



42 CFR Part 2 Frequently Asked Questions

1. *What is Part 2 and who does it apply to?*

Part 2 is referred to as “Substance Use Disorder” under the SAMHSA regulation enacted on March 21, 2017.

Part 2 applies to “federally assisted” substance abuse “programs.” The definition of “federal assistance” is broad: any entity that receives federal funding, is certified by Medicare, is registered to distribute controlled substances, or is a tax exempt non-profit is considered to have received federal assistance. 42 C.F.R. § 2.12(b). As a result, nearly all substance abuse providers meet the test for federal assistance, although some for-profit substance abuse clinics may not be federally assisted. However, in order to be subject to Part 2 an entity must also be a substance abuse “program.” That typically means that the entity must “hold itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment.” 42 C.F.R. § 2.11. Merely providing substance abuse treatment on a periodic basis as part of a broader set of services does not make a provider a “program.” Part 2 “would not apply, for example, 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 alcohol or drug abuse 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.” 42 C.F.R. § 2.12(e)(1).

2. *Do the consent forms used by RHIO/QEs for health information exchange in New York comply with 42 CFR Part 2?*

Yes, the consent forms designed by NYSDOH meet the SAMHSA requirements.

HealthConnections uses the NYSDOH-approved model consent form and is, therefore, compliant with the 42 CFR Part 2 requirements.

3. *Can a Part 2 facility disclose data to a health information exchange?*

Yes. A Part 2 facility must be signed up as a Participant of HealthConnections by signing the HealthConnections’ Participation Agreement (PA) and Business Associate Agreement (BAA). In addition, a Qualified Service Organization Agreement (QSOA) must be in place. Section 10.5 and Exhibit B of the HealthConnections Terms & Conditions outlines the Qualified Service Organization Agreement (QSOA) between HealthConnections and its Participants. Signing the HealthConnections agreements and becoming a participant covers the requirements of a QSOA for a Part 2 facility.

4. *As a Part 2 facility, what regulations does my organization need to follow?*

Part 2 facilities need to follow the regulation as enacted on March 21, 2017. Refer to the link at the end of this document for references to consent and disclosure.

5. *Who can access a patient’s Part 2 data?*

As with any patient data, the patient’s affirmative consent is required to access and view all data through the HealthConnections portal for non-emergency treatment.

Part 2 data will be accessible for a Break-the-Glass emergency event and Minor Consent Override functionality.

Public Health users, that bypass consent, will not be allowed to access Part 2 data.

6. *Is access to Part 2 data audited?*

Yes, all data that is accessed within the HealtheConnections portal is audited and reports are provided to all participating organizations each month. Each participating organization is required to attest annually to an audit.

A patient may also request an audit of their data per HealtheConnections policies.

7. *Can a minor's Part 2 be accessed?*

Yes, a minor's Part 2 data can be accessed and viewed through the HealtheConnections portal with an affirmative consent from a parent/guardian for non-emergency treatment. Affirmative consent is not needed in the event of an emergency, using Break-the-Glass functionality. NOTE: A parent/guardian affirmative consent does not allow the parent to have access to the minor's records.

In addition, if a parent/guardian has consented "No", "No except in an emergency", or has not yet consented for the minor, a minor may override the parent/guardian consent to allow a provider to access his/her data when the provider is treating the minor for a Minor Consented Service such as Substance Use Disorder (Part 2).

SAMHSA REGULATION:

For additional information, refer to the Federal Register <https://www.regulations.gov/document?D=HHS-OS-2016-0005-0377> for the specific topics below:

Subpart B – General Provisions

- Section 2.13 Confidentiality Restrictions
- Section 2.14 Minor Patients

Subpart C – Disclosures With Patient Consent

- Section 2.31 Consent Requirements

Subpart D – Disclosures Without Patient Consent

- Section 2.51 Medical Emergencies