CHECKLIST
42 C.F.R. Part 2 Consent Form – Required Elements

(1) Required Elements for ALL Part 2 Consents ("Part 2 Standard Consent")

> ***When to Use***: *A "Part 2 Standard Consent" must be obtained before any & all uses or disclosures of Part 2 Records that are not otherwise permitted under a Part 2 exception or de-identified. This includes, but is not limited to, any disclosure of Part 2 Records for treatment, payment or health care operations* (TPO). **[NOTE:** additional requirements apply to Part TPO Consents].

- ❑ **Patient's Name**[1]
- ❑ **Discloser Name or Description** (i.e., "The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure.")[2]
- ❑ **Description of the Information** (i.e., "A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion.")[3]
- ❑ **Recipient(s) Name or Description** (i.e., "The name(s) of the person(s), or class of persons, to which a disclosure is to be made.")[4]
- ❑ **Purpose(s)** (i.e., "A description of each purpose of the requested use or disclosure.")[5]
  - *Example*: "***At the request of the patient***" [NOTE: this is a sufficient description of the purpose **only when the patient initiates** the consent and does not, or elects not to, provide a statement of the purpose].[6]
  - *Fundraising*: If the purpose is to allow the Part 2 Program to use/disclose Part 2 Records/Information to fundraise, the Part 2 Standard consent **must** include a statement about the patient's right to elect not to receive any fundraising communications. [7]
  - **TPO Consent**: If the purpose is for treatment, payment and/or health care operations (TPO), see below "(2) Part 2 TPO Consent" for additional required elements.
- ❑ **Right to Revoke + Instructions** (i.e., "The patient's right to revoke the consent **in writing**, 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, **and how** the patient may revoke consent.")[8]
- ❑ **Expiration Date *or* Event** (i.e., "An expiration date or an expiration event that relates to the individual patient or the purpose of the use or disclosure.")[9]
  - *Example*: A statement "***end of the research study***" or similar language is sufficient if the consent is for a use or disclosure for a research purpose, including for the creation and maintenance of a research database or research repository. IF the Part 2 Program is also a HIPAA covered entity, an expiration date of "***none***" is allowed **ONLY** in the context of research studies or if a HIPAA Authorization is not required. "*None*" ***is*** allowed for a Part 2 TPO Consent (see below "(2) Part 2 TPO Consent").
- ❑ **Signature** (i.e., "The signature of the patient and, when required for a patient who is a minor, the signature of a person authorized to give consent under § 2.14; or, when required for a patient who has been adjudicated as lacking the capacity to make their own health care decisions or is deceased, the signature of a person authorized to sign under § 2.15. Electronic signatures are permitted to the extent that they are not prohibited by any applicable law.")[10]
- ❑ **Date** (i.e., "The date on which the consent is signed.")[11]
- ❑ **DISCLOSURE NOTICES:** Each disclosure **must** be *accompanied by:*
  - ❑ "***42 C.F.R. Part 2 prohibits unauthorized use or disclosure of these records***."[12]
  - ❑ A **copy of the consent** OR a **clear explanation** of the scope of the consent provided.[13]

NOTE: *the required notice statement and consent copy or explanation are not required to be contained in the Part 2 Standard Consent. However, depending on the implementation approach, including these required notices within the consent form might be the most practical approach*.

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(2) Part 2 TPO Consent

When to Use: When the ***purpose*** of the disclosure of Part 2 Records/Information to the Recipient is for **treatment**, **payment** AND/OR **health care operations**.

- ❑ **Must** include **ALL the required elements** of the Part 2 Standard Consent (*see above*).

Additionally, include the following (*as applicable*):

- ❑ Purpose ***may*** be described as "***For treatment, payment, and health care operations."***[14]
- ❑ Recipient ***may*** be described as "***My treating providers, health plans, third-party payers, and people helping to operate this program****",* or something similar.[15]
  - ❑ **HIPAA Covered Entity & Business Associate Statement.** If the Recipient is (or could be) a **HIPAA Covered Entity** or **Business Associate of a HIPAA Covered Entity**, the Part 2 TPO Consent **must** contain the following statement:

    "***Your Part 2 Record (or information contained in your Part 2 Record) may be redisclosed in accordance with the permissions contained in the HIPAA regulations, except for uses and disclosures for any civil, criminal, administrative, and legislative proceedings against you***."[16]
- ❑ **Required TPO Statements**. All Part 2 TPO Consents **must** contain the following statements:
  - ❑ **"*These Part 2 Records may be subject to redisclosure by the Recipient and no longer protected by 42 C.F.R. Part 2*."** [17]
  - ❑ **"If you refuse to sign this consent,** [**insert consequences e.g., _____**]." (i.e., a statement of the consequences to the patient of a refusal to sign the consent.")[18]

    Sample Language: "*You have the right to refuse to sign this consent form. However, if you choose not to sign, we may not be able to bill your health plan, meaning you would be responsible for full payment at the time of service. Additionally, we may not be able to coordinate treatment referrals with other providers, which could affect your continuity of care. If you have paid in full and wish to restrict disclosures to your health plan, you must notify us in writing. Additionally, if we require your consent to disclose information for your treatment, payment or health care operations, we will take reasonable steps to ensure a process is in place to accommodate your requests for restrictions on such disclosures, in accordance with regulatory guidance."*[19]
- ❑ Expiration date/event may be described as "***end of the treatment.***" Additionally, a description of "***none***" is allowed where the consent is ONLY for **treatment, payment** or **health care operations**. Note, although HIPAA generally does not permit "none" as a compliant expiration date or event, since HIPAA does not require a signed HIPAA Authorization for TPO disclosures, that HIPAA restriction does not apply here. In contrast, although Part 2 requires a signed consent for TPO, it expressly permits listing "***none***" as the expiration date/event.[20]

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(3) Part 2 Intermediary Consent

When to Use: To disclose Part 2 Records/Information to an Intermediary (i.e., Recipient that is a person/entity, ***other than*** **a Part 2 Program, HIPAA Covered Entity, or HIPAA Business Associate**) under a general designation in a Part 2 Standard Consent to be disclosed to one or more of its member participant(s) who has a treating provider relationship with the patient.

- ❑ **Must** include **ALL the required elements** of the Part 2 Standard Consent (*see above*).
- ❑ Recipient Name or Description:
  - ❑ **Intermediary Name** (required)
  - ❑ **Names** of all member participants of the Intermediary **OR general designation** of a participant(s) or class of participants, which must be ***limited to*** a participant(s) who has a treating provider relationship with the patient whose information is being used or disclosed.

NOTE: A "HIPAA Covered Entity & Business Associate Statement" (see Part 2 TPO Consent) is not required here because, by definition, an Intermediary is not a HIPAA Covered Entity or Business Associate.

- ❑ **TPO Statements**. IF the purpose of the Part 2 Intermediary Consent is for treatment, payment or health care operations (TPO), the consent **must** contain required TPO Statements:
  - ❑ **"*These Part 2 Records may be subject to redisclosure by the Recipient and no longer protected by 42 C.F.R. Part 2*."**
  - ❑ **"If you refuse to sign this consent,** [**insert consequences e.g., _____**]."

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[1] 42 C.F.R. 2.31(a)(1).
[2] 42 C.F.R. 2.31(a)(2).
[3] 42 C.F.R. 2.31(a)(3).
[4] 42 C.F.R. 2.31(a)(4)(i).
[5] 42 C.F.R. 2.31(a)(5).
[6] 42 C.F.R. 2.31(a)(5)(i).
[7] 42 C.F.R. 2.31(a)(5)(iii).
[8] 42 C.F.R. 2.31(a)(6).
[9] 42 C.F.R. 2.31(a)(7).
[10] 42 C.F.R. 2.31(a)(8).
[11] 42 C.F.R. 2.31(a)(9).
[12] 42 C.F.R. 2.32(a)(2).
[13] 42 C.F.R. 2.32(b).
[14] 42 C.F.R. 2.31(a)(5)(ii).
[15] 42 C.F.R. 2.31(a)(4)(i).
[16] 42 C.F.R. 2.31(a)(4)(iii).
[17] 42 C.F.R. 2.31(a)(10)(i).
[18] 42 C.F.R. 2.31(a)(10)(ii). NOTE HHS Comment in Preamble to Final Rule: "A Part 2 Program is not subject to the HIPAA Privacy Rule unless it is also a covered entity. The substantive differences between the HIPAA Privacy Rule and part 2 regarding conditioning treatment on signing a consent or authorization arise from the fact that the HIPAA Privacy Rule does not require any type of consent or authorization for TPO. Thus, the need to condition treatment, for example, on an authorization for payment disclosures, does not arise under HIPAA. However, **Part 2 expressly allows conditioning treatment on a consent for disclosures for payment**, for example, in § 2.14 (Minor patients). And we stated in the NPRM preamble that **a "Part 2 program may condition the provision of treatment on the patient's consent to disclose information as needed, for example, to make referrals to other providers, obtain payment from a health plan (unless the patient has paid in full), or conduct quality review of services provided**.' Because the prohibition on conditioning treatment on a signed authorization under HIPAA does not track closely to part 2, we are adopting, as proposed, only language from paragraph (c)(2)(ii)(B) of 45 CFR 164.508, and only a modified version of the first part of that paragraph. Thus, **with respect to conditioning treatment on consent,** § 2.31 requires a statement of 'the consequences to the patient of a refusal to sign the consent.'" See 89 Fed Reg at 12472, 12546 (February 16, 2024).

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[19] NOTE HHS Comment in Preamble to Final Rule: "We believe that **a Part 2 Program should not condition treatment on a TPO consent unless it has taken reasonable steps to establish a workable process to address patients' requests for restrictions on uses and disclosures for TPO**." See 89 Fed Reg at 12546.

[20] 42 C.F.R. 2.31(7).

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