



## Do the federal confidentiality regulations regarding SUD treatment information (Part 2) permit patients to sign consent forms remotely, including with electronic signatures?



### What You Need to Know

At times, Part 2 programs<sup>1</sup> may need clients/patients who are not on the premises to sign a consent form to release information protected by 42 CFR Part 2 (Part 2). This may be increasingly necessary due to the rapid expansion of telehealth services during the COVID-19 pandemic, and for patients that are living in rural locations or those who are unable to physically come to a facility.

#### **Part 2 permits patients to sign consent forms remotely, including with an electronic signature.**

Programs may mail or electronically transmit a consent form to a patient, including by fax, email, or other form of electronic transmission.

Patients may sign remotely and mail or electronically transmit the consent form back to the program. Electronic signatures are also permissible, unless prohibited by another law.

Part 2 does not require a patient to sign a consent form in person at the Part 2 program, or otherwise have the signature validated, witnessed, or notarized. Providers should check with their state licensing agency to see whether state law imposes any additional requirements.

This InFocus Brief only address consent forms authorizing *disclosure of records* (sometimes known as a “Release of Information”). Providers should check with their state licensing agency for requirements regarding other types of patient consent forms, such as consent to treatment.



### Additional Background Information

Part 2 programs, and other lawful holders of Part 2-protected records,<sup>4</sup> may disclose patient-identifying information according to the terms of a properly executed consent form, signed by the patient. The requirements for valid patient consent are set out in section 2.31 of the regulations. Subsection 2.31(a)(8) requires consent forms to contain: “The signature of the patient . . . . Electronic signatures are permitted to the extent that they are not prohibited by any applicable law.” In general, the consent form must be signed by the patient, not a patient representative or healthcare proxy.<sup>2</sup>

There is no requirement in the regulations that the signature of the patient be witnessed by the Part 2 program or any other person.<sup>5</sup> Shortly after the regulations were originally promulgated, the U.S. Department of Health and Human Services issued an official sub-regulatory guidance letter, indicating that a program did not need to require patients to have their signature notarized if signing consent forms off-premises (“... section 2.31(a)(8) does not require that the patient’s signature be witnessed by anyone.”).<sup>6</sup> The signature requirements in Part 2 have not changed since 1976, except to permit electronic signatures as discussed above.

**Federal law therefore permits a program to send a Part 2 consent form to a patient, for the patient to sign off-site and return to the program via mail or electronic transmission. Programs should still take care to (a) explain the nature and purpose of the consent form to the patient, and (b) take steps to avoid unintentional disclosures of patient-identifying information when sending consent forms to patients, consistent with the program’s privacy and security policies.**

### For More Information

#### Resources

This resource is one of many that are available within the Center of Excellence for Protected Health Information's resource library which can be found at [coephi.org](https://coephi.org).

#### Request Technical Assistance

You can request brief, individualized technical assistance and join our mailing list for updates, including news about the publication of new resources and training opportunities, [here](#).

### Disclaimer

Resources, training, technical assistance, and any other information provided through the Center of Excellence for Protected Health Information do not constitute legal advice. For legal advice, including legal advice on other applicable state and federal laws, please seek out local counsel.

Funding for the Center of Excellence for Protected Health Information was made possible by grant no. 1H79TI081743-01 from SAMHSA. The views expressed herein do not necessarily reflect the official policies of the Department of Health and Human Services; nor does mention of trade names, commercial practices, organizations imply endorsement by the U.S. Government.

## References

- 1 A "Part 2 program" is an individual or entity receiving "federal assistance," defined at 42 CFR § 2.12(b), that meets the definition of a "program." 42 CFR § 2.11. A "program," defined at 42 CFR § 2.11, is an individual, entity (other than a general medical facility), or an identified unit in a general medical facility that holds itself out as providing, and provides, diagnosis, treatment, or referral for treatment for a substance use disorder. Individuals in a general medical facility whose primary function is to provide diagnosis, treatment, or referral for treatment for a substance use disorder are also "programs," if they are identified as providing such services. For more information, see "Disclosure of Substance Use Disorder Patient Records: Does Part 2 Apply to Me?" (SAMHSA & ONC, 2018), <https://www.samhsa.gov/sites/default/files/does-part2-apply.pdf>.
- 2 In some cases, the signature of a minor patient's parent or legal guardian may be required (see § 2.14), or in the case of a patient who is deceased or has been adjudicated by a court to lack capacity, the signature of an individual authorized to sign under § 2.15. For the purposes of this resource, we refer to the "patient" to encompass any individual authorized under Part 2 to sign a consent form.
- 3 See 42 CFR § 2.31(a)(8).
- 4 A "lawful holder" of patient-identifying information protected by Part 2 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, or guidance and, therefore, is bound by 42 CFR part 2." Confidentiality of Substance Use Disorder Patient Records, 82 Fed. Reg. 6052, 6068 (Jan. 18, 2017), available at <https://www.federalregister.gov/d/2017-00719/p-364>.
- 5 See 42 CFR 2.31.
- 6 U.S. Dep't of Health & Human Svcs., Opinion Letter 76-61, Letter to New York State Association of Councils on Alcoholism (Sept. 23, 1976).