



March 30, 2020

Dear Whitney:

Thank you for reaching out to the Center of Excellence for Protected Health Information (CoE-PHI) to request Technical Assistance related to federal health privacy laws.

In response to your request dated November 22, 2019, regarding data linkages for information protected by HIPAA and 42 CFR Part 2, we have prepared the enclosed written response. We look forward to your thoughts on this response, and whether any additional information would be useful in implementing the information contained within this written Technical Assistance.

Sincerely,
The CoE-PHI Team

The CoE-PHI is funded by the Substance Abuse and Mental Health Services Administration (SAMHSA) to improve provider communication, treatment access, and quality of care for people receiving care for substance use disorder (SUD) and/or mental health (MH). The CoE-PHI is a partnership between Cicatelli Associates Inc. (CAI) and the Legal Action Center (LAC).



DATA LINKAGE SYSTEMS AND PROTECTED HEALTH INFORMATION

Question: In a data linkage system like the Linked Information Network of Colorado (LINC),¹ how can participants share data protected by HIPAA and 42 CFR Part 2 (Part 2)?

Answer: Participants may share HIPAA- and Part 2-protected data with a data linkage system like LINC for the purpose of disclosing de-identified data to third parties; LINC and each participant must enter an agreement that meets the contractual requirements of HIPAA's Privacy Rule and, if applicable, Part 2. The data linking hub may then re-disclose the de-identified data to third parties, because neither HIPAA nor Part 2 regulate disclosures of de-identified data.

Discussion: A data linkage system like LINC involves two sets of disclosures: first, a disclosure from the participants to the linking hub; and second, a disclosure from the linking hub to the third-party end users. Each of these disclosures is discussed in turn below.

Disclosures to linking hub:

Participants may disclose HIPAA-protected health information (PHI) to a linking hub like LINC for the purpose of de-identifying the PHI, so long as there is a valid business associate agreement (BAA) authorizing this use of the PHI. 45 CFR § 164.504(e). The Office for Civil Rights (OCR), which promulgates and enforces the HIPAA Privacy Rule, squarely addresses this issue in written guidance: "A covered entity may use a business associate to de-identify PHI on its behalf only to the extent such activity is authorized by their business associate agreement."² The linking hub may only use and disclose the PHI for the purposes authorized by the BAA.³

Participants may also disclose Part 2-protected patient-identifying information (PII) to a linking hub like LINC for the purpose of de-identification, but the mechanism for disclosure depends on whether the participant is (1) a Part 2 program,⁴ or (2) a lawful holder⁵ of Part 2-protected data.

¹ This technical assistance is based on documents provided by the Colorado Evaluation and Action Lab and information provided by telephone on Dec. 17, 2019. One key feature of the LINC system is that the linking hub only uses protected data for the purpose of de-identifying it, and only re-discloses de-identified data to third parties.

² OCR, "Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule," (rev. Nov. 6, 2015), <https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html#coveredentities>.

³ See 45 CFR § 164.504(e) for all BAA requirements. For a sample BAA, see OCR, "Business Associate Contracts: Sample Business Associate Agreement Provisions," (Jan. 25, 2013), <https://www.hhs.gov/hipaa/for-professionals/covered-entities/sample-business-associate-agreement-provisions/index.html>.

⁴ A "Part 2 program" in an individual or entity receiving "federal assistance," defined at 42 CFR § 2.12(b), that meets the definition of a "program," 42 CFR § 2.11. Visit www.coephi.org for more resources about how to define "Part 2 program."

⁵ A lawful holder is an individual or entity that receives Part 2-protected patient identifying information through patient consent or as permitted by the statute or regulations, and is therefore bound by Part 2. See 82 Fed. Reg. 6052, 6068 (Jan. 18, 2017), available at <https://www.federalregister.gov/documents/2017/01/18/2017-00719/confidentiality-of-substance-use-disorder-patient-records#p-364>.



(1) Participants that are Part 2 programs

Part 2 programs may disclose PII to a linking hub like LINC so long as there is a qualified service organization agreement (QSOA) authorizing this use of the PII. 42 CFR § 2.12(c)(4). SAMHSA, which promulgates Part 2, has not issued guidance on this topic, but the plain language of the regulations permits the use of QSOAs to provide “data processing” services to Part 2 programs. 42 CFR § 2.11.

Only Part 2 programs may use QSOAs to disclose PII to contractors. 42 CFR §§ 2.11, 2.12(c)(4). Part 2 programs that are also HIPAA-covered entities should make sure the QSOA also meets the requirements for a BAA; the CoE-PHI is currently developing a sample template that meets the requirements for both a BAA and QSOA.

(2) Participants that are lawful holders

Data linkage participants that receive Part 2-protected data pursuant to patient consent for the purpose of payment or healthcare operations activities (i.e., third-party payers) may re-disclose protected data to contractors to carry out payment/healthcare operations on their behalf. 42 CFR § 2.33(b). SAMHSA has published an illustrative list of permissible activities, including “business management and general administrative activities, including management activities relating to implementation of and compliance with the requirements of this or other statutes or regulations.”⁶ De-identifying data likely constitutes business management or general administrative activities although SAMHSA has not issued guidance directly addressing this topic.

Participants that are lawful holders must have a written contract with the linking hub, which provides that the linking hub “is fully bound by the provisions of Part 2 upon receipt of the patient identifying information.”⁷ 42 CFR § 2.33(c).⁷ Lawful holders that are also HIPAA-covered entities should also have a BAA.

Disclosures by linking hub:

Once HIPAA- and Part 2-protected information has been de-identified by a linking hub like LINC, it may be re-disclosed to third parties; neither HIPAA nor Part 2 restrict disclosures of de-identified information. “[T]he [HIPAA] Privacy Rule does not restrict the use or disclosure of de-identified health information, as it is no longer considered protected health information.”⁸ Likewise, Part 2 does not restrict the disclosure of de-

⁶ 83 Fed. Reg. 239, 243 (Jan. 3, 2018), available at <https://www.federalregister.gov/d/2017-28400/p-38>.

⁷ See 42 CFR § 2.33(c) for a full list of contractual requirements.

⁸ OCR, “Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule,” (rev. Nov. 6, 2015), <https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html#rationale>.

identified substance use disorder patient records,⁹ because it no longer constitutes PII.¹⁰

Although de-identified data is no longer protected by HIPAA and Part 2, the possible risk of re-identification may still necessitate additional privacy and security safeguards.

For additional RESOURCES:

The resources cited in this technical assistance are also available among the Center of Excellence for Protected Health Information's [resource library](#). Please consider [signing up for updates](#) regarding the Center of Excellence for Protected Health Information, including news about the publication of new resources and training opportunities addressing federal privacy protections for SUD and mental health records.

Resources, training, technical assistance, and any other information provided through the Center of Excellence for Protected Health Information do not constitute legal advice. For legal advice, including legal advice on other applicable state and federal laws, please seek out local counsel.

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⁹ SAMHSA, "The Confidentiality of Alcohol and Drug Abuse Patient Records Regulation and the HIPAA Privacy Rule: Implications for Alcohol and Substance Abuse Programs," 3 (June 2004), <https://www.samhsa.gov/sites/default/files/part2-hipaa-comparison2004.pdf>.

¹⁰ See 42 CFR § 2.11 (definition of "patient identifying information").