



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 considered to have received federal assistance. 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.” 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.

2. *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 HealtheConnections by signing the HealtheConnections’ 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 HealtheConnections Terms & Conditions outlines the Qualified Service Organization Agreement (QSOA) between HealtheConnections and its Participants. Signing the HealtheConnections agreements and becoming a participant covers the requirements of a QSOA for a Part 2 facility.

3. *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.

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

4. *Can a HealtheConnections Participant re-disclose Part 2 data?*

A HealtheConnections Participant may access and view a patient’s Part 2 data in the portal with the patient’s affirmative consent obtained through the HealtheConnections consent form. If the Participant wishes to download the data into its own EHR, the Participant may do so for its own use. If the Participant wants to re-disclose the information with another entity, it must obtain a written consent from the patient prior to any further re-disclosure of that data.

Refer to the link at the end of this document for the complete regulation and further details on re-disclosure.



5. 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 the complete regulation.

6. 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 HealtheConnections portal for non-emergency treatment.

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

Public Health and organ procurement users, that bypass consent, will not be allowed to access Part 2 data per the SAMHSA regulation. HealtheConnections will prohibit access to these users through configuration settings in the portal.

7. 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.

8. 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 during the minor's visit 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