm that the patient still wishes to authorize broad disclosures of their records with little oversight.

It should be as clear as possible – to patients, providers, and the recipients of Part 2 records – whether a consent form is authorizing uses, disclosures, and redisclosures pursuant to the new TPO consent rules, or whether the consent form is authorizing more limited uses and disclosures. This is particularly important for consent forms authorizing uses and disclosures for purposes like "treatment," "care coordination," and "payment," since these purposes all fall within the definition of TPO, but a patient may not necessarily wish to authorize disclosure pursuant to the new TPO rules. *See also* our comments below regarding proposed changes to Section 2.32, proposing that disclosures pursuant to a TPO consent should be accompanied by a TPO-specific notice prohibiting redisclosure.

- **General consent form requirements:**

HHS also proposes a number of changes to the consent form requirements in Section 2.31 that go beyond the changes required by the CARES Act, although HHS indicates that the changes "are not intended to create substantive changes, but merely to align with the wording of similar requirements in the Privacy Rule."[71]

HHS proposes to modify § 2.31(a)(3) by removing the regulatory requirement for consent forms to explicitly describe the SUD records to be disclosed, and replacing it with a requirement for a "specific and meaningful" description. HHS "believes that its treatment of consent requirements here remains consistent with that of SAMHSA's prior expressed guidance . . . [and] requests comments on this assumption."[72] However, LAC does not agree that the proposed change is consistent with SAMHSA's prior expressed guidance. Moreover, the proposed new language **would undermine many patients' (and providers') understanding of the scope of information covered by the consent form.**

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In 2017, SAMHSA added a requirement for consent forms to include an "explicit description of the substance use disorder information that may be disclosed."[73] According to SAMHSA, the change was meant to promote patients' informed consent to disclose substance use disorder information,[74] similar to many other privacy laws' consent requirements for HIV information, mental health information, and reproductive health information.[75] Also according to SAMHSA guidance, consent forms must give patients the option to authorize disclosure of more "granular" options, so that patients have "the opportunity to specify whether all of their substance use disorder treatment information or only some may be disclosed and sets the limits on what a part 2 program or other lawful holders may disclose."[76]

Many providers, health plans, and health information exchanges ask patients to sign complex consent forms authorizing disclosures to a wide range of recipients and releasing a significant amount of their past, present, and future health records. The consent forms are even harder to parse when a patient receives care from different providers in the same corporate entity, and may be asked to sign a consent form in a general healthcare setting without realizing they are also authorizing disclosure of records from more specialized providers, including Part 2 programs. Part 2's requirement for an "explicit" description of substance use disorder-related information helps ensure that patients can make informed decisions when signing the consent form.

- ▲ **Fundraising:**

HHS proposes to permit Part 2 programs to use or disclose patient-identifying information in fundraising for the benefit of the program, § 2.31(a)(5)(iii).[77] We do not see a need for permitting programs to use patients' treatment records in order to fundraise, nor do we agree that HHS's proposal is consistent with Congressional intent in the CARES Act.[78] If HHS decides to finalize this provision, it should prohibit programs from requiring patients to authorize such a disclosure as a condition of treatment.

J. Proposed changes to § 2.32 (Notice to Accompany Disclosure) should have specific notice requirements for TPO consents

HHS proposes to amend the contents of notices that accompany disclosures of Part 2 records (also known as notices of prohibition on redisclosure). LAC overall supports these changes, but we anticipate that the changes will cause confusion as currently drafted.

Disclosures of Part 2 records with patient consent must be accompanied by a notice advising the recipient of their obligations to continue protecting the records pursuant to Part 2. Currently, all recipients of records are subject to the same redisclosure prohibition: they may

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only use or disclose the records with patient consent, pursuant to a court order, or subject to one of the other limited exceptions in Part 2 that apply to lawful holders.[79] This rulemaking, however, introduces a new standard for some recipients who receive records pursuant to a TPO consent: these recipients may redisclose records pursuant to the HIPAA Privacy Rule, except if the records will be used against the patient in a legal proceeding.[80]

A recipient of Part 2 records, however, will have *no way of knowing* which redisclosure standard applies to the records they receive: the standard Part 2 redisclosure prohibition, described in proposed Section 2.32(a)(1)(i), or redisclosures as permitted by the HIPAA Privacy Rule except for legal proceedings against the patient, described in proposed Section 2.32(a)(1)(ii).

Finally, LAC recommends that HHS move sub-paragraph (a)(1)(iv) to the main text of paragraph (a)(1), so that it does not appear to be one of the exceptions following sub-paragraphs (a)(1)(i), (ii), and (iii). For example, HHS could re-write this section as follows:

> § 2.32(a)(1) . . . other legal requirement. A general authorization for the release of medical or other information is NOT sufficient to meet the required elements of written consent to further use or redisclose the record (see 42 CFR 2.31). In addition, the federal rules prohibit you from making any other use or disclosure of this record unless at least one of the following applies:
> . . . .
> ~~(iv) A general authorization for the release of medical or other information is NOT sufficient to meet the required elements of written consent to further use or redisclose the record (see 42 CFR 2.31).~~

K. Proposed changes to § 2.33 (Uses and Disclosures Permitted with Written Consent) should include a suppression remedy and additional guidance.

LAC supports HHS's proposal in Section 2.33(b)(1) to protect patient records from unauthorized uses and disclosures in civil, criminal, administrative, and legislative proceedings against the patient,[81] even when the records have been disclosed pursuant to a TPO consent. This requirement is consistent with HHS's statutory mandate and good policy.

The CARES Act amended Section 290dd-2 of Title 42 of the U.S. Code to permit redisclosures of Part 2 records in accordance with the HIPAA regulations in some circumstances.[82] The CARES Act also amended the statutory prohibition on the *use* of Part 2 records in criminal, civil, or administrative contexts,[83] and introduced a new prohibition on the *use* of Part 2 records to discriminate against an individual in a variety of contexts, including healthcare, housing, and employment.[84] These statutory prohibitions on *use* of Part 2 records still apply to records

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disclosed pursuant to a TPO consent; the new redisclosure provision in subsection (b)(1)(B) does not address uses permitted by HIPAA.[85] HHS also has broad statutory authority to promulgate regulations to "effectuate the purposes of this section," including the purposes outlined in subsections (c) and (i) to protect individuals against discrimination and prosecution on the basis of their treatment records.[86] The rulemaking's proposed changes to Section 2.33(b)(1) appropriately implement these protections by prohibiting certain uses of the Part 2 records even once redisclosures are permitted pursuant to HIPAA.

In order to meaningfully implement this change, HHS should clarify the regulations and issue guidance clarifying how recipients of Part 2 records – and their health information technology vendors – should take steps to avoid disclosing Part 2 records in legal proceedings against the patient, including in response to a subpoena, non-Part 2 court order, search warrant, or other lawful process that complies with the HIPAA Privacy Rule but does not comply with Part 2. HHS should also identify financial incentives for adopting health information technology with the technical capacity to appropriately segment, tag, share, and protect records. HHS should also clarify that the TPO consent is *not* the default: if a recipient receives Part 2 protected records, including for a purpose that falls within the umbrella of "treatment, payment, or healthcare operations," the recipient should still treat the records as protected by Part 2 unless the records are accompanied by the specific notice for TPO consents.

HHS should also include a suppression remedy so that patients can move to suppress records used and disclosed in violation of this provision. Some courts have recognized an implicit right for patients to seek to suppress records disclosed illegally, but other courts have not.[87] A patient should not be limited to filing a complaint with their Part 2 program or HHS if their records are illegally used or disclosed in a civil, criminal, legislative or administrative proceeding against them. An investigation by HHS will take too long and may only result in a corrective action plan or fines for the party that disclosed the records; meanwhile, the records may have been used against the patient in a criminal prosecution, or sentencing hearing, or child custody determination, or eviction proceeding.

HHS should also make sure the restriction in Section 2.33(b)(1) is expressed consistently throughout the rulemaking, including, for example, in Section 2.53(h).[88]

L. Proposed change to § 2.51 (Medical Emergencies) should be withdrawn.

In many ways, Part 2's Section 2.51 is an exceptional provision: it permits emergency disclosures of protected information without the patient's knowledge or consent,[89] and the information shared with medical emergency personnel permanently loses its protections under Part 2.[90] For this reason, Section 2.51 includes a documentation requirement: following an emergency disclosure of Part 2 records without the patient's prior written consent, Part 2

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programs must document the disclosure in the patient's file.[91] The documentation must include all of the following: the name of the medical personnel to whom disclosure was made and their affiliation with a healthcare facility*; the name of the individual making the disclosure*; the date and time of the disclosure, and the nature of the disclosure.[92]

As part of its efforts throughout the rulemaking to standardize regulatory language, HHS proposes to replace the word "individual" with the word "person" in the documentation requirements. HHS proposes to define "person" by reference to the HIPAA Privacy Rule as a "natural person, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private."[93] Even though HHS says this change will promote "clarity,"[94] it will actually result in *less* clarity for patients, who may no longer be able to tell who disclosed their Part 2-protected information to 911 and medical personnel. The patient already knows that the Part 2 program was the "person" making a disclosure of Part 2 records during a medical emergency. For this reason, it is the identity of the *individual* making the disclosure that is important to document.

In general, LAC supports the efforts throughout the rulemaking to streamline language by replacing the phrase "individual or entity" with the word "person," but in this instance, the change will diminish patients' rights and transparency with no clear benefit to impacted patients.

M. Proposed change to § 2.68 (Report to the Secretary) should be clarified and strengthened.

LAC supports the proposal to create a new requirement for annual reports by law enforcement. We have the following questions about implementation:

- How will HHS advise federal, state, and local law enforcement of the requirement to submit annual reports?
- What will be the consequence of failing to submit an annual report?
- What will be the purpose of reviewing the annual reports, and what criteria will HHS apply?
- How will HHS use the information in the annual reports to safeguard patient privacy rights and improve law enforcement's understanding of the rule?

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N. HHS should reexamine its focus on investigating and prosecuting "bad actors" and move towards proven public health strategies.

HHS solicits comments on "the need for investigation of Part 2 programs and holders of Part 2 records," citing the Department of Justice and asserting that the opioid overdose epidemic requires increased "investigation and prosecution of bad actors."[95] Instead, HHS should focus on how to improve the quality of substance use disorder treatment programs without relying on the failed tools of criminal investigation and prosecution.

There is no evidence that increased criminal investigation or prosecution will ameliorate the opioid overdose epidemic or lead to better health outcomes. In fact, there is substantial evidence that failed "Drug War" criminalization policies *undermine* public health goals:

- A public health strategy that emphasizes "investigation and prosecution of bad actors" will disproportionately harm Black, Indigenous, and People of Color, due to the national patterns of racially targeted surveillance, policing, prosecution, and punishment.[96]

- Prescribers' fear of prosecution can lead to reducing or eliminating prescriptions for patients in need, which harms patients with substance use disorders as well as patients with other types of health concerns, in particular chronic pain patients.[97]

- Overblown concerns about buprenorphine diversion – which "do not accurately reflect the relative risks and safety profile" of diverted buprenorphine[98] – harm individuals in jail and prison settings by justifying unnecessary restrictions and prohibitions on life-saving medication.

- In 2022, dozens of patients at a local harm reduction services program lost access to treatment and medication for opioid use disorder after the Drug Enforcement Agency (DEA) asked the program's contracted buprenorphine prescriber to surrender their license due to an investigation unrelated to their buprenorphine prescribing. The DEA visited the provider's home at night to rescind their license, leaving no time to plan for maintaining the continuity of patients' treatment. It is difficult to see how *more* prosecution and investigation will promote better outcomes for people who need substance use disorder treatment.

Moreover, LAC is concerned that HHS is inquiring into the need for increased investigation and prosecution in the context of the Part 2 rulemaking. Current Part 2 requirements already

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offer multiple avenues to access necessary information and enforce standards of care, including through audits and evaluations, disclosures of de-identified patient information, court orders to criminally investigate a Part 2 program or holder of records, and court orders authorizing the placement of undercover agents to criminally investigate a Part 2 program. The previous Administration already amended Part 2 – twice[99] – to facilitate greater disclosures to law enforcement, including changes requested by the Department of Justice[100] to authorize placement of undercover officers in Part 2 programs with less judicial oversight. Further eroding Part 2 in this regard would only serve to stigmatize and harm SUD patients who seek or have sought SUD treatment.

O. Additional Issues Not Addressed in Rulemaking: Mobile Health (mHealth), Information Blocking, and Applicability

HHS should amend the regulations or issue guidance clarifying Part 2's applicability to websites and mobile health (mHealth) companies, including virtual care platforms for substance use disorder treatment, telehealth platforms, and more. Despite receiving millions of dollars in federal funding and claiming to be "private," "secure," and "confidential," the actual privacy practices of many websites and apps for virtual SUD treatment services do not always comport with the privacy and security standards in Part 2 or HIPAA.[101] A recent investigation by the Legal Action Center and the Opioid Policy Institute examined the websites for 12 mHealth services for opioid use disorder treatment and recovery, and found trackers on all 12 websites.[102] A similar investigation by *STAT* and *The Markup* found 49 out of 50 telehealth websites shared health data via tracking technology.[103]

HHS should work with the Office of the National Coordinator for Health Information Technology (ONC) to issue guidance addressing the Information Blocking Rule's intersections with 42 CFR Part 2, and in particular, the Information Blocking Rule's exceptions for Privacy (45 CFR 171.202) and Infeasibility (45 CFR 171.204). Many providers are unsure how to protect Part 2 records while also complying with the new requirements in the Information Blocking Rule, particularly when providing access to Part 2 records on patient portals with proxy access. Guidance is also necessary to dispel confusion surrounding the Privacy Exception; some providers are mistakenly interpreting the Information Blocking Rule to require sharing Part 2 records unless patients affirmatively request a restriction on Part 2 records, without realizing that the Privacy Exception applies.

Finally, HHS should issue guidance clarifying the scope of Part 2 to integrated behavioral health settings and schools. As substance use disorder treatment services become more integrated into healthcare and other settings, it is important for both providers and patients to have a clear understanding of the applicable confidentiality standard for treatment records.

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We look forward to working with HHS in its efforts to uphold individuals' important privacy rights, while promoting access to quality treatment and care coordination. If you should have any questions or need additional information, please do not hesitate to contact Jacqueline Seitz, jseitz@lac.org.

Sincerely,

Paul N. Samuels
Director/President

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Appendix 1: 2021 National Survey on Drug Use and Health

Table 5.41B – Detailed Reasons for Not Receiving Substance Use Treatment in Past Year: Among People Aged 12 or Older Classified as Needing But Not Receiving Substance Use Treatment at a Specialty Facility and Who Perceived a Need for Substance Use Treatment in Past Year; Percentages, 2021

Reason for Not Receiving Substance Use Treatment	
TOTAL POPULATION	100.0
No Health Care Coverage and Could Not Afford Cost	24.9
Had Health Care Coverage But Did Not Cover Treatment or Did Not Cover Full Cost	12.0
No Transportation/Programs Too Far Away or Hours Inconvenient	6.1
Did Not Find Program That Offered Type of Treatment That Was Wanted	15.8
Not Ready to Stop Using	36.7
No Openings in a Program	3.0
Did Not Know Where to Go for Treatment	17.9
Might Cause Neighbors/Community to Have Negative Opinion	**10.4**
Might Have Negative Effect on Job	**14.7**
Did Not Feel Need for Treatment at the Time	9.3
Could Handle the Problem Without Treatment	15.0
Treatment Would Not Help	5.5
Did Not Have Time	5.2
Did Not Want Others to Find Out	**9.9**
Some Other Reason	1.8

Source: U.S. Department of Health & Human Services, Substance Abuse & Mental Health Services Administration, Center for Behavioral Health Statistics & Quality, *available at* https://www.samhsa.gov/data/sites/default/files/reports/rpt39441/NSDUHDetailedTabs2021/NSDUHDetailedTabs2021/NSDUHDetTabsSect5pe2021.htm?s=5.4&#tab5.41b.

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References & Endnotes

[1] Confidentiality of Substance Use Disorder Patient Records, 87 Fed. Reg. 74,216, 74,257 (proposed Dec. 2, 2022) (to be codified at 42 CFR Part 2).
[2] *See* Appendix 1 – 2021 National Survey on Drug Use and Health, Table 5.41B.
[3] *See, e.g.*, N.Y. Public Health Law Article 27-F.
[4] *See, e.g.*, Eric Boodman et al., "HIPAA won't protect you if prosecutors want your reproductive health records," STAT (June 24, 2022), https://www.statnews.com/2022/06/24/hipaa-wont-protect-you-if-prosecutors-want-your-reproductive-health-records/.
[5] Office of National Drug Control Policy, "The Biden-Harris Administration's Statement of Drug Policy Priorities for Year One," (2021), https://www.whitehouse.gov/wp-content/uploads/2021/03/BidenHarris-Statement-of-Drug-Policy-Priorities-April-1.pdf.
[6] *Id.*
[7] 42 CFR § 2.12(d).
[8] Office of National Drug Control Policy, "The Biden-Harris Administration's Statement of Drug Policy Priorities for Year One," (2021), https://www.whitehouse.gov/wp-content/uploads/2021/03/BidenHarris-Statement-of-Drug-Policy-Priorities-April-1.pdf.
[9] U.S. Department of Health & Human Services, "About HHS," (accessed Jan. 17, 2023), https://www.hhs.gov/about/index.html ("The mission of the U.S. Department of Health and Human Services (HHS) is to enhance the health and well-being of all Americans, by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services.")
[10] *See* George Karway et al., "Recommendations to Inform Substance Use Disorder Data Sharing Research: Scoping Review and Thematic Analysis," JOURNAL OF ADDICTION MEDICINE 16(3): 261-271 (2022), https://europepmc.org/backend/ptpmcrender.fcgi?accid=PMC8755843&blobtype=pdf.
[11] Confidentiality of Substance Use Disorder Patient Records, 87 Fed. Reg. at 74,249-65.
[12] *Id.*
[13] *Id.*
[14] *Id.* at 74,220.
[15] *Id.* at 74,221. HHS does not explain, however, why elected law enforcement officials that enforce state laws should be considered a particularly compelling stakeholder in the debate about individuals' federal health privacy protections.
[16] *See, e.g.*, Legal Action Center, "Campaign to Protect Patient Privacy Rights" (Aug. 2018), https://www.lac.org/news/campaign-to-protect-privacy-rights-principles. Hundreds of comments from directly impacted individuals and advocacy organizations in the last four rounds of rulemakings – in 2017, 2018, and twice in 2020 – supported patient privacy rights.
[17] George Karway *et al.*, "Recommendations to Inform Substance Use Disorder Data Sharing Research: Scoping Review and Thematic Analysis," JOURNAL OF ADDICTION MEDICINE 16(3): 261-271 (2022), https://europepmc.org/backend/ptpmcrender.fcgi?accid=PMC8755843&blobtype=pdf.
[18] 42 USC § 290dd-2(i).
[19] Confidentiality of Substance Use Disorder Patient Records, 87 Fed. Reg. at 74,217.
[20] 42 USC § 290dd-2(i).
[21] Confidentiality of Substance Use Disorder Patient Records, 87 Fed. Reg. at 74,253.
[22] *Id*. at 74,257.
[23] Feijun Luo *et al*., "State-Level Economic Costs of Opioid Use Disorder and Fatal Opioid Overdose – United States, 2017," MORBIDITY AND MORTALITY WEEKLY REPORT 70:541 (April 16, 2021), https://www.cdc.gov/mmwr/volumes/70/wr/mm7015a1.htm.

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[24] *See generally* Recovery Centers of America, "Economic cost of substance abuse disorder in the United States," (2019), https://recoverycentersofamerica.com/resource/economic-cost-of-substance-abuse-disorder-in-united-states-2019/.
[25] Confidentiality of Substance Use Disorder Patient Records, 87 Fed. Reg. at 74,257.
[26] LAC regularly represents individuals denied access to healthcare or admission to a skilled nursing facility. *See generally*, Legal Action Center, "Addressing Discrimination in Health Care Settings," (Dec. 2022), https://www.lac.org/resource/addressing-discrimination-in-health-care-settings.
[27] Confidentiality of Substance Use Disorder Patient Records, 87 Fed. Reg. at 74,257.
[28] *Id*. at 74,281 (proposing changes to § 2.32(a)(1)).
[29] Confidentiality of Substance Use Disorder Patient Records, 87 Fed. Reg. at 74,227.
[30] For example, PDMPs do not contain any information from Part 2 programs that do not prescribe controlled substances to patients. As of 2020, opioid treatment programs may report methadone prescribing information to PDMPs, but only if the reporting is mandated by state law and authorized by a Part 2-compliant consent form. See 42 CFR § 2.36.
[31] *See* U.S. Department of Health & Human Services, Substance Abuse and Mental Health Services Administration, "Behavioral Health Locator," https://www.findtreatment.gov (last accessed Jan. 25, 2023).
[32] Confidentiality of Substance Use Disorder Treatment Records, 87 Fed. Reg. at 74,228.
[33] *Id*. at 74,279 (proposed changes to 42 CFR § 2.22).
[34] *Id*. at 74,274.
[35] *See generally* U.S. Department of Health & Human Services, "Culturally Competent LEP and Low-literacy Services," (Apr. 21, 2022), https://www.samhsa.gov/section-223/cultural-competency/lep-services; U.S. Department of Health & Human Services, Agency for Health Care Research and Quality, "AHRQ Health Literacy Universal Precautions Toolkit," (Apr. 2010), https://www.ahrq.gov/health-literacy/improve/precautions/index.html.
[36] Confidentiality of Substance Use Disorder Patient Records, 87 Fed. Reg. at 74,275.
[37] *Id*. at 74,230.
[38] *See, e.g.,* Microsoft, "Health Insurance Portability and Accountability Act (HIPAA) & Health Information Technology for Economic and Clinical Health (HITECH) Act," (Sept. 20, 2022) https://learn.microsoft.com/en-us/compliance/regulatory/offering-hipaa-hitech?view=o365-worldwide.
[39] Substance Use Disorder Patient Records, 87 Fed. Reg. at 74,276.
[40] *Id*. at 74,226.
[41] 42 CFR §§ 2.12(d), 2.65.
[42] *See* Hortensia Amaro, *et al*., "Social Vulnerabilities for Substance Use: Stressors, Socially Toxic Environments, and Discrimination and Racism," NEUROPHARMACOLOGY (2021), https://www.sciencedirect.com/science/article/pii/S0028390821000721. "Given the impact of criminal justice policies on minority communities and their direct and indirect effects on health, it is not possible to discuss racial and ethnic health disparities without considering the impact of the criminal justice system on the health outcomes of minorities in general and substance use in particular. . . . At every level of the criminal justice system, racial and ethnic disparities and biases are present. . . . Although drug use is common in the incarcerated population, there is reverse causality in this relationship. That is, drug use can lead to incarceration." *Id.* at 11-12.
[43] *See, e.g.,* Nkechi Taifa, "Race, Mass Incarceration, and the Disastrous War on Drugs," Brennan Center for Justice (May 10, 2021), https://www.brennancenter.org/our-work/analysis-opinion/race-mass-incarceration-and-disastrous-war-drugs.
[44] *See, e.g.,* Legal Action Center, "No Health = No Justice," (last accessed Jan. 11, 2023), https://www.lac.org/major-project/no-health-no-justice.

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[45] *See* Beth Schwartzapfel & Keri Blakinger, "Federal Prisons Were Told to Provide Addiction Medications. Instead, They Punish People Who Use Them," THE MARSHALL PROJECT (Dec. 12, 2022), https://www.themarshallproject.org/2022/12/12/suboxone-federal-prison-opioid-addiction-treatment-overdose.
[46] *See generally* Legal Action Center, "MAT/MOUD Advocacy Toolkit" (Nov. 2022), https://www.lac.org/resource/mat-advocacy-toolkit.
[47] *See* Guttmacher Institute, Interactive Map: US Abortion Policies and Access After Roe (Jan. 16, 2023), https://states.guttmacher.org/policies/.
[48] *See, e.g.,* American College of Obstetricians and Gynecologists, Opposition to Criminalization of Individuals During Pregnancy and the Postpartum Period (2020), https://www.acog.org/clinical-information/policy-and-position-statements/statements-of-policy/2020/opposition-criminalization-of-individuals-pregnancy-and-postpartum-period.
[49] *See, e.g.,* Elizabeth Brico, "A Cop at My Bedside: The Nightmare of Disclosing MAT Before Giving Birth," Filter (April 5, 2019), https://filtermag.org/a-cop-at-my-bedside-the-nightmare-of-disclosing-methadone-use-before-giving-birth/.
[50] U.S. Department of Health & Human Services, Substance Abuse & Mental Health Services Administration, "Clinical Guidance for Treating Pregnant and Parenting Women with Opioid Use Disorder and Their Infants," https://www.samhsa.gov/resource/ebp/clinical-guidance-treating-pregnant-parenting-women-opioid-use-disorder-their-infants (accessed Jan. 23, 2023).
[51] 42 USC § 290dd-2(g).
[52] Coronavirus Aid, Relief, and Economic Security (CARES) Act § 3221(e) (amending 42 USC § 290dd-2(c)), Public Law 116-136, 134 Stat. 281 (March 27, 2020), https://www.congress.gov/bill/116th-congress/house-bill/748/text.
[53] *See, e.g., Matter of Daleena Q.T.,* 211 A.D.3d 497 (N.Y. App. Div. 2022) (citing a parent's refusal to sign a consent form authorizing disclosure of her behavioral health records as evidence in support of terminating parental rights).
[54] Confidentiality of Substance Use Disorder Patient Records, 87 Fed. Reg. at 74,256.
[55] *Id.*
[56] *See, e.g.,* Jeffrey Juergens & David Hampton, "Cost Of Drug And Alcohol Rehab," https://www.addictioncenter.com/rehab-questions/cost-of-drug-and-alcohol-treatment/ (last accessed Jan. 26, 2023).
[57] Confidentiality of Substance Use Disorder Patient Records, 87 Fed. Reg. at 74,256.
[58] *Id.*
[59] *See* Legal Action Center, "Sample Forms Regarding Substance Use Treatment Confidentiality" (Aug. 2020), https://www.lac.org/resource/sample-forms-regarding-substance-use-treatment-confidentiality.
[60] *See* Confidentiality of Substance Use Disorder Patient Records, 82 Fed. Reg. 6,052, 6077 (Jan. 18, 2017) (codified at 42 CFR Part 2).
[61] For example, we support HHS's interpretation that the changes will not limit patients' right to sign a consent form with more "granular" provisions, including for treatment, payment and healthcare operations.
[62] Confidentiality of Substance Use Disorder Patient Records, 87 Fed. Reg. at 74,281 (proposed changes to § 2.31(a)(7)).
[63] *Id.* (proposed changes to § 2.31(a)(4)(i)).
[64] In LAC's experience, the vast majority of patients and providers do not know the full scope of the HIPAA Privacy Rule's definitions of "treatment," "payment," and in particular, "health care operations," which include both clinical and non-clinical activities, such as sale of assets, customer service, underwriting, and resolution of internal grievances. *See generally* HHS, Office for Civil Rights,

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Treatment, Payment, and Healthcare Operations (April 3, 2003), https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/coveredentities/sharingfortpo.pdf.
[65] Confidentiality of Substance Use Disorder Patient Records, 87 Fed. Reg. at 74,240
[66] *Id*.
[67] *Id*. at 74,257.
[68] *Id*. at 74,244.
[69] *See generally*, U.S. Department of Health & Human Services, Office of the National Coordinator for Health Information Technology, "Information Blocking," https://www.healthit.gov/topic/information-blocking (accessed Jan. 21, 2023).
[70] *See also* Jacqueline Seitz & Deborah Reid, "Proposal for CARES Act Amendments to 42 CFR Part 2," LEGAL ACTION CENTER (July 1, 2021), https://www.lac.org/assets/files/Final-CARES-Act-recs-07-01-21.pdf.
[71] Confidentiality of Substance Use Disorder Patient Records, 87 Fed. Reg. at 74,240.
[72] *Id*.
[73] *Id*. at 74,282-83.
[74] Confidentiality of Substance Use Disorder Patient Records, 82 Fed. Reg. at 6,086-87.
[75] For example, New York State Department of Health consent form with boxes for different types of sensitive health information. New York State Department of Health, "Authorization for Release of Health Information: DOH 5032," https://www.health.ny.gov/forms/doh-5032.pdf.
[76] Confidentiality of Substance Use Disorder Patient Records, 82 Fed. Reg. at 6,087.
[77] Confidentiality of Substance Use Disorder Patient Records, 87 Fed. Reg. at 74,281.
[78] *See* CARES Act, § 3221(k)(4).
[79] Section 2.12(c)(6) permits recipients of Part 2 records to report suspected child abuse and neglect if required by state law. In LAC's experience, the other exceptions for lawful holders – research, and audit/evaluation – do not regularly lead to disclosures in legal proceedings against the patient. *See* 42 CFR §§ 2.52, 2.53.
[80] *See* Confidentiality of Substance Use Disorder Patient Records, 87 Fed. Reg. at 74,281-82.
[81] Confidentiality of Substance Use Disorder Patient Records, 87 Fed. Reg. 74,281-82.
[82] *See* 42 USC § 290dd-2(b)(1)(B).
[83] *See id*. at (c).
[84] *See id*. at (i).
[85] *See id*. at (b)(1)(B) ("...Any information so disclosed may then be redisclosed in accordance with the HIPAA regulations.")
[86] As SAMHSA has acknowledged many times in previous rulemakings and guidances, the purpose of the privacy protections is to ensure that an individual is not made more vulnerable to criminalization, discrimination, or stigma as a result of seeking treatment than if they had not sought treatment at all. See, e.g., Confidentiality of Substance Use Disorder Patient Records, 82 Fed. Reg. 6,052, 6,053 (Jan. 18, 2017) (to be codified at 42 CFR Part 2) (" The laws and regulations governing the confidentiality of substance use disorder records were written out of great concern about the potential use of substance use disorder information against individuals, causing individuals with substance use disorders not to seek needed treatment. The disclosure of records of individuals with substance use disorders has the potential to lead to a host of negative consequences, including: Loss of employment, loss of housing, loss of child custody, discrimination by medical professionals and insurers, arrest, prosecution, and incarceration. The purpose of the regulations . . . is to ensure that a patient receiving treatment for a substance use disorder in a part 2 program is not made more vulnerable by reason of the availability of their patient record than an individual with a substance use disorder who does not seek treatment.")

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[87] *Compare United States v. Eide*, 875 F.2d 1429 (9th Cir. 1989) (holding that records obtained illegally were not admissible at a criminal trial against the patient) *and Warburton v. State*, 662 N.Y.S.2d 706, 173 Misc.2d 879 (Ct. of Claims 1997) (holding that fines are the exclusive remedy for a violation of Part 2, where a patient moved to suppress Part 2 treatment records illegally disclosed and used in his pre-sentencing report).
[88] Confidentiality of Substance Use Disorder Patient Records, 87 Fed. Reg. at 74,283.
[89] Section 2.51 only permits disclosures if the patient is unable to provide prior written consent, most commonly in cases where the patient is unconscious or does not have capacity to consent at the time of the disclosure. See Confidentiality of Substance Use Disorder Patient Records, 82 Fed. Reg. at 6,095.
[90] U.S. Department of Health & Human Services, "Frequently Asked Questions: Applying the Substance Abuse Confidentiality Regulations to Health Information Exchange," FAQ 33 (2010), https://www.samhsa.gov/sites/default/files/faqs-applying-confidentiality-regulations-to-hie.pdf.
[91] 42 CFR 2.51(c).
[92] *Id.*
[93] Confidentiality of Substance Use Disorder Patient Records, 87 Fed. Reg. at 74,275.
[94] *Id.* at 74,219.
[95] *Id.* at 74,227.
[96] *See* Drug Policy Alliance, "Drug War Statistics," https://drugpolicy.org/issues/drug-war-statistics (last accessed Jan. 11, 2023); *see generally* Legal Action Center, "No Health, No Justice," https://www.lac.org/major-project/no-health-no-justice (last accessed Jan. 23, 2023).
[97] *See, e.g.,* Maia Szalavitz, "What the Opioid Crisis Took from People in Pain," N.Y. TIMES (March 7, 2022), https://www.nytimes.com/2022/03/07/opinion/opioid-crisis-pain-victims.html.
[98] Molly Doernberg *et al.,* "Demystifying buprenorphine misuse: Has fear of diversion gotten in the way of addressing the opioid crisis?" SUBSTANCE ABUSE JOURNAL 40:2, 148-153 (April 22, 2019), https://www.tandfonline.com/doi/full/10.1080/08897077.2019.1572052.
[99] *See* Confidentiality of Substance Use Disorder Patient Records, 85 Fed. Reg. 42,986 (July 15, 2020) (to be codified at 42 CFR Part 2); Confidentiality of Substance Use Disorder Patient Records, 85 Fed. Reg. 80,626 (Dec. 14, 2020) (to be codified at 42 CFR Part 2).
[100] Confidentiality of Substance Use Disorder Patient Records, 85 Fed. Reg. at 43,029 ("Based on consultation with DOJ, the current policy is burdensome on, and overly restrictive of, some ongoing investigations of part 2 programs.").
[101] *See* ExpressVPN Digital Security Lab, "Apps for opioid addiction treatment and recovery: data sharing and privacy risks" (2021), https://www.expressvpn.com/digital-security-lab/opioid-telehealth-research; Jonathan Stoltman & Jacqueline Seitz, "Websites for Opioid Addiction Treatment and Recovery Services: Data Sharing and Privacy Risks," OPIOID POLICY INSTITUTE & LEGAL ACTION CENTER (2022), https://www.lac.org/resource/websites-for-opioid-addiction-treatment-and-recovery-services-data-sharing-and-privacy-risks.
[102] *Id.*
[103] Todd Feathers, Katie Palmer & Simon Fondrie-Teitler, "'Out of Control': Dozens of Telehealth Startups Sent Sensitive Health Information to Big Tech Companies," THE MARKUP & STAT (Dec. 13, 2022), https://themarkup.org/pixel-hunt/2022/12/13/out-of-control-dozens-of-telehealth-startups-sent-sensitive-health-information-to-big-tech-companies.

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