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Selected Changes to the SAMHSA Part 2 Regulations as a Result of the Final Rule (published Jan. 18, 2017)[1]

What information is protected by the SAMHSA Part 2 regulations?	▪ The SAMHSA Part 2 regulations apply to any information (including information on referral and intake) that would identify an individual, directly or indirectly, as having received diagnosis, treatment, or referral for treatment for a substance use disorder, which is maintained in connection with the performance of a program subject to these regulations ("Patient Identifying Information"). ▪ Patient Identifying Information need not be recorded to be subject to the regulations and includes: o diagnosis, treatment, and referral for substance use disorder treatment information; o intake information; o billing information; o voicemails; o emails; o texts; and o any paper or electronic records containing Patient Identifying Information. See 42 C.F.R. § 2.12.[2] **S&G Note:** The Final Rule revises the definition of "records" to include electronic records containing Patient Identifying Information and verbal communications created, received, or acquired by a Part 2 Program. The Final Rule also addresses the security and disposition of electronic records, including a requirement for sanitizing associated media.
What types of providers are covered under the SAMHSA Part 2 regulations?	▪ For providers to be considered "Part 2 Programs," they must be both "federally assisted" and satisfy the regulatory definition of "program." **A health care provider must satisfy the following criteria to be considered a "program":** ▪ (i) "an individual or entity (other than a general medical facility) who holds itself out as providing, *and* provides, substance use disorder diagnosis, treatment, or referral for treatment"; OR

[1] Confidentiality of Substance Use Disorder Patient Records, 82 Fed. Reg. 11, 6052 (Jan. 18, 2017), available at https://www.gpo.gov/fdsys/pkg/FR-2017-01-18/pdf/2017-00719.pdf.

[2] Please note that the citations in this chart are to the relevant provisions of the federal regulations and are subject to change.

	▪ (ii) "an identified unit within a general medical facility that holds itself out as providing *and* provides substance use disorder diagnosis, treatment, or referral for treatment"; OR ▪ (iii) "Medical personnel or other staff in a general medical facility whose primary function in the general medical facility is to provide substance use disorder diagnosis, treatment, or referral for treatment *and* who are identified as such providers." ▪ For example, these regulations would not apply to ER personnel who refer a patient to the intensive care unit for an apparent drug overdose. See 42 C.F.R. § 2.11. **S&G Note:** There was no substantive change to what entities are considered covered programs under the Part 2 regulations. The Final Rule, however, extends application of the Part 2 requirements to "lawful holders" of Patient Identifying Information (i.e., an individual or entity who received such information as a result of a part 2-compliant patient consent or as otherwise permitted under Part 2).
What does it mean for a program to be "federally assisted"?	**Subject to a few limited exceptions, a program is considered to be "federally assisted" if it is:** ▪ (i) conducted in whole or in part by any federal department or agency; ▪ (ii) being carried out under authorization from the federal government; ▪ (iii) supported by funds provided by any federal department or agency; or ▪ (iv) assisted by the IRS through a grant of tax exempt status or allowance of tax deductions for contributions. ▪ Providers who are authorized to conduct business by the federal government are considered to be "federally assisted." Examples include providers who are: o (i) participating in Medicare; o (ii) registered with the DEA to dispense a controlled substance used in the treatment of a substance use disorder; or o (iii) authorized to conduct opioid treatment. See 42 C.F.R. § 2.12. **S&G Note:** There was no substantive change to this section, just further clarification.
Disclosures permitted *with* written patient consent	If a patient provides written consent to a disclosure of his or her records, a program may disclose those records in accordance with the consent. The consent form must include the following information: ▪ (i) the specific name or general designation of the program or person permitted to make the disclosure;

	▪ (ii) ***the recipient of the information:*** ○ ***(a) the name(s) of the individual(s) to whom a disclosure is to be made; or*** ○ ***(b) If the patient has a treating provider relationship with the recipient entity (e.g., hospital, health care clinic, or a private practice), the name of the entity; or*** ○ ***(c) If the recipient entity does not have a treating provider relationship with the patient and is a third-party payer, the name of the entity; or*** ○ ***(d) If the recipient entity does not have a treating provider relationship with the patient and is not a third party payer (e.g., research institute or health information exchange), the name of the entity and:*** • ***(1) the name(s) of an individual participant(s);*** • ***(2) the name(s) of an entity participant(s) that has a treating provider relationship with the patient; or*** • ***(3) a general designation of an individual or entity participant(s) or class of participants that must be limited to participant(s) who has a treating provider relationship with the patient whose information is being disclosed (e.g., "my treating providers")*** **(New)**. ▪ (iii) the patient's name; ▪ (iv) the purpose of the disclosure; ▪ (v) "how much and what kind of information is to be disclosed, ***including an explicit description of the substance use disorder information that may be disclosed"*** **(New)**; ▪ (vi) the patient's signature (electronic signatures are permitted to the extent not prohibited by any applicable law); ▪ (vii) the date on which the consent is signed; ▪ (viii) a statement that the consent is subject to revocation at any time except to the extent that the program or person making the disclosure has already acted in reliance on it (e.g., provision of treatment services in reliance on a valid consent to disclose information to a third-party payer); and ▪ (ix) the date, event, or condition upon which the consent will expire if not revoked before. See 42 C.F.R. §§ 2.31; 2.32. **S&G Note:** The Final Rule provides patients with the option of providing a general designation in the "To Whom" section of the consent form, as opposed to specifically naming each provider in the consent form, so long as those individuals or entities have a treatment relationship with the patient (i.e. "past," "current," and/or "future" treating providers). It also provides patients with the right to receive, upon request, from the entity that serves as the intermediary (e.g., HIE, ACO, CCO) a list of entities to which

	their information has been disclosed pursuant to the general designation. SAMHSA clarifies that intermediaries may not disclose Patient Identifying Information pursuant to a general designation on a consent form until they have the ability to comply with the list of disclosures requirement.
Disclosures permitted *without* patient consent	**Under the following circumstances, Patient Identifying Information may be disclosed without written patient consent:** ▪ **(i) Medical Emergencies:** o Patient Identifying Information may be disclosed to medical personnel to the extent necessary to meet a ***bona fide medical emergency*** in which the patient's prior written consent cannot be obtained. o **S&G Note:** The Final Rule "revises the medical emergency exception to make it consistent with the statutory language and to give providers more discretion to determine when a 'bona fide medical emergency' exists." 82 Fed. Reg. 11, 6054 (Jan. 18, 2017). ▪ **(ii) Research:** o A Part 2 Program or other "lawful holder" may disclose Patient Identifying Information to qualified personnel for the purpose of conducting scientific research if the individual designated as director or managing director, or other individual with comparable authority determines that the researcher satisfies the following requirements, as applicable: (a) has obtained and documented patient authorization or a waiver of authorization consistent with HIPAA; and (b) has complied with the Department of Health and Human Services ("HHS") regulations regarding the protection of human subjects. o **S&G Note:** The Final Rule requires that the researcher satisfy the above regulatory requirements and also permits researchers to link to federal and non-federal data repositories holding Patient Identifying Information if the request has been reviewed and approved by an Institutional Review Board registered with HHS. ▪ **(iii) Audit and Evaluation Activities:** Patient Identifying Information may be disclosed in the course of a review of records of the Part 2 Program to any individual or entity who agrees in writing to only re-disclose the information back to the Part 2 Program from which it was obtained and to only use the information to carry out an audit or evaluation, and who performs the audit/evaluation on behalf of: o (a) any federal, state, or local government agency which provides financial assistance to the program or is authorized to regulate the program; o (b) any individual or entity who provides financial assistance to the program, which is a

	third-party payer, or is a quality improvement organization performing a utilization or quality control review. ○ **S&G Note:** The Final Rule makes clear that disclosures of Patient Identifying Information to ACOs and other CMS-regulated entities to carry out Medicare, Medicaid, and Children's Health Insurance Program (CHIP) audit and evaluation activities are permitted if the above requirements are satisfied. See 42 C.F.R. §§ 2.51 - 2.53.
Prohibition of Re-disclosure	▪ Patient Identifying Information that is disclosed with the patient's written consent must be accompanied by a written statement notifying the recipient of the information that such information may not be re-disclosed without the patient's consent, or as otherwise permitted under the Part 2 Regulations. **S&G Note:** SAMHSA clarifies in the Final Rule that "the prohibition on re-disclosure only applies to information that would identify, directly or indirectly, an individual as having been diagnosed, treated, or referred for treatment for a substance use disorder, such as indicated through standard medical codes, descriptive language, or both . . . ." Other health-related information may be re-disclosed. 82 Fed. Reg. 11, 6054 (Jan. 18, 2017).