MIDWEST HEALTH CONNECTION

ISSUE BRIEF

Regulatory Changes to Substance Use Disorder Privacy Law & Its Impact on Health Information Exchange (HIE) Services for Health Care Providers

On July 15, 2020, the Substance Abuse Mental Health Services Administration (SAMHSA) published the final rule changes to 42 CFR Part 2 (Part 2). **These changes are effective August 14, 2020**.

Part 2 governs the confidentiality of substance use disorder (SUD) patient records. It imposes more stringent privacy protections than HIPAA on the use and disclosure of information that identifies a patient either directly or indirectly as having (or having had) a SUD, if that information originates from a federally-assisted SUD provider (called a Part 2 program). The Part 2 privacy protections follow the protected Part 2 information under certain circumstances, thus requiring non-Part 2 program providers, health plans, health information exchanges (HIEs) and others to follow Part 2's more stringent privacy protections with respect to the Part 2 information they receive.

SAMHSA has revised Part 2 to better facilitate coordination of care in response to the opioid epidemic while maintaining its confidentiality protections against unauthorized disclosure and use. This final rule change does **not** implement the changes brought about in Section 3221 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). (Please see Coppersmith Briefs, The CARES Act: Sweeping Changes to Substance Use Disorder Privacy Law (42 USC 290dd-2) for a summary of the CARES Act changes.) SAMHSA will propose additional regulatory changes to implement the CARES Act by March 27, 2021—the deadline required by the CARES Act. SAMHSA provides important clarification to the community that the "statutory timeline in § 3221 prevents the part 2-related provisions of the CARES Act from taking effect before March 27, 2021."

In the interim, this final rule makes the following changes to Part 2:

- **Limiting when Part 2's Disclosure Restrictions Apply to Non-Part 2 Program Providers.** Part 2's downstream redisclosure restrictions on non-Part 2 program treating providers now only apply to the "records" of Part 2 programs that non-Part 2 program treating providers receive pursuant to the patient's written consent and that are accompanied by the prohibition on redisclosure notice. The redisclosure restrictions no longer apply to the recording of SUD information (oral or non-oral) that a non-Part 2 program treating provider may include in the patient's general (non-Part 2) medical record.

  SAMHSA is drawing a distinction between the actual Part 2 program "record" and SUD "information." SAMHSA's intent is to restrain the scope of Part 2's applicability so that treatment records created by non-Part 2 program treating providers—even if they

incorporate a patient's SUD information from a Part 2 program—are explicitly not covered by Part 2. This is an important and fundamental change to the applicability of the Part 2 regulations to non-Part 2 program providers who provide direct patient treatment. However, SAMHSA emphasizes that:

- The Part 2 program must still get the patient's written consent to disclose any information from the Part 2 records (including oral and non-oral disclosures) to non-Part 2 program providers. The change SAMHSA has made affects Part 2 applicability to non-Part 2 program treating providers only.

- Non-Part 2 program treating providers must still protect any actual Part 2 program records that they hold under Part 2's stringent redisclosures restrictions.

- This change "will not immunize the misconduct of a non-part 2 provider who engages in the wholesale transcription of a received SUD patient record, without her own direct patient encounter and without clinical purpose." The intent behind SAMHSA's changes to the applicability provision (and definition of records) is "to allow the part 2 program to make a disclosure, with the patient's consent, to the recipient non-part 2 provider. In turn, the non-part 2 provider can then carry out her own encounter with the patient, and create her own patient record, which will not fall under the coverage of part 2."

This final rule change does not address Part 2's downstream applicability to health plans. Part 2 continues to apply to "[t]hird-party payers with regard to records disclosed to them by part 2 programs," and the definition of records continues to be, "any information . . . [of] a part 2 program relating to a patient (*e.g.*, diagnosis . . . billing information)." *See* 42 C.F.R. §§ 2.11, 2.12(d)(2)(i)(A).

This change in applicability has also resulted in a change to the full length prohibition on redisclosure notice. The abbreviated version has not changed.

Impact on Health Care Provider Participation with MHC's HIE Network & Services:
This change positively impacts a health care provider's investment and relationship with a HIE because it provides much needed clarification that SUD information contained in the medical records of non-Part 2 program providers—*that is, not the Part 2 program record from a Part 2 program*—is not protected by Part 2. Thus, such SUD information contained in non-Part 2 medical records **does not need to be segregated** and kept apart for the rest of the patient's medical records for Part 2 compliance purposes within the HIE environment. Moreover, a non-Part 2 program provider who has a treating provider relationship with a patient and who has the patient's written consent to access the patient's Part 2 records available through a HIE, now has greater certainty that her use of the SUD information in the Part 2 program record as part of her own patient encounter and the recording of that SUD information in the non-Part 2 program's medical record will not bring her medical record (or the SUD information within it) under the coverage of Part 2.

- **Permitting Patients to Consent to Disclosures to Any Named Entity, Regardless of Whether the Named Entity Has a Treating Provider Relationship with the Patient.** In its 2017 final rule, SAMHSA changed the Part 2 consent form requirements to require that the patient name the person who will receive the patient's Part 2 information, unless the receiving entity was a health plan, had a treating provider relationship with the patient, or was an intermediary entity who facilitated the exchange of the Part 2 information to such persons/entities. This restriction prevented patients from authorizing disclosures of their Part 2 information to entities—like the social security administration (SSA) and community based organizations (CBOs)—that lack this treating provider relationship but are critical to patients receiving important services. This restriction has been lifted. A patient may now consent to disclosure of the patient's Part 2 information to any entity named on the consent form, without naming a specific person as the recipient for the disclosure.

  Impact on Health Care Provider Participation with MHC's HIE Network & Services: This return to consent practices that existed prior to the 2017 rule change will enable HIEs like MHC to support, and their Part 2 program Participants to participate in, important patient-centered use cases involving patient authorized or consented disclosures to CBOs that may or may not have a treating provider relationship with a patient (such as sober living homes), SSA and life insurance companies.

- **Removing the Patient Consent Requirement for Contractors who Perform Care Coordination/Case Management Functions under a Part-2 Compliant Agreement.** In the 2017 and 2018 rule changes, SAMHSA declined requests that it permit patient consented disclosures for "health care operations" purposes to include care coordination and case management activities. This decision caused Part 2 programs and non-Part 2 programs alike to not use vendors (or at least limited their use of vendors) to provide important care coordination and case management services to those patients often most in need of these services—patients suffering or recovering from SUDs. In this 2020 final rule, SAMHSA has reversed its earlier decision and now includes care coordination/case management services in the list of illustrative activities that can be done by contractors of Part 2 programs (under a Qualified Service Organization Agreement) or non-Part 2 programs (that are holding the Part 2 records pursuant to a patient's consent that allows the non-Part 2 program to use the Part 2 program records for payment or health care operations activities).

  Impact on Health Care Provider Participation with MHC's HIE Network & Services: If the appropriate contractual arrangements and protections are in place, MHC's HIE Participants that have the patient's consent to access Part 2 information through MHC's HIE network for health care operations activities may share that information with their vendors for care coordination and case management purposes, such as identifying and closing gaps in patient care. However, it's unclear how this change may impact MHC's actual HIE operations. HIEs like MHC that also perform care coordination and case management functions on behalf of their participants may find that this rule change enables them to expand this service to Part 2 program participants. HIEs, like MHC, and their

participants may also want to consider whether this change could facilitate access to Part 2 information available through the HIE network to a participant's care coordination/case management vendor (provided that the patient has consented to access by the HIE participant for health care operation purposes and the appropriate contracts are in place).

- **Permitting Patients to Consent to Non-Part 2 Program Provider Access to Central Registries.** Part 2 now permits central registries to respond to requests from non-Part 2 program providers who have a treating provider relationship with the patient to ensure appropriate coordinated care (that is, to inform prescriber decision making). SAMHSA recognizes that non-Part 2 program provider access to central registries is needed to fully inform decision making regarding appropriate prescription drugs for patients. However, the patient consent requirement for these disclosures remain. SAMHSA thus anticipates that Part 2 programs will update their consent forms to include new language regarding information shared with non-Part 2 program providers or create a new consent form for this purpose. SAMHSA also expects non-Part 2 program providers to demonstrate their treating provider relationship prior to making a query to a central registry.

  Impact on Health Care Provider Participation with MHC's HIE Network & Services: Many states do not operate a central registry. However, because of the opioid epidemic and the increased need for SUD treatment programs and provider understanding of all the medications a patient may be taking, there is a need nationwide for more registries. HIEs, especially MHC, are uniquely positioned to fill this gap because of their expertise in establishing and managing data sharing platforms, including consent management, for accessing patient health information. MHC will explore supporting a central registry throughout the Midwest to support its Participants.

- **Permitting Patients to Consent to Prescription Data Monitoring Programs (PDMPs).** SAMHSA has also finalized the proposed rule change that will allow Part 2 programs to participate in state mandated (required) PDMP reporting. This change might not apply if state law does not require certain Part 2 programs to report to the PDMP (*e.g.*, state PDMP laws with exceptions for opioid treatment programs (OTPs)). Moreover, patient consent for disclosures to the PDMP is still required. SAMHSA expects Part 2 programs to update their consents forms or create new ones to allow for these disclosures. With respect to satisfying the "to whom" consent form requirement (that is, who is authorized to receive the information disclosed to the PDMP), SAMHSA suggests that capturing the patient's consent to disclose to the PDMP is good enough because SAMHSA writes: "[w]e do not expect the proposed changes to require additional consent for redisclosure to each registered PDMP end-user."

  Impact on Health Care Provider Participation with MHC's HIE Network & Services: HIEs that operate state PDMP programs (or are interested in supporting or operating PDMPs) will benefit from this rule change. So long as state law requires Part 2 program reporting to the PDMP, the Part 2 information reported may be disclosed to the PDMP and PDMP end users pursuant to a patient's PDMP-specific direct consent. SAMSHA clarified in the final rule that use and implementation of a general designation consent and

compliance with the list of disclosure requirement is not required for PDMP disclosures. MHC is hopeful to expand its operations in midwestern states to include PDMP data for the benefit of its Participants.

- **Adding Natural Disasters to the Medical Emergency Exception.** The final rule permits Part 2 programs to disclose Part 2 information to medical personnel without the patient's consent during a temporary state of emergency declared by a state or federal authority as the result of a natural/major disaster (*e.g.*, hurricane, wildfire), during which the Part 2 program is closed and not able to provide services or obtain the patient's written consent due to the emergency. In such circumstances, Part 2 programs are still required to document the name of the medical personnel to whom the disclosure was made (and their facility affiliation), the name of the individual making the disclosure, the date/time of the disclosure, and the nature of the medical emergency. SAMHSA further emphasizes that "consent should still be obtained if at all feasible," and this exception is "rescinded when the part 2 program resumes operation." This exception does not extend to public health emergencies, such as the opioid epidemic or COVID-19 pandemic.

  Impact on Health Care Provider Participation with MHC's HIE Network & Services: HIEs that offer a medical emergency exception (often called "break the glass") to access Part 2 information available through a HIE without patient consent can now expand use of this break the glass functionality to apply in circumstances where the medical emergency documented is the result of: (1) a state or federal declaration of a temporary state of emergency caused by a natural/major disaster; and (2) the Part 2 program is closed and either not able to provide services or obtain the patient's consent due to that emergency. Like other medical emergencies, HIEs will need to promptly notify the closed Part 2 program when this type of break the glass disclosure occurs, as well as provide the information the Part 2 program must document in the patient's Part 2 record. HIEs should consider proactively working with their Part 2 programs participants to discuss how the HIE could support this type of access so that these electronic systems are in place when natural disasters strike. Under MHC's current patient consent policy, the "break the glass" option is not available. Thus, this change is helpful to those HIEs that need it but is not applicable to MHC.

- **Expanding the Research Exception.** The final rule changes Part 2 research exception in two significant ways. First, it permits the disclosure of Part 2 information by a Part 2 program, HIPAA covered entity or HIPAA business associate pursuant to the HIPAA research requirements at 45 C.F.R. § 164.512(i). It also continues to permit such disclosures if a person with director/CEO level authority determines that the recipient of the Part 2 information is a HIPAA covered entity or HIPAA business associate who has obtained the patient's HIPAA authorization or waiver of that requirement under 45 C.F.R. § 164.512(i), or is subject to the Common Rule (45 C.F.R. Part 46) and has obtained the patient's informed consent, waiver of consent, or the research qualifies for an exemption to the Common Rule. Second, the final rule extends the director/CEO's decision making authority to include recipients who are determined to be subject to the FDA human subjects

regulations (21 C.F.R. Parts 50 and 56) and have obtained the patient's informed consent or waiver of consent.

Impact on Health Care Provider Participation with MHC's HIE Network & Services: HIEs and their participants that engage in research use cases under existing federal human subject research laws and HIPAA will benefit from this rule change because it expands the circumstances in which Part 2 information may be used for research without having to obtain a Part 2 compliant consent. For example, because HIEs are HIPAA business associates, under this rule change (and assuming it's permitted by their agreements with the covered entity data sources), they will be able to disclose Part 2 information for research purposes, so long as it is done in compliance with the HIPAA research rules set out in 45 C.F.R. § 164.512(i)—such as, IRB or privacy board waiver of the HIPAA authorization requirement, reviews preparatory to research, and research on decedent's information (provided the requirements of these rules are met).

MHC's current permitted uses do not include a research use case. However, this may change in the near future given the pressing need in the patient and provider community for SUD research as a result of the opioid epidemic. If and when MHC does expand its permitted uses to include research, this provision will serve that endeavor well and provide great benefit to MHC's Participants.

- **Adding Clarifying Language Regarding the Scope of the Audit and Evaluation Exception.** The final rule also adds much needed clarifying language to explain the scope of the audit and evaluation exception. Under the final rule changes, it is clear that this exception includes activities by governmental agencies and third party payers (and their contractors) that need access to Part 2 information for purposes of making policy/procedural changes to improve patient care and outcomes across Part 2 programs, to target limited resources more effectively, and to adjust payment policies to enhance care or coverage for SUD patients. It also applies to agency and third party payer activities related to reviews of appropriateness of medical care, medical necessity, and utilization of services. SAMHSA further clarified that auditors may include any entity that has direct administrative control over the Part 2 program and quality assurance entities, like accreditation bodies.

  Impact on Health Care Provider Participation with MHC's HIE Network & Services: While this rule change is beneficial to MHC's diverse Participants base, it should have little to no impact on MHC's current HIE operations.

- **Expanding the Audit and Evaluation Exception to Allow for Mandated Disclosures to Governmental Agencies without Requiring the Agency (or its Contractors) to Enter into a Written Agreement with the Disclosing Entity.** The final rule now permits Part 2 programs and non-Part 2 programs to disclose Part 2 information to federal, state or local governmental agencies (and their contractors) during an audit or evaluation mandated by law, if the audit or evaluation cannot be carried out using de-identified information,

without requiring the agency (or contractor) to enter into a written agreement requiring compliance with Part 2.

Impact on Health Care Provider Participation with MHC's HIE Network & Services: This rule change should have little to no impact on MHC's Participants or MHC's HIE operations, unless there is a state or federal law that would require a MHC to disclose Part 2 information to a governmental agency for an audit or evaluation purpose.

- **Extending the Time Undercover Agents/Informants can be Placed in a Part 2 Program.** Court-ordered placement of undercover agents or informants has been extended to up to 12 months, with the option of a court-ordered extension, in order to assist law enforcement efforts in uncovering bad actor providers within Part 2 programs.

  Impact on Health Care Provider Participation with MHC's HIE Network & Services: This rule change will not impact MHC's Participants or MHC's HIE operations.

- **Providing Further Details on How Personal Devices may be Sanitized under Part 2's Record Disposition Requirement.** The 2017 changes to Part 2's record disposition requirements have resulted in Part 2 programs confiscating or destroying Part 2 program personnel's personal devices in order to meet Part 2's sanitization requirements for records disposition. Under this 2020 final rule, in instances where Part 2 program personnel receive an incidental patient message to the personnel's personal device, deleting that message is sufficient to meet Part 2's disposition requirements.

  Impact on Health Care Provider Participation with MHC's HIE Network & Services: This rule change will not impact MHC's Participants or MHC's HIE operations.

For additional information, please check out these resources:

- Final Rule, 85 Fed. Reg. 42986 (July 15, 2020)
- Proposed Rule, 84 Fed. Reg. 44568 (Aug. 26, 2019)
- 42 C.F.R. Part 2
- 42 U.S.C. § 290dd-2
- Fact Sheet: SAMHSA 42 CFR Part 2 Revised Rule (July 13, 2020)
- HHS 42 CFR Part 2 Proposed Rule Fact Sheet (Aug. 22, 2019)
- SAMHSA, Substance Abuse Confidentiality Regulations, FAQs
- Focus:PHI, The Centers for Excellence for Protected Health Information

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