LEGAL ACTION CENTER

Questions & Answers: 42 CFR Part II

This document provides the Legal Action Center's responses to questions posed concerning 42 CFR Part 2 compliance during the Medicaid Innovation Accelerator Program webinar held on April 13, 2015.

Q.1. Today's webinar is focused on Substance Use Disorder ("SUD"). Is it accurate to apply what has been used here to mental health information? Are there significant differences of note?

A.1. There are three confidentiality laws that should be considered with regard to mental health information: (1) any state mental health confidentiality law, (2) 42 CFR Part 2 ("Part 2"), and (3) Health Insurance Portability and Accountability Act ("HIPAA"). First, many states have laws that give heightened confidentiality protections to mental health information. State Departments of Health should be able to provide information on what types of state mental health confidentiality laws exist in their own state.

Second, 42 CFR Part 2 ("Part 2") protections apply in certain circumstances involving mental health information. If mental health providers also provide addiction and substance use disorder services through "diagnosis, treatment, [and/or] referral for treatment or prevention" and are federally-assisted, then they are considered as "programs" that must adhere to the confidentiality protections of Part 2.[1] Mental health programs have to apply 42 CFR Part 2 rules to the substance use information only, not to mental health information that does not reveal substance use.

Third, most mental health providers must also adhere to HIPAA requirements.[2] Moreover, HIPAA applies special protections for sharing protected health information for patients being treated for mental health conditions. For more information on how mental health information can be shared under HIPAA, visit this web page by the Department of Health and Human Services.

Q.2. Given the specification requirements (of providers receiving information) in 42 C.F.R. Part 2, is it possible to build a universal consent form that covers an entire network of providers? And does that consent need to be completed at the point of care or can it be completed at another point (e.g., enrollment into a managed care plan)?

A.2. Proposed universal patient consent forms for Accountable Care Organizations ("ACOs"), Patient Centered Medical Homes ("PCMHs"), Coordinated Care Organizations ("CCOs"), and other similar networks of providers would have to satisfy several Part 2 requirements. While a Part 2 consent form can allow communications relating to a patient between multiple parties, the form must:

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[1] *See* 42 C.F.R. § 2.11 (Program definition).

[2] *See* 45 C.F.R. § 160.103.

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- include the specific name or general designation of the program or person permitted to make the disclosures;
- include the patient's name;
- identify by name or title each recipient of authorized disclosures;
- state the purpose of the disclosures;
- specify the quantity and type of information that can be disclosed to each party;
- include the right of the patient to revoke consent for the disclosure at any time, except when the disclosing parties acted in reliance on the consent (such as disclosing information to a third party payer);
- indicate the date, event, or condition when the consent expires, if the consent is not previously revoked; and
- prohibit re-disclosures of information to network member providers without the patient's consent.[3]

The consent form must also be accompanied by a "Notice Prohibiting Re-disclosure," and any information disclosed pursuant to the consent cannot be re-disclosed beyond the recipient(s) named in the consent form.[4] Note that a patient can consent to both a disclosure and a re-disclosure in the same consent form.

In addition, network providers cannot use an existing Part 2 consent form to disclose patient information to future network health care providers.[5] A new patient consent for disclosures of Part 2 data is required when additional providers join the health care network.

There are several situations where Part 2 allows disclosures of confidential Part 2 information without patient consent. Some of these include:

- *"Internal communications"* - Information can be disclosed among staff of the Part 2 program or organizations that have direct administrative control over the Part 2 program (but only those who need the information in connection with their duties that arise out of the provision of diagnosis, treatment, or referral for treatment for SUD). However, this exemption does not allow disclosure to other providers in the health network.[6]
- *Disclosures to a Qualified Service Organization* ("QSO") - A Part 2 program may disclose information to a QSO without patient consent if there is an established

[3] 42 C.F.R. § 2.31(a)(1); *id.* § 2.31(a)(2); *id.* § 2.13(a); *id.*(the amount of information to be disclosed "must be limited to that information which is necessary to carry out the purpose of the disclosure."); *id.* § 2.31(a)(8); *id.* § 2.31(a)(9); *id.* § 2.32.
[4] *Id*. § 2.32 (provides details on the written statement on re-disclosures that must accompany the consent form).
[5] *See* SAMHSA, *Frequently Asked Questions: Applying the Substance Abuse Confidentiality Regulations to Health Information Exchange*, Q.19 (2010), *available at* http://www.samhsa.gov/sites/default/files/faqs-applying-confidentiality-regulations-to-hie.pdf.
[6] *See* 42 C.F.R. § 2.12(c)(3).

Qualified Service Organization Agreement ("QSOA").[7] A QSO is a person or entity that provides services to a Part 2 program or its patients, and that has entered into a QSOA with the Part 2 program. Note that the QSO may not re-disclose the information it receives from the Part 2 program, other than back to the program itself.

- *Medical Emergencies* - Part 2 programs can disclose patient-identifying information to medical personnel who need the information to treat a medical emergency, meaning a condition that creates an immediate threat to the health of any individual and that requires immediate medical intervention.[8] Note that disclosures made under the medical emergency exception must be documented by the Part 2 program making the disclosure.

Part 2 programs are required to inform individuals of confidentiality regulations at the time of admission to the Part 2 program, or as soon as the person is capable of rational communication.[9] Although the Part 2 regulations do not specify when consent should be obtained, we suggest that consent should be obtained during time of admission to the program (or when the patient can rationally communicate), since the patient must also be given a written summary of Part 2 regulations during this time.[10]

Q.3. Can consent forms have an open end, with no listed end date?

A.3. The consent form must have an expiration, but that can be either a date, an event or a condition. Part 2 requirements first specify that the consent should last "no longer than reasonably necessary to serve the purpose for which it is given."[11] Because the consent form does not have to include a specific expiration date, it can instead include an identified event or condition, such as "throughout the patient's treatment program," if the consent is needed for reimbursement purposes.

In addition, it is important to note that some state laws limit the length of time patient consent forms remain valid, so Part 2 programs should determine whether their states restrict consent periods.

Q.4. Can an intoxicated person sign a consent form?

A.4. The level of intoxication determines when a patient can provide consent. Because Part 2 requires the individual to be informed of the confidentiality regulations "as soon as the patient is capable of rational communication," the program should delay obtaining consent from an intoxicated person until this is possible.[12] Accordingly, consent should

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[7] *See id.* §§ 2.12 (c)(4), 2.11. *See also id.* § 2.11 (b)(1)-(2) (Definition section provides details for written QSO agreements).
[8] 42 C.F.R. § 2.51(a).
[9] *Id.* § 2.22(a).
[10] *See id.* § 2.22(a)(1)-(2).
[11] *Id.* § 2.31(a)(9).
[12] *See id.* § 2.22(a).

be obtained when the individual is sufficiently sober to be able to communicate rationally.

However, for medical emergencies, Part 2 allows for disclosures of patient identifying information to medical personnel who may need this information for "treating a health condition that poses an immediate threat to the health of any individual and which requires immediate medical intervention."[13] In this circumstance, the Part 2 program is required to document the disclosure in writing in the patient's record.[14]

[13] *Id.* § 2.51(a).
[14] *Id.* § 2.51(c)(1)-(4). The documentation should include the name of the medical personnel who received the patient-identifying information, and their affiliation with any health care facility; the name of the person making the disclosure; the date and time of the disclosure; and the nature of the emergency. *Id*.