

DISCLOSURES OF SUBSTANCE USE DISORDER PATIENT RECORDS

Policy Number: [Enter]

Effective Date: [Enter]

[GPM Note: In January 2017, the Department of Health and Human Services, Substance Abuse and Mental Health Services Administration (“SAMHSA”) issued a final rule amending 42 CFR Part 2. See 82 Fed. Reg. 6115 (Jan. 18, 2017). The final rule became effective on March 21, 2017. This policy has been updated to incorporate these changes.]

I. Policy

A. Purpose

This policy establishes guidelines to be followed by [Organization]’s workforce when using or disclosing substance use disorder patient records. It sets forth the general rule for disclosures; because other exceptions may apply in unique scenarios, [Organization] staff should refer to additional policies when appropriate.

B. Applicability

The rules in this policy originate from 42 C.F.R. Part 2, the federal substance use disorder patient records rule (“Part 2”). Part 2 places restrictions on the use and disclosure of substance use disorder patient records and establishes specific consent standards. It applies to all records that would identify a patient as having a substance use disorder (either directly by reference or through verification), including identity, diagnosis, prognosis, or treatment information.

Part 2 applies to substance use disorder “programs” that are federally assisted. The term “Program” includes the following:

1. 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;
2. 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
3. Medical personnel or other staff in a general medical facility whose primary function is the provision of substance use disorder diagnosis, treatment, or referral for treatment and who are identified as such providers.

In addition, individuals or entities who receive patient records directly from a Program or other lawful holder of patient identifying information, and who are notified of the prohibition on re-disclosure, are subject to these restrictions on disclosure. **[GPM Note: Insert one of the following options: (1) [Organization] is a “program” because it falls within number one above; (2) [Organization] is a “program” because it falls within number two above; (3) [Organization]’s medical personnel are subject to Part 2 because they fall within number three above; OR (4) [Organization] is subject to the restrictions on disclosure because it receives patient records from part 2 programs or other lawful holders of patient identifying information].** In addition, [Organization] is federally assisted pursuant to 42 C.F.R. § 2.12(b), and does not fall within any applicability exceptions. **[GPM Note: To help determine whether [Organization] and its workforce are subject to Part 2, use the Flow Chart: Am I Subject to 42 C.F.R. Part 2?]** For these reasons, [Organization] is subject to Part 2 and must comply with this policy when disclosing substance use disorder patient records.

It is important to note that not every entity or provider is subject to Part 2. For example, Part 2 does not apply to general medical facilities (although it may apply to an identified unit within a general medical facility). It does not apply to emergency room personnel who refer a patient to the intensive care unit for an apparent overdose (unless the primary function of such personnel is the provision of substance use disorder diagnosis, treatment, or referral and they are identified as providing such services, or the emergency room has promoted itself to the community as a provider of such services). For additional detail on the applicability of Part 2, refer to [Organization]’s Flow Chart: Am I Subject to 42 C.F.R. Part 2?

C. Policy Implementation—General Rule

The general rule is that [Organization] or its workforce may not say to a person outside of [Organization] that an individual receives care at [Organization] for substance use disorder, or disclose any information identifying the individual as a substance use disorder patient unless:

1. The patient consents in writing;
2. The disclosure is allowed by a court order; or
3. The disclosure is made to medical personnel in a medical emergency or to qualified personnel for research, audit, or program evaluation.

Part 2 prohibits the disclosure and use of substance use disorder patient records unless certain circumstances exist. If any circumstances exist under which disclosure is permitted, that circumstance acts to remove the prohibition on

disclosure, but it does not compel disclosure. Thus, *Part 2 does not require disclosure under any circumstances.*

D. Disclosures made pursuant to written consent

[*Organization*] may disclose substance use disorder patient records pursuant to written consent of the individual. A written consent to a disclosure must include:

1. The name of the patient;
2. The specific name(s) or general designation(s) of the Part 2 program(s), entity(ies), or individual(s) permitted to make the disclosure;
3. 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;
4. One or more of the following:
 - a. The names of the individuals to whom a disclosure it to be made;
 - b. If the recipient of the information has a treating provider relationship with the patient who information is being disclosed, such as a hospital or health care clinic, or a private practice: the name of that entity;
 - c. If the recipient entity does not have a treating provider relationship with the patient whose information is being disclosed and is a third-party payer, the name of the entity;
 - d. If the recipient entity does not have a treating or provider relationship with the patient whose information is being disclosed and is not covered by subsection 4(c) above (i.e., is not a third-party payer), such as an entity that facilitates the exchange of health information or a research institution, must include the name of the entity(ies) and either: (1) the name(s) of the individual participants; (2) the name(s) of an entity participants(s) that has a treating provider relationship with the patient whose information is being disclosed; or (3) a general designation of an individual or entity participant(s) or class of participants that must be limited to a participant(s) who has a treating provider relationship with the patient whose information is being disclosed.
 - i. When using a general designation, a statement must be included on the consent form that the patient (or other individual authorized to sign in lieu of the patient), confirms their understanding that, upon their request and consistent with this part, they must be provided a list of entities to which their information has been disclosed pursuant to the general designation.

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5. The purpose of the disclosure. Note that the disclosure must be limited to that information which is necessary to carry out the stated purpose.
6. A statement that the consent is subject to revocation at any time except to the extent that the part 2 program or other lawful holder of patient identifying information that is permitted to make the disclosure has already acted in reliance on it. Acting in reliance includes the provision of treatment services in reliance on a valid consent to disclose information to a third-party payer.
7. The date, event, or condition upon which the consent will expire if not revoked before. This date, event, or condition must ensure that the consent will last no longer than reasonably necessary to serve the purpose for which it is provided.
8. The signature of the patient and, when required for a patient who is a minor, the signature of an individual authorized to give consent under 42 CFR § 2.14; or, when required for a patient who is incompetent or deceased, the signature of an individual authorized to sign under 42 CFR § 2.15. Electronic signatures are permitted to the extent that they are not prohibited by any applicable law.
9. The date on which the consent is signed.

Each disclosure made pursuant to written consent must be accompanied by the following written statement:

This information has been disclosed to you from records protected by federal confidentiality rules (*42 CFR part 2*). The federal rules prohibit you from making any further disclosure of information in this record that identifies a patient as having or having had a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person unless further disclosure is expressly permitted by the written consent of the individual whose information is being disclosed or as otherwise permitted by 42 CFR part 2. A general authorization for the release of medical or other information is *NOT* sufficient for this purpose (see §2.31). The federal rules restrict any use of the information to investigate or prosecute with regard to a crime any patient with a substance use disorder, except as provided at §§2.12(c)(5) and 2.65.

E. Disclosures that may be made without written patient consent

[*Organization*] may make disclosures without written consent according to the following circumstances:

1. Medical emergencies

[*Organization*] may disclose information to medical personnel to the extent necessary to meet a bona fide medical emergency in which the patient's prior informed consent

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cannot be obtained. The treating provider is responsible for determining whether a bona fide medical emergency exists. Immediately following disclosure, [Organization] must document the following in the individual's records:

- a. The name of the medical personnel to whom disclosure was made and their affiliation with any health care facility;
- b. The name of the individual making the disclosure;
- c. The date and time of the disclosure; and
- d. The nature of the emergency.

2. Research activities

[Organization] may disclose patient identifying information for the purpose of conducting scientific research if the [Organization] [director] [chief executive officer] or their designee makes a determination that the recipient of patient information:

- a. If a HIPAA-covered entity or business associate: has obtained and documented HIPAA authorization from the patient, or a waiver or alteration of authorization, as applicable.
- b. If subject to the HHS regulations regarding the protection of human subjects (45 CFR part 46): either provides documentation that the researcher is in compliance with the requirements of the HHS regulations, including the requirements related to informed consent or a waiver of consent (found in 45 CFR 46.111 and 46.116), or that the research qualifies for exemption under the HHS regulations (found in 45 CFR 46.101(b)) and any successor regulations.
- c. If subject to both HIPAA and the HHS regulations regarding the protection of human subjects: has met the requirements for both (a) and (b) above.
- d. If subject to neither HIPAA nor the HHS regulations regarding the protection of human subjects: these rules governing disclosure of Part 2 data for research (42 CFR § 2.52) do not apply.

A person conducting research may disclose individual identifying information obtained under this policy only back to [Organization] and may not identify any individual in any report of that research or otherwise disclose an individual's identity.

Minnesota law sets forth specific rules for the disclosure of health records for external research. In regards to records generated on or after January 1, 1997, [Organization] must:

1. Disclose in writing to patients currently being treated by [Organization] that health records, regardless of when they were generated, may be released

and that the patient may object, in which case [Organization] will not release the records;

2. Use reasonable efforts to obtain the patient's written general authorization that describes the release of records; and

3. Advise the patient of his/her right to receive information on how the patient may contact the external researcher and the date information was released, and provide such information when requested.

Because Minnesota law is more restrictive than Part 2 in this regard, [Organization] must comply with this rule when disclosing information to an external researcher. Minnesota law does not set forth specific requirements for disclosures to internal researchers; thus, [Organization] must follow the general rule and obtain patient consent prior to such disclosures.

For more information, [Organization] staff should refer to policy number [Enter], Using and Disclosing Information for Research Purposes.

3. Audit and evaluation activities

[Organization] may disclose substance use disorder patient records, without patient consent, for audit and evaluation activities as follows: If records are not downloaded, copied or removed from [Organization]'s premises or forwarded electronically to another electronic system or device, individual identifying information may be disclosed in the course of a review of records on [Organization]'s premises to any individual or entity who agrees in writing to comply with the limitations on re-disclosure and use and who:

- a. Performs the audit or evaluation activity on behalf of any federal, state, or local government agency which provides financial assistance to [Organization] or is authorized by law to regulate its activities, or to any individual or entity who provides financial assistance to [Organization], which is a third party payer covering patients at [Organization], or which is a quality improvement organization performing a utilization or quality control review; or
- b. Is determined by [Organization] to be qualified to conduct an audit or evaluation of [Organization].

Records may be copied or removed from [Organization]'s premises or downloaded or forwarded to another electronic system or device from [Organization]'s electronic records by any individual or entity who:

- c. Agrees in writing to maintain and destroy the information in a manner consistent with the policies and procedures established under 42 CFR 2.16;

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retain records in compliance with applicable federal, state, and local record retention laws; and comply with the limitations on disclosure and use; and

- d. Performs the audit or evaluation on behalf of any federal, state, or local government agency or individual or entity that meets the requirements of (a) above.

[*Organization*] may also disclose patient identifying information to any individual or entity for the purpose of conducting a Medicare, Medicaid, or Children's Health Insurance Program (CHIP) audit or evaluation, including an audit or evaluation necessary to meet the requirements for a CMS-regulated ACO or similar CMS-regulated organization, provided that the individual or entity agrees in writing to the requirements set forth at 42 CFR 2.53(c). The audit or evaluation must be conducted in accordance with the requirements set forth at 42 CFR 2.53(c). These requirements contain significant detail related to the parameters of permitted audit/evaluation activities. A Medicare, Medicaid, or CHIP audit or evaluation includes a civil or administrative investigation of [*Organization*] by any federal, state, or local government agency with oversight responsibilities for Medicare, Medicaid, or CHIP and includes administrative enforcement, against [*Organization*] by the government agency, of any remedy authorized by law to be imposed as a result of the findings of the investigation.

Except as permitted by Part 2, identifying information disclosed pursuant to an audit/review may be disclosed only back to [*Organization*] and used only to carry out an audit or evaluation purpose or to investigate or prosecute criminal or other activities, as authorized by a court order.

F. Disclosures and uses which may be made with an authorizing court order

[*Organization*] may disclose identifying information pursuant to a court order. Workforce should refer to [*Organization*]'s policy on Disclosures for Judicial and Administrative Proceedings (policy number [Enter]).

G. Other exceptions

There are a number of other exceptions to the general rules set forth in this policy. For example, [*Organization*] may disclose information without patient consent to a qualified service organization, provided certain requirements are met. Staff should review policy number [Enter], Disclosing Information to Business Associates, for more detail.

In addition, Part 2 permits [*Organization*] to exchange substance use disorder patient records without patient consent to [*Organization*] personnel who have a need for the information in connection with their duties, and to an entity with direct administrative control over [*Organization*]. Part 2 also permits [*Organization*] to communicate with law enforcement officials or agencies about crimes that occur on [*Organization*]'s premises or against [*Organization*] personnel, or to report incidents of suspected child

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abuse or neglect. These exceptions are narrow, and [Organization] staff should consult with the [compliance officer/privacy officer/other designee] prior to any disclosure. Minnesota law may require patient consent for some, but not all, of these exceptions.

Because this policy applies to those situations in which other exceptions do not apply, staff should refer to other applicable policies, and/or consult with [Organization]'s [compliance officer/privacy officer/other designee] to determine whether a disclosure of substance use disorder patient records is permitted without patient consent.

H. Minimum necessary

Any disclosure made under Part 2 must be limited to that information which is necessary to carry out the purpose of the disclosure.

II. Procedure

[Organization] and its workforce will adhere to this policy when disclosing substance use disorder patient records, and will adhere to other relevant policies referencing Part 2 requirements, when applicable.