

42 CFR Part 2 Definitions

Audit and Evaluation: Broad regulating activities including the need to review records to appropriately evaluate compliance with applicable policies, rules, and laws, including waivers and state plans, as well as utilization and quality control reviews. Evaluations may also include assessing performance and outcomes under a Medicaid waiver as well as civil or administrative investigations of a Part 2 program. Patient identifying information may be disclosed for the purposes of conducting a Medicaid audit or evaluation.

Consent: Valid, written permission by the patient allowing for disclosure of the patient's Part 2 protected information. Consent requirements depend upon whether the Part 2 protected information is being disclosed to an individual or entity with a treating provider relationship.¹

Direct Administrative Control: An entity with administrative personnel who oversee a substance use disorder unit that is a component of a larger behavioral health program or of a general health program, and who, in connection with their duties, needs to know specific information about a patient arising out of that patient's diagnosis, treatment or referral to treatment.² Part 2 programs can disclose Part 2 information to entities having direct administrative control over the Part 2 programs without patient consent but the entity is prohibited from re-disclosure.³

General Designation: A broad category describing "to whom" patient consent is granted for sharing of Part 2 information. Specifications for using the general designation depend upon whether consent is granted to someone with a treating provider relationship with the patient.

Health Information Exchange: Health Information Exchange ("HIE") is a generic term that refers to a number of methods and mechanisms through which information can be exchanged electronically.⁴

Lawful Holder: A "lawful holder" of patient identifying information is an individual or entity who has received such information as the result of a Part 2-compliant patient consent (with a prohibition on re-disclosure notice) or as permitted under the Part 2 statute, regulations, and guidance, and therefore is bound by 42 CFR Part 2.⁵

Patient Identifying Information: The name, address, social security number, fingerprints, photograph, or similar information by which the identity of a patient, as defined in this section, can be determined with reasonable accuracy either directly or by reference to other information. The term does not include a number assigned to a patient by a part 2 program, for internal use only by the part 2 program, if that number does not consist of or contain numbers (such as a social security, or driver's license number) that could be used to identify a patient with reasonable accuracy from sources external to the part 2 program.⁶

¹ 42 CFR Part 2, 2.31.

² SAMHSA Frequently Asked Questions, Applying the Substance Abuse Confidentiality Regulations to Health Information Exchange (HIE), 2010, <https://www.samhsa.gov/sites/default/files/faqs-applying-confidentiality-regulations-to-hie.pdf>.

³ 42 CFR Part 2, 2.12(c)(3)(ii).

⁴ SAMHSA Frequently Asked Questions, Applying the Substance Abuse Confidentiality Regulations to Health Information Exchange (HIE), 2010, <https://www.samhsa.gov/sites/default/files/faqs-applying-confidentiality-regulations-to-hie.pdf>.

⁵ 42 CFR Part 2 Final Rule, January 18, 2017, p. 6068.

⁶ 42 CFR Part 2, 2.11.

Part 2 Program: A federally assisted program, where:

- An individual or entity (other than a general medical facility) holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment; or
- An identified unit within a general medical facility holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment; or
- Medical personnel or other staff in a general medical facility have the primary function of diagnosis, treatment, or referral for treatment for substance use disorder and who are identified as such providers.⁷

Payment and/or Health care Operations: A broad set of activities, ranging from claims management to accreditation, customer service to risk adjustment, that allow for re-disclosure of Part 2 information as necessary with patient consent.⁸ If a patient consents to a disclosure of their records under § 2.31 for payment and/or health care operations activities then re-disclosure is allowed for purposes of carrying out the payment and/or health care operations. SAMSHA does not specifically define payment and health care operations but provides a robust list of examples⁹:

- 1) Billing, claims management, collections activities, obtaining payment under a contract for reinsurance, claims filing and related health care data processing;
- (2) Clinical professional support services (*e.g.*, quality assessment and improvement; initiatives, utilization review and management services);
- (3) Patient safety activities;
- (4) Activities pertaining to:
 - (i) The training of student trainees and health care professionals;
 - (ii) The assessment of practitioner competencies; and
 - (iii) The assessment of provider and/or health plan performance;
 - (iv) Training of non-health care professionals;
- (5) Accreditation, certification, licensing, or credentialing activities;
- (6) Underwriting, enrollment, premium rating, and other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits, and ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care;
- (7) Third-party liability coverage;
- (8) Activities related to addressing fraud, waste and abuse;

⁷ 42 CFR Part 2, 2.11.

⁸ 42 CFR Part 2, 2.33(b), 42 CFR Part 2 Final Rule, January 3, 2018, p. 243.

⁹ 42 CFR Part 2, Supplemental Notice of Proposed Rulemaking, January 18, 2017, p. 5489.

- (9) Conducting or arranging for medical review, legal services, and auditing functions;
- (10) Business planning and development, such as conducting cost-management and planning-related analyses related to managing and operating, including formulary development and administration, development or improvement of methods of payment or coverage policies;
- (11) Business management and general administrative activities, including, but not limited to, management activities relating to implementation of and compliance with the requirements of this or other statutes or regulations;
- (12) Customer services, including the provision of data analyses for policy holders, plan sponsors, or other customers;
- (13) Resolution of internal grievances;
- (14) The sale, transfer, merger, consolidation, or dissolution of an organization;
- (15) Determinations of eligibility or coverage (*e.g.* coordination of benefit services or the determination of cost sharing amounts), and adjudication or subrogation of health benefit claims;
- (16) Risk adjusting amounts due based on enrollee health status and demographic characteristics;
- (17) Review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges.

Qualified Service Organization: Provides services to a Part 2 program, such as data processing, bill collecting, dosage preparation, laboratory analysis, legal, accounting, population health management, medical staffing, other professional services, and services to prevent or treat child abuse or neglect (including training on nutrition, child care, and group therapy).¹⁰ Restrictions on disclosure do not apply to communications between a Part 2 program and a QSO about information needed by the QSO to provide services to the program.¹¹

Third-Party Payer: Any organization, public or private, that pays or insures health or medical expenses on behalf of beneficiaries or recipients, such as commercial insurance companies, Medicare, and Medicaid.¹² A third-party payer can receive Part 2 information and re-disclose to an agent for purposes of audit and evaluation.¹³

Treating Provider Relationship: Treating provider relationship means regardless of whether there's been an in-person encounter:

¹⁰ 42 CFR Part 2, 2.11.

¹¹ 42 CFR Part 2 Final Rule, January 3, 2018, p. 246.

¹² The American Health Lawyers Association, accessed 3.18.18,
<https://www.healthlawyers.org/hlresources/Health%20Law%20Wiki/Third%20Party%20Payor.aspx>.

¹³ 42 CFR Part 2, 2.53(b)(2), 42 CFR part 2 Final Rule, January 3, 2018, p. 246.

- The patient is, agrees to, or is legally required to be diagnosed, evaluated and/or treated, or agrees to accept consultation, for any condition by an individual or entity; and
- The individual or entity undertakes or agrees to undertake diagnosis, evaluation and/or treatment of the patient, or consultation with the patient for any condition.
- The treating provider does NOT need to be a Part 2 provider.