ABHW
Advancing Health Care Policy
for Mental Health and Addiction

SECTION-BY-SECTION DESCRIPTION OF PROPOSED AMENDMENTS[1] TO 42 CFR PART 2

Section	Title/content	Summary	Key issues for comment
Effective date	-	The Department proposes to provide the same compliance period for both the proposed modifications to 45 CFR 164.520 and the more extensive Part 2 modifications. This 24-month compliance period would allow Part 2 programs to revise existing policies and practices, complete other implementation requirements, and train their workforce members on the changes, as well as minimize administrative burdens on entities subject to the Privacy Rule.	The Department requests comment on whether the 22-month compliance period is an appropriate length of time for entities subject to a final rule to come into compliance and any benefits or unintended adverse consequences for entities or individuals of a shorter or longer compliance period.
Subparts A and B	**Introductory and General Provisions**		
§ 2.1	Statutory authority for confidentiality of SUD patient records	Proposes clarifying amendments to the regulatory language at § 2.1 to mirror the language that is already in the statute at 42 U.S.C. 290dd–2(g).	None
§ 2.2	Purpose and effect.	Additional language is proposed to be added to paragraph (b)(1) of § 2.2 to clarify that the regulations do not require the use or disclosure	The Department requests comments on all proposed changes to § 2.2.

[1] Confidentiality of Substance Use Disorder (SUD) Patient Records, 87 Fed. Reg. 74216 (Dec. 2, 2022).

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		of Part 2 records under any circumstance, except when disclosure is required by the Secretary to investigate or determine a person's compliance with this rule. The language has been added to conform paragraph (b)(1) of § 2.2 to changes proposed to § 2.3(b), using language adapted from a similar provision of the Privacy Rule at 45 CFR 164.502(a)(2)(ii). Further, the existing paragraph (b)(3) of § 2.2 (which stated that there is a criminal penalty for violating the regulations and that they should be construed in favor of a potential violator in the same manner as a criminal statute) has been replaced with a new paragraph (b)(3) that incorporates the rules of construction included in the CARES Act – specifically, that nothing in this rule shall be construed to limit a patient's right to request restrictions on use of records for TPO or a covered entity's choice to obtain consent to use or disclose records for TPO purposes as provided in the Privacy Rule. Additional amendments are proposed throughout § 2.2 to replace the phrase "disclosure and use" with "use or disclosure"; to add the word "use" before "disclosure" where applicable to more accurately describe the scope of activity that is subject to the rule; to clarify that SUD patient records will be referred to as "records" throughout the rule; and to remove "patient" when it appears in from of the term "record".	
§ 2.3	Civil and criminal penalties for violations (proposed heading).	**The proposed changes would align enforcement and penalties with HIPAA** by replacing existing criminal penalties for violations with references to the HIPAA enforcement authorities at sections 1176 (related to civil enforcement, including the Civil Monetary Penalty tiers established by the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009) and 1177 (related to criminal penalties) of the Social Security Act, thereby establishing specific civil and criminal penalties for violations of the rule, as required by the CARES Act. Further, the proposed	Comments are requested on: • the need for investigation of Part 2 programs and holders of Part 2 records and a related safe harbor for law enforcement due to proposed changes in enforcement of Part 2 requirements;

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		regulations specify that the HIPAA Enforcement Rule applies to violations of Part 2 in the same manner as they apply to covered entities and business associates for violations of HIPAA. Additional language is proposed to be added to create a safe harbor against civil or criminal liability for persons acting on behalf of investigative agencies when, in the course of investigating or prosecuting a Part 2 program or other person holding Part 2 records (or their employees or agents), they may unknowingly receive Part 2 records without first obtaining the requisite court order. This safe harbor would be limited to only instances where records are obtained for the purposes of investigating a program or person holding the record, not a patient. Investigative agencies are required to follow Part 2 requirements for obtaining, using, and disclosing Part 2 records as part of an investigation or prosecution; such requirements include seeking a court order, filing protective orders, maintaining security for records, and ensuring that records obtained in program investigations are not used in legal actions against patients who are the subjects of the records. The limitation on liability would be available for uses or disclosures inconsistent with Part 2 when the person acted with reasonable diligence to determine in advance whether Part 2 applied to the records or program. "Reasonable diligence" (as proposed) requires acting within a reasonable period of time, but no more than 60 days prior to, the request for records or placement of an undercover agent or informant. "Reasonable diligence" also includes taking the following actions to determine whether a health care practice or provider (where it is reasonable to believe that the practice or provider provides SUD diagnostic, treatment, or referral for treatment services) provides such services by: (1) checking a prescription drug monitoring program in the state where the provider is located, if available and accessible to	• the impact of the proposed safe harbor on patient privacy and access to SUD treatment; • situations for which a safe harbor should be considered for SUD providers that unknowingly hold Part 2 records and unknowingly disclose them in violation of Part 2; and • the likely benefits and costs of the proposed changes to the enforcement regime under Part 2.

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		the agency under state law; or (2) checking the website or physical location of the provider.	
§ 2.4	Complaints of violations (proposed heading).	**The proposed changes would revise processes for reporting complaints to more closely align with HIPAA.** The existing § 2.4 requires that reports of Part 2 violations be directed to the U.S. Attorney for the judicial district in which the violation occurs, and reports of any violation by an opioid treatment program may be directed to the U.S. Attorney and also to SAMHSA. This language is proposed to be replaced with three paragraphs that align with Privacy Rule provisions concerning the reporting of complaints to a Part 2 program or the Secretary. However, the proposed rule notes that SAMHSA continues to regulate OTPs and may receive reports of alleged violations by OTPs of federal opioid treatment standards, including privacy and confidentiality requirements. Specifically, proposed § 2.4(a) requires a Part 2 program to have a process to receive complaints concerning the program's compliance with the Part 2 regulations. This is consistent with the administrative requirements in 45 CFR 164.530(d), Standard: Complaints to the covered entity. Proposed § 2.4(b) prohibits a Part 2 program from intimidating, threatening, coercing, discriminating against, or taking other retaliatory action against any patient for the exercise of any right established, or for participation in any process provided for, in Part 2, including the filing of a complaint. This aligns with the Privacy Rule provision at 45 CFR 164.530(g), Standard: Refraining from intimidating or retaliatory acts. Proposed § 2.4(c) prohibits a Part 2 program from requiring patients to waive their right to file a complaint as a condition of the provision	Comments are requested on the proposed changes to the mechanism for reporting violations of Part 2, including any concerns about potential unintended negative consequences on programs or patients of aligning § 2.4 with the cited provisions of the Privacy Rule.

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		of treatment, payment, enrollment, or eligibility for any program subject to Part 2. This is consistent with the Privacy Rule provision at 45 CFR 164.530(h), Standard: Waiver of rights. **Part 2 programs that are also covered entities will already have these requirements in place, but programs that are not covered entities would need to adopt new policies and procedures.**	
§ 2.11	Definitions.	The Department proposes to add thirteen defined regulatory terms and modify the definitions of ten existing terms. **Most of the proposed terms and definitions would be added or modified by referencing existing HIPAA regulatory terms** in 45 CFR parts 160 and 164, either as required by the CARES Act or as a logical outgrowth of CARES Act amendments. **The proposals seek to make clear the specific components of the relevant HIPAA statutory and regulatory provisions that would be incorporated into the rule**. The proposed rule adds new terms and definitions to align with the following statutory and regulatory HIPAA terms: Breach, Business associate, Covered entity, Health care operations, HIPAA, HIPAA regulations, Payment, Person, Public health authority, Treatment, Unsecured protected health information, and Use. The proposed rule creates new defined terms for: Intermediary, Investigative agency, and Unsecured record. The proposed rule modifies the existing definitions of the following terms: Informant, Part 2 program director, Patient, Program, Qualified service organization, Records, Third-party payer, and Treating provider relationship. **The Department proposes to modify the definition of Qualified service organization (QSO) by adding HIPAA business associates to the regulatory text to clarify that they are QSOs in**	Comments are requested on all proposals to add new or modify existing definitions to this part. Specific comments are requested on: • the benefits and burdens of creating additional privacy protection for SUD counseling notes that are maintained primarily for use by the originator of the notes, similar to psychotherapy notes as defined in the Privacy Rule (i.e., such notes would be Part 2 records, but could not be disclosed based on a general consent for TPO; they could only be disclosed with a separate written consent that is not combined with a consent to disclose any other type of health information); • whether the modifications to the use of the terms "person" and "individual" provide clarity and promote understanding of when the terms are being used to refer to someone who is the subject of the records at issue under Part 2 and the HIPAA Rules; • the number and type of third-party payers that would not be considered health plans (and therefore would be subject to

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		circumstances when Part 2 records also meet the definition of PHI (i.e., when a Part 2 program is also a covered entity). The HIPAA Rules generally permit disclosures from a covered entity to a person who meets the definition of a business associate (i.e., a person who works on behalf of or provides services to the covered entity) without individual authorization, when based on a business associate agreement that incorporates certain protections. Similarly, the use and disclosure restrictions of this part do not apply to the communications between a Part 2 program and QSO when the information is needed by the QSO to provide services to, or work "on behalf of", the Part 2 program.	limitations on redisclosures of Part 2 records); • the alignment of the definition of "unsecured record" with "unsecured protected health information" in order to implement the newly required breach notification standards for Part 2 records; • the proposed definition of "intermediary" and whether, in light of the new permission to disclose records for TPO based on a single prior consent, the requirements for an intermediary should be retained or removed **We recommend providing comments to encourage the Department to create a regulatory definition of "lawful holder," and to use that mechanism to further expand exceptions for the re-disclosure of Part 2 records.** **We recommend providing comments on the proposal to continue to require intermediaries to be named whenever they are used to exchange Part 2 records.** Under this proposal, an intermediary would be a person who has received records, under a general designation in a written patient consent, for the purpose of disclosing the records to one or more of its member participants who has a treating provider relationship with the patient. We recommend commenting on whether removing the specific

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			intermediary requirements would significantly diminish the regulatory burden of compliance for intermediary entities and eliminate inconsistencies in the requirements for intermediary and non-intermediary entities that serve TPO functions. **We recommend commenting on whether the definition of "treatment", as revised, including as used in section 2.12(a)(1)(ii), would still apply Part 2 protections to a condition which is identified as having been caused by an SUD.** **We recommend commenting on the proposed revisions to the QSO definition that would add HIPAA business associates to the regulatory text to clarify that they are QSOs in circumstances when Part 2 records also meet the definition of PHI (i.e., when a Part 2 program is also a covered entity).**
§ 2.12	Applicability.	The existing § 2.12 outlines the scope of the rule's requirements as follows: • paragraph (a) of § 2.12 describes which records are protected and describes the restrictions on use and disclosure of Part 2 records; • paragraph (b) outlines what constitutes federal assistance for purposes of the regulation's applicability; • paragraph (c) specifies exceptions for certain disclosures;	Specific comments are requested on: • whether the modification to the "Armed Forces" language will change how SUD treatment records are treated for USPHS and NOAA Commissioned Corps personnel; • the Department's approach to adopt the "use and disclosure" terminology, to make clear that a Part 2 record could be both used and disclosed for purposes related to

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		• paragraph (d) provides restrictions that apply to: (1) any recipient of Part 2 records, and (2) third-party payers and administrators; and • paragraph (e) details the types of records and diagnoses to which the restrictions apply. Proposed amendments add the terms "use" and "disclosure" to make clear that these provisions include both uses and disclosures that are restricted by Part 2. Proposed amendments replace the use of the phrase "Armed Forces" with "Uniformed Services" to align the regulatory text with the statutory language at 42 U.S.C. 290dd– 2(e). The proposed change would create consistency with the Department's proposal to expand the Privacy Rule permission for covered entities, at 45 CFR 164.512(k), to use or disclose the PHI of Armed Services personnel when deemed necessary by certain military command authorities to all Uniformed Services, which would then include the U.S. Public Health Service (USPHS) and the National Oceanic and Atmospheric Administration (NOAA) Commissioned Corps. Proposed amendments to paragraph (d)(1) would expand the restrictions on the use of records as evidence in criminal proceedings against the patient by incorporating the four prohibited actions specified in 42 U.S.C. 290dd–2(c), as amended by the CARES Act, and expanding the regulatory prohibition to cover civil, administrative, or legislative proceedings in addition to criminal proceedings. Absent patient consent or a court order, the proposed prohibitions are: (1) the introduction into evidence of a record or testimony in any criminal prosecution or civil action before a Federal or State court, (2) reliance on the record or testimony to form part of the record for decision or otherwise be taken into account in any proceeding before a Federal, State, or local agency, (3) the use of such record or testimony by any Federal, State, or local agency for a law enforcement purpose or to conduct any law enforcement	the provision of health care, but also for the purpose of initiating legal proceedings; • data on the number and types of third-party payers to which the redisclosure limitations would continue to apply, and in particular how this provision would apply to grant-funded programs; and • whether the proposed clarification that excludes from Part 2 those diagnoses of SUD that are created solely to be used as evidence in a legal proceeding would tighten the nexus between a law enforcement or judicial request for the diagnosis and the use or disclosure of the SUD diagnosis based on that request.

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		investigation, and (4) the use of such record or testimony in any application for a warrant. Proposed amendments to paragraph (e)(3) would expand the restrictions on the use of Part 2 records in criminal proceedings against the patient to expressly include disclosures of Part 2 records and to add civil and administrative proceedings as additional types of forums where use and disclosure of Part 2 records is prohibited, absent written patient consent or a court order. Proposed amendments to subparagraph (e)(4)(i) would exclude from Part 2 those diagnoses of SUD that are created solely to be used as evidence in a legal proceeding.	
§ 2.13	Confidentiality restrictions and safeguards.	The existing § 2.13 applies confidentiality restrictions and safeguards to how Part 2 records may be "disclosed and used", and specifically provides that Part 2 records may not be disclosed or used in any civil, criminal, administrative, or legislative proceedings. The existing § 2.13 also provides that unconditional compliance is required by programs and lawful holders and restricts the ability of programs to acknowledge the presence of patients at certain facilities. Clarifying amendments are proposed to be made to the regulatory language to make it clear that confidentiality restrictions and safeguards apply to both uses and disclosures of Part 2 records. Existing paragraph (d) of § 2.13 includes a requirement for intermediaries to provide patients with a list of entities to which an intermediary, such as a health information exchange (HIE), has disclosed the patient's identifying information pursuant to a general designation. As proposed, § 2.13(d) would be removed and the contents redesignated as § 2.24. This change is intended to distinguish the right to a list of disclosures made by intermediaries	Comments are requested on the extent to which Part 2 programs look to the HIPAA Security Rule as a guide for safeguarding Part 2 electronic records and whether the same, similar, or other safeguard requirements should apply to electronic Part 2 records as the HIPAA Security Rule applies to ePHI. In response to the Department's request for comments (see section 2.24 below), **we recommend providing comments on the extent to which providing patients with a list of disclosures will be problematic for intermediaries, and whether there are concerns with applying the HIPAA Security Rule's safeguard requirements to electronic Part 2 records.**

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		from the proposed new right to an accounting of disclosures made by a part 2 program.	
§ 2.14	Minor patients.	Modifies the existing regulation to clarify that, where the patient is a minor and lives in a state that does not require parental consent for treatment, only the patient may provide written consent for disclosure *or use* of information including patient identifying information. For states that require parental consent for treatment, a minor's application may be communicated to the minor's parent or guardian only if the minor has given consent or been determined to lack capacity. The NPRM rewords determinations of the program director finding that a minor lacks capacity, deleting all instances of "judged" to lack capacity and replacing with "determined" to lack capacity.	None
§ 2.15	Patients who lack capacity and deceased patients (proposed heading).	The NPRM replaces outdated language regarding capacity. For patients who have been judicially determined to lack capacity, the NPRM changes the phrasing from "lacking the capacity to manage their own affairs" to "lacking capacity to make their own health care decisions." For patients who have not been judicially determined to lack capacity, the NPRM changes the phrasing from "a patient, other than one who has been adjudicated incompetent" to "other than one who has been adjudicated as lacking the capacity to make health care decisions." The proposed amendment also adds health plans to the list of entities to which a program may disclose records without consent where the patient lacks capacity. (Existing language already provided this clarity for "third-party payors"; proposed language adds "and health plans.")	None

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§ 2.16	Security for records and notification of breaches (proposed heading).	The NPRM applies the HITECH Act breach notification provisions that are currently implemented in the Breach Notification Rule to breaches of records by Part 2 programs and retitles the provision to include breach notification to implement CARES Act provisions. It also clarifies that formal policies and procedures designed to reasonably protect against unauthorized uses and disclosures of patient identifying information must address *all* issues regarding paper and electronic records listed in this part. Applies the provisions of 45 CFR part 160 and subpart D of part 164, which require notification in the case of a breach of unsecured protected health information, in the same manner as the provisions apply to covered entities regarding breaches of unsecured protected health information. For both paper and electronic records, the NPRM specifies that de-identified patient identifying information must be rendered in accordance with the requirements of HIPAA at 45 CFR 164.514(b), "such that there is no reasonable basis to believe that the information can be used to identify a particular patient as having or having had a substance use disorder."	The Department requests comment on several aspects of this section: • Address the Department's assumptions about the application of the Breach Notification Rule to Part 2 records, including the treatment of disclosure or re-disclosure of Part 2 records outside of Part 2 requirements as a breach and the burden of requiring lawful holders to maintain and follow Part 2 breach identification/response policies and procedures as a condition of compliance. • Provide examples of persons who are lawful holders under the existing regulation, such as MCOs, who may not be appropriate to hold liable under the Breach Notification Rules for compliance with the administrative requirements for protecting Part 2 records they have received. • Encourage the Department to create a regulatory definition of "lawful holder" and to use that mechanism to further expand exceptions for the re-disclosure of Part 2 records. In particular, recommend commenting that a definition of "lawful holder" should provide for a safe-harbor from the imposition of civil or criminal monetary penalties under the Breach Notification Rule for the unintentional re-disclosure of Part 2 records by lawful holders that would have otherwise been a compliant disclosure of PHI under HIPAA TPO.

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			• Provide examples of situations in which Part 2 programs or covered entities render Part 2 information not readily identifiable but the information is not de-identified in accordance with the Privacy Rule.
§ 2.17	Undercover agents and informants.	The NPRM further clarifies protections from use in criminal investigations Part 2 records obtained by undercover agents or informants. To fully implement 42 U.S.C. 290dd-2(c)(3), as amended by section 3221(e) of the CARES Act, The Department proposed to add "or disclosed" behind "used" in this section so that the use and disclosure of Part 2 records is prohibited by this section pursuant to the statutory authority.	None
§ 2.19	Disposition of records by discontinued programs.	The NPRM adds an exception to clarify that when a part 2 program discontinues operations or is taken over or acquired by another program, it must remove patient identifying information from its records by either destroying its records or sanitizing them such that patient identifying information is non-retrievable, unless: 1) The patient gives written consent to a transfer of the records, 2) There is a legal requirement that the records be kept for a period specified by law, or 3) *newly proposed*, program is transferred, retroceded, or reassumed pursuant to the Indian Self-Determination and Education Assistance Act (ISDEAA)and its implementing regulations. Updates the language of the regulation to specify that all records in "non-electronic (e.g. paper) form" must be sealed and labeled in envelopes.	None
§ 2.20	Relationship to state laws.	The Department proposes to add the term "use" to § 2.20 to clarify that this section applies to both uses and disclosures under Part 2 and state law.	None

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§ 2.21	Relationship to federal statutes protecting research subjects against compulsory disclosure of their identity.	The Department proposes to reorder "disclosure and use" to read "use and disclosure" to better align the wording of this section with language used in the Privacy Rule.	None
§ 2.22	Notice to patients of federal confidentiality requirements; and 45 CFR 164.520—Notice of privacy practices for protected health Information.	The NPRM significantly changes § 2.22 to require all part 2 programs, at the time of admission, to inform the patient that federal law protects the confidentiality of substance use disorder, and provides a detailed Notice of Privacy Practices of a Part 2 Program that programs are required to provide. Notification requirements now specify interaction between HIPAA NPP and the Part 2 NPP.	The Department requests comment on ways to make the proposed notices more easily understandable, including examples of possible approaches, such as requiring the document to be at a particular reading grade level, maximum number of pages, or other suggestions. The Department specifically requests comment from legal, clinical, privacy, and civil rights experts on this matter. We recommend comment on proposed approach for notification, including implications for network provider agreements.
§ 2.23	Patient access and restrictions on use and disclosure (proposed heading)	The NPRM also adds "disclosure" of information, to the restriction on the use and disclosure of records to initiate or substantiate any criminal charges against a patient.	None
§ 2.24	Requirements for intermediaries (Redesignated and proposed heading).	Moves and redesignates current section § 2.13(d)), and retitles this section as "Requirements for intermediaries" to clarify the responsibilities of recipients of records received under a consent with a general designation, such as health information exchanges, research institutions, accountable care organizations, and care management organizations. Intermediaries, upon request, must provide to patients who have consented to the disclosure of their records a list of persons	The Department solicits comment on the proposed reorganization and clarification of requirements for entities that facilitate health information exchange and whether there is a continued need for these requirements in light of the accounting of disclosures proposed in § 2.25.

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		to which the records have been disclosed. The section also prescribes the form of the patient request and the intermediary's response.	Specifically, the Department solicits comment on how Part 2 programs have been implementing the existing requirements for intermediaries in § 2.13(d) and § 2.31(a)(4)(ii) and examples of how those requirements have affected the ability of Part 2 programs to utilize HIEs. As noted above, consider commenting on the administrative burden and relative value of requirements for providing reports on specific record re-disclosures by intermediaries. An alternative would be to allow for general listing of entity types that receive redisclosures under general broad designations. Another alternative would be to or allowing for a more limited or streamlined accounting of disclosures if the disclosure was made under TPO with consent.
§ 2.25	Accounting of disclosures (proposed heading).	A newly proposed section. A Part 2 program must provide to a patient, upon request, an accounting of all disclosures made with consent under § 2.31 in the six years prior to the date of the request. This section also states that a Part 2 program must provide a patient with an accounting of disclosures of records for treatment, payment, and health care operations only where such disclosures are made through an electronic health record, and that a patient only has a right to receive an accounting of these disclosures during the three years prior to the date on which the accounting is requested. This proposed right to an accounting of disclosures of records mirrors the standard in the Privacy Rule at 45 CFR 164.528.	The Department requests comment on the proposals to add a requirement for an accounting of disclosures for non-TPO disclosures and an accounting of disclosures through an electronic health record for TPO. The Department also welcomes comment on the provider burden and costs to respond to a request for an accounting for both TPO disclosures and non-TPO disclosures.

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			We recommend supporting Department's approach to aligning this requirement with HITECH accounting of disclosure requirements and effective date.
§ 2.26	Right to request privacy protection for records (proposed heading).	**A newly proposed section that incorporates two distinct patient rights into Part 2: 1) a patient right to request restrictions on disclosures of records otherwise permitted for TPO purposes, and 2) a patient right to obtain restrictions on disclosures to health plans for services paid in full by the patient. A Part 2 program must permit a patient to request that the Part 2 program restrict uses or disclosures of records about the patient to carry out treatment, payment, or health care operations.** Once requested, a Part 2 program may not use or disclose the records unless the patient is in need of emergency treatment and the restricted record is needed to provide the treatment. If a record is disclosed to provide emergency care, the program must request that the emergency health care provider not further disclose the information. A requested restriction is not effective to prevent uses or disclosures required by law, such as for payment and other health care operations. A Part 2 program is <u>not</u> generally required to agree to a requested restriction. However, a Part 2 program <u>must</u> agree to restrict the disclosure of a patient record to a health plan if the disclosure is for payment or health care operations and is not required by law, and the record pertains solely to an item or service for which the patient has paid in full. A program may only terminate a restriction under certain listed circumstances.	The Department requests comment and data on the extent to which covered entities and Part 2 programs receive requests from patients to restrict disclosures of patient identifying information for TPO purposes, how entities and programs track such requests, and the procedures and mechanisms used to comply with patient requests to which they have agreed or that they are otherwise required to comply with by law. **We recommend commenting to request a safe harbor for redisclosures under TPO with consent by intermediaries made after request for restriction submitted to Part 2 program**.

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Subpart C	**Uses and disclosures with patient consent (proposed heading).**		
§ 2.31	Consent requirements.	**The required elements of the written authorization forms for Part 2 records have been modified to more closely track the core elements of a written authorization form under HIPAA**, at 45 CFR 164.508(c). Several of the proposed changes to the language do not substantively change the requirements, but merely align the wording of similar requirements under HIPAA (e.g., changes related to identity of the discloser, description of information to be disclosed, the right to revoke consent, and the expiration of consent). For example, the wording is modified to clarify the limits on a patient's ability to "pull back" Part 2 information from a covered entity, business associate, or Part 2 program once it is disclosed, in alignment with the Privacy Rule. Thus, once a Part 2 program discloses a record for TPO purposes to a Part 2 program, covered entity, or business associate with prior written consent, a revocation would only be effective to prevent additional disclosures to those entities. It would not prevent a recipient Part 2 program, covered entity, or business associate from using the previously disclosed record for TPO, or redisclosing the record in the same manner as permitted by the Privacy Rule. More substantive updates, which align with updates proposed elsewhere in the Part 2 rules, include that the written authorization contain the following: • Where applicable, language indicating a single patient consent is meant to apply for all future uses and disclosures for TPO; • Where the disclosure is for TPO – a statement that the patient's record may be redisclosed in accordance with HIPAA, except for uses and disclosure for civil, criminal, administrative, and legislative proceedings against the patient; • A description of purpose statements sufficient for relaying (i) when a patient initiates the consent and elects not to provide a statement of purpose, (ii) when a patient provides consent once for all TPO	The Department requests comment on whether there are other changes that should be made to further align § 2.31 with the Privacy Rule using its general regulatory authority in § 3221(i)(1) of the CARES Act to "make such revisions to regulations as may be necessary for implementing and enforcing the amendments." For example, • the extent to which Part 2 programs segment out SUD treatment records considered SUD counseling notes. • whether to propose special protection for SUD counseling notes to add a layer of regulatory protection that equates to the protection granted to psychotherapy notes in the Privacy Rule by requiring a separate written consent for their disclosure. The Department requests comment on whether and to what extent the Department should require Part 2 programs to inform requestors when a preexisting consent exists for disclosure and the scope of such consent for disclosure. This input would be helpful as the Department considers how to facilitate covered entities' abilities to use the new permissions for TPO disclosures and related redisclosures under the Privacy Rule and Part 2. The Department requests comment on the extent to which Part 2 programs accept or

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		uses and disclosures; and (iii) when the patient consents to uses or disclosures for fundraising. • Statements around (i) the potential for the records to be redisclosed and no longer protected by Part 2, and (ii) the consequences of refusal to sign the consent. Where "disclosure" is referenced, the language is updated to refer to "use and disclosure" to align with HIPAA and clarify that disclosures *and uses* are subject to the rules. The proposed rule also includes wording changes for defined terms and phrases of art, which were updated for alignment with HIPAA. The proposed rule: • replaces the term "individuals" with the term "persons"; • replaces the phrase "individual or entity" with the term "person" (which by definition would include both individuals and entities); • where disclosure is referenced, also refers to "uses" to clarify that disclosures *and uses* are subject to the rules.	rely on oral revocations of consent, and if so, whether and how this is documented or tracked.
§ 2.32	Notice to accompany disclosure (proposed heading).	The required contents for the notice to be attached to Part 2 record disclosures are updated to align with updates proposed elsewhere in Part 2. Specifically, the written statement is updated to reflect the expanded prohibition on use and disclosure of Part 2 records in certain proceedings against the patient, which includes testimony that relays information in a Part 2 record and the use or disclosure of such records or testimony in civil, criminal, administrative, and legislative proceedings, absent consent or a court order. The written statement is also updated to include the boarded exceptions to the general rule prohibiting further use or disclosure of Part 2 records:	The Department requests comment on whether the alternative simplified notice in paragraph (a)(2) is sufficient to inform recipients of Part 2 records and whether the revised notice in paragraph (a)(1) should include different elements. The Department requests comment on whether and how the proposed changes to the redisclosure permissions in § 2.32 are likely to reduce data segregation and positively affect the ability to provide treatment to patients with SUD and perform other beneficial activities. Specifically, **the Department requests comment on whether different or**

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		• The recipient is a covered entity or business associate that received the record for TPO and may now redisclose the records as permitted by HIPAA (under the proposed rules) • The recipient received the records from a covered entity or business associate as provided for above. Where "disclosure" is referenced, the language is often updated to refer to "use and disclosure" to align with HIPAA and clarify that disclosures *and uses* are subject to the rules.	**additional modifications to Part 2 would be more effective to promote integration of Part 2 records with PHI, reduce stigma for patients with SUD, and improve access to SUD treatment while maintaining the confidentiality of Part 2 records**.
§ 2.33	Uses and disclosures permitted with written consent (proposed	Currently Section 2.33 allows disclosure with the written consent of the patient, and if the patient consents to disclosure of their records for payment or health care operations, allows a lawful holder to further disclose those records as necessary for its contractors, subcontractors, or legal representatives to carry out the payment or operations specified in the consent, on behalf of the lawful holders. It includes a list of examples of permissible payment or operations activities. All such redisclosures must be pursuant to a written contract binding the contractor, subcontractor, or representative to Part 2. **The proposed rule identifies how a recipient may further disclose records related to treatment, payment, and health care operations (TPO).** Specifically, the Department proposes to create two categories of redisclosure permissions. The first category would apply to Part 2 programs, covered entities, and business associates that have received a Part 2 record with consent for TPO. These entities would be permitted to redisclose the records for uses and disclosures as permitted by the Privacy Rule (subject to the limitations of proposed subpart E of Part 2 pertaining to legal proceedings). Thus:	The Department requests comment on whether it would be helpful to define the terms "contractors, subcontractors, and legal representatives" and, if so, what definitions would appropriately retain the existing accepted understanding of the business relationships. The extent to which the proposed changes to § 2.33 would result in reduction of patient trust that their Part 2 records will be kept confidential and thus affect the ability to provide treatment to patients with SUD. How Part 2 programs and recipients of Part 2 records would identify records for which a patient has given consent for TPO uses and disclosures generally as compared to consent for one purpose or a consent limited to certain segments of Part 2 information. The ways to increase coordination amongst not only Part 2 programs or recipients of Part 2 records and providers of other

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		• 1 - **Where disclosed for TPO activities to a program, covered entity, or business associate, the recipient may further use or disclose of the records *as permitted under HIPAA*.** The second category of redisclosure permissions would apply to lawful holders that are NOT business associates, covered entities, or Part 2 programs and have received Part 2 records with written consent. For payment and health care operations purposes, this category would permit the recipient to redisclose the records for uses and disclosures to its contractors, subcontractors, and legal representatives to carry out the intended purpose, also subject to the limitations of proposed subpart E of part 2 pertaining to legal proceedings. However, for treatment purposes, a lawful holder under this provision would not be permitted to redisclose Part 2 records it receives before obtaining an additional written consent from the patient. Thus: • 2 - Where disclosed with a consent given once for all future TPO to a Part 2 program that is NOT a covered entity or business associate, the recipient may further disclose only *as consistent with the consent*. • 3 - Where disclosed for payment or operations activities to a lawful holder that is NOT a covered entity, business associate, or Part 2 program, the recipient may further use or disclose those records *as necessary for its contractors, subcontractors, or legal representatives to carry out the payment or health care operations specified in the consent*, on behalf of the lawful holders. Thus the proposed rule would prohibit redisclosure for the purposes of treatment by a provider that is not a Part 2 program, covered entity, or business associate (under 2.33(b)(3)), while allowing redisclosure for the purposes of treatment by a provider that is a Part 2 program, covered entity, or business associate (under 2.33(b)(1)).	healthcare services but also with the health IT developer and HIE communities to protect privacy for Part 2 records within EHRs. How the proposed revisions to § 2.33 might affect the future data segregation practices of Part 2 programs and recipients of Part 2 records. Whether or how recipients of Part 2 records are informed that the records have been disclosed based on patient consent and the scope of the consent that is provided. Specifically, how Part 2 programs and recipients of Part 2 records communicate information about the purpose of a disclosure or set of disclosures and the extent of the information communicated about the purpose or the scope of the disclosure permission, authorization, or mandate. Should the Department consider requiring Part 2 programs to provide a copy of the written patient consent when disclosing records? Should the Department consider requiring Part 2 programs, covered entities, and business associates to retain a copy of the written patient consent for a minimum period of time so that they can provide documentation of the consent to future

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		The proposed rule would also exclude covered entities and business associates from the requirements for a written agreement between a lawful holder and redisclosure recipient, because these entities are already subject to the HIPAA requirements for business associate agreements. The proposed update removes the current list of permitted "payment or health care operations activities" for which a disclosure must be limited. These examples of "payment or health care operations" are likely eliminated to better align with the interpretation of "TPO" under HIPAA. Where "disclosure" is referenced, the language is often updated to refer to "use and disclosure" to align with HIPAA and clarify that disclosures *and uses* are subject to the rules.	recipients, or to the Secretary for purposes of investigating compliance with Part 2? Are programs already doing this? To what extent would such requirements be useful to recipients of Part 2 records or impose a burden on programs? Additionally, should the Department require programs to inform an HIE when a patient revokes consent for TPO so that additional uses and disclosures by the HIE would not be imputed to the programs that have disclosed Part 2 records to the HIE? The Department also welcomes comments on the potential unintended negative effects on confidentiality and privacy from the combined application of the proposed disclosure permissions for TPO with consent under § 2.33, and the removal of § 2.53 protections for audit and evaluation activities that fall within the definition of health care operations, and suggested regulatory approaches.
§ 2.34	Uses and disclosures to prevent multiple enrollments (proposed	The proposed rule includes minor wording changes (four words): • Replaces the phrase "re-disclosure or use" with "use or redisclosure"- this more closely tracks the language used in HIPAA; and • Includes a minor wording change to refer to "use of information *in records*" instead of just "use of information" to make clear that this provision relates to Part 2 records.	None.
§ 2.35	Disclosures to elements of the	Revisions to this section are minor, and the regulatory summary adequately summarizes the updates. The proposed rule:	None.

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	criminal justice system which have referred patients.	• replaces the phrase "individuals" with the term "persons" to align with HIPAA terminology; and • includes a minor wording change to refer to "use of information *in records*" instead of just "use of information" to make clear that this provision relates to Part 2 records. These slight wording changes have been applied throughout the proposed updates to Part 2.	
Subpart D	**Uses and Disclosures Without Patient Consent (proposed heading).**		
§ 2.51	Medical emergencies.	Revisions to this section are minor. The proposed rule replaces the phrase "individual or entity" with the term "person" to align with the HIPAA terminology (note - the defined term "person" encompasses individuals and entities).	None.
§ 2.52	Scientific research (proposed heading).	Section 2.52 permits Part 2 programs to disclose patient identifying information for research, without patient consent, under limited circumstances. The proposed rule changes the standard required for including Part 2 de-identified aggregate data in research reports, to more closely mirror the HIPAA de-identification standard. Instead of requiring that the information be "rendered non-identifiable such that the information cannot be re-identified and serve as an unauthorized means to identify a patient, directly or indirectly, as having or having had a substance use disorder", the proposed rule requires that ". . . patient identifying information has been de-identified in accordance with the requirements of the Privacy Rule at 45 CFR 164.514(b) such that there is no *reasonable* basis to believe that the information can be used to identify a patient as having or having had a substance use disorder."	The Department requests public comment on whether any Part 2 programs conduct research using their own Part 2 records. The Department also requests public comment regarding the application of the HIPAA de-identification standard to Part 2 records disclosed for research, as provided in the proposed modifications to § 2.52(a)(3), including any unintended adverse consequences that may result from this proposed change.

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		The proposed rule also includes wording changes for defined terms and phrases of art, which were updated for alignment with HIPAA. The proposed rule: • replaces the term "individuals" with the term "persons"; • replaces the phrase "individual or entity" with the term "person" (which by definition would include both individuals and entities); • where disclosure is referenced, also refers to "uses" to clarify that disclosures *and uses* are subject to the rules.	
§ 2.53	Management audits, financial audits, and program evaluation (proposed heading).	**The proposed rule adds a new paragraph (h), allowing disclosure for health care operations, consistent with the proposed new TPO permission that includes the ability of entities to use or disclose Part 2 records for health care operations with a general consent.** Per the proposed new provision, Part 2 programs, covered entities, and business associates are permitted to disclose Part 2 records pursuant to a consent for all future TPO uses and disclosures when a requesting entity is seeking records for activities described in paragraphs (c) or (d) of § 2.53. The proposed rule also includes wording changes for defined terms and phrases or art, which were updated for alignment with HIPAA. The proposed rule: • replaces the term "individuals" with the term "persons"; • replaces the phrase "individual or entity" with the term "person" (which by definition would include both individuals and entities); • where disclosure is referenced, also refers to "uses" to clarify that disclosures *and uses* are subject to the rules.	**The Department requests comment on its proposal to acknowledge within this section the applicable permission for use and disclosure of records for health care operations purposes based on written consent of the patient for all future uses and disclosures for TPO and the permission for the third party conducting such audit or evaluation activities to redisclose the records as permitted by the HIPAA Privacy Rule if the third-party recipient is a Part 2 program, covered entity, or business associate that is not acting as a health oversight agency**. Whether the new redisclosure permission for Part 2 programs, covered entities, and business associates may create incentives for such recipients to rely on patient consent more frequently when performing audit and evaluation of records made available by Part 2 programs.
§ 2.54	Disclosures for public health	The current Part 2 regulations do not permit the disclosure of Part 2 records for public health purposes.	The Department requests comment on its proposal to permit disclosures only of de-

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	(proposed heading).	The proposed rule adds permissible disclosure for public health purposes without patient consent, provided that the information is de-identified in accordance with the HIPAA standard for de-identification. Once the de-identified information is disclosed to the public health authority, Part 2 no longer applies to those de-identified records.	identified records for public health purposes without patient consent.
Subpart E	**Court Orders Authorizing Use and Disclosure (proposed heading).**		
§ 2.61	Legal effect of order.	This addition would clarify that the legal effect of a court order with respect to Part 2 records would include authorizing the use of Part 2 records, in addition to the disclosure of Part 2 records. It is an effort to have the language be consistent with the CARES Act amendments to 42 U.S.C. 290dd-2.	
§ 2.62	Order not applicable to records disclosed without consent to	As it currently stands, this section provides that a court order may not authorize "qualified personnel" who have received patient identifying information without consent for research, audit, or evaluation, to disclose the information or use it to conduct a criminal investigation of the patient. The proposed changes would replace the term "qualified personnel" with a definition of who falls within the term.	
§ 2.63	Confidential communications	Currently, section 2.63(a) of 42 CFR part 2 provides that a court order may authorize disclosure of confidential communications made by a patient to a Part 2 program during diagnosis, treatment, or referral only if necessary: (1) to protect against a threat of serious bodily injury; (2) to prosecute the patient for a serious crime; or (3) in connection with litigation or an administrative proceeding in which the patient introduces their own Part 2 records. 42 U.S.C. 290dd-2(c) as amended by the CARES Act, provides that Part 2 records may be disclosed in noncriminal legal proceedings only with patient consent or a court order, and added civil litigation and administrative proceedings to the list of proceedings for which	

Section	Title/content	Summary	Key issues for comment
		Part 2 records cannot be used or disclosed by a government authority against a patient, absent a court order. To implement the changes to 42 U.S.C. 290dd-2, the proposal specifies that civil, as well as criminal, administrative, and legislative proceedings are circumstances under which a court may authorize disclosures of confidential communications made by a patient to a Part 2 program in part 2 records when the patient opens the door by introducing their records or testimony that relays information in their records as evidence.	
§ 2.64	Procedures and criteria for orders authorizing uses and disclosures for noncriminal purposes (proposed heading).	The proposal is to modify the heading, paragraph (a), and paragraph (e) to include use, not only disclosure, of Part 2 records, and the use or disclosure of testimony relaying the information in such records. The proposal further modifies 2.64(a) by adding administrative, or legislative proceedings to the types of noncriminal proceedings for which a use or disclosure of Part 2 records must be authorized by a court order, absent patient consent or the application of 2.53(e). 2.64(e) sets forth limitations for court orders authorizing the disclosure of patient records in noncriminal proceedings, limiting such disclosures to the portions of the patient's record that are essential to fulfill the purpose of the order. The proposed changes would add the word "only" to clarify the extent of the limitation. The disclosure must also be limited to people whose need for the information is the basis for the order and must include necessary measures to limit the use or disclosure. The proposal would also modify (e)(1)-(3) to include the use of patient records and the use or disclosure of testimony relaying the information in patient records to align with 42 U.S.C. 290dd-2(c)(1)-(3) as amended by the CARES Act.	

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§ 2.65	Procedures and criteria for orders authorizing use and disclosure of records to criminally investigate or prosecute patients (proposed heading).	Under 265(a), the custodian of the patient's records, or a law enforcement or prosecutorial official responsible for conducting investigative or prosecutorial activities with respect to the enforcement of criminal laws, may apply for a court order authorizing the disclosure of Part 2 records to criminally investigate or prosecute a patient of a Part 2 program. The proposed change would refer to "use and disclosure" throughout the section instead of "disclosure and use." The proposed changes would modify 2.65(a) to include the use and disclosure of testimony relaying the information in patient records because the current provision is limited to disclosure of records and does not address the CARES Act expanded privacy protection which also prohibits the use or disclosure of testimony relaying the contents of a patient's records. The proposal would further modify 2.65(a) to add administrative, and legislative criminal proceedings to the criminal proceedings for which the use or disclosure of Part 2 patient records may be authorized by a court order, consistent with the CARES Act. The proposal would modify 2.65(d) and (d)(2) to include the use or disclosure of testimony relaying the information in Part 2 records. Under the proposed modification, the criteria in 2.65(d) would apply to court orders authorizing not only the use and disclosure of Part 2 records, but also the use and disclosure of testimony relaying the information in those records which would be consistent with the CARES Act. The proposal would modify 2.65(e) in a manner similar to 2.65(a) and 2.65(d) above.	
§ 2.66	Procedures and criteria for orders	The proposal would add a new paragraph (a)(3) that details procedures for investigative agencies to follow in the event they	The Department seeks comment on creating a limitation on civil and criminal

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	authorizing use and disclosure of records to investigate or prosecute a part 2 program or person holding the records (proposed heading).	unknowingly obtain Part 2 records during an investigation or prosecution of a Part 2 program or person holding Part 2 records. Specifically, the Department would require an investigative agency that discovers in good faith that it has obtained Part 2 records to secure the records according to 2.16 and cease using or disclosing them until it obtains a court order authorizing the use and disclosure of the records and any records later obtained, within a reasonable period of time, but not more than 120 days after discovering it received the records. If the agency does not seek a court order, it must return the records to the Part 2 program or person holding the records if it is legally permissible to do so, within a reasonable period of time, but not more than 120 days from discovery; or, if the agency does not seek a court order or return the records, it must destroy the records in a manner that renders the patient identifying information non-retrievable, within a reasonable period of time, but not more than 120 days from discovery. Finally, if the agency's application for a court order is rejected by the court and no longer subject to appeal, the agency must return the records to the Part 2 program or person holding the records, if it is legally permissible to do so, or destroy the records immediately after notice of rejection from the court.	liability for investigative agencies that in good faith discover they have received Part 2 records before obtaining the required court order in the course of investigating or prosecuting a program, and the related requirement for agencies that make use of these provisions to submit a report to the Secretary.
§ 2.67	Orders authorizing the use of undercover agents and informants to investigate employees or agents of a part 2 program in connection with a criminal matter.	The proposed changes would clarify that the good cause criteria for a court order in paragraph (c)(2) includes circumstances when obtaining the evidence another way would "yield complete evidence." The proposal would also create a new paragraph (c)(4) addressing investigative agencies' belated applications for a court order authorizing placement of an undercover informant or agent to investigate a Part 2 program or its employees. The provision would require the investigative agency to satisfy the conditions proposed in 2.3(b) before applying for a court order for Part 2 records after discovering that it unknowingly had received such records. The proposal would also replace the phrase "law enforcement or prosecutorial" with "investigative" in paragraph (a) and add the	The Department seeks comment on creating a limitation on civil and criminal liability for investigative agencies that in good faith discover they have received Part 2 records before obtaining the required court order in the course of investigating or prosecuting a program, and the related requirement for agencies that make use of these provisions to submit a report to the Secretary.

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		words "using or" in front of "disclosing" in paragraph (d)(3) and add "and disclosure" after the term "use" in paragraph (e) to be consistent with the CARES Act.	
§ 2.68	Report to the Secretary (proposed heading).	The proposal would create this section to require investigative agencies to file an annual report with the Secretary of the applications filed for court orders after use or disclosure of records in an investigation or prosecution of a program or holder of records under 2.66(a)(3)(ii) and after placement of an undercover agent or informant under 2.67(c)(4). The report would also include the number of instances in which such applications were denied due to findings by the court of violations of this part during the calendar year, and the number of instances in which the investigative agency returned or destroyed Part 2 records following unknowing receipt without a court order, in compliance with 2.66(a)(3)(iii), (iv), or (v), respectively during the calendar year. The proposal would have these reports due within 60 days following the end of the calendar year.	The Department seeks comment on creating a limitation on civil and criminal liability for investigative agencies that in good faith discover they have received Part 2 records before obtaining the required court order in the course of investigating or prosecuting a program, and the related requirement for agencies that make use of these provisions to submit a report to the Secretary.