Confidentiality of Substance Use Disorder Records (Part 2) Notice of Proposed Rule Making

K&L GATES

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2.1 Statutory Authority for Confidentiality of Substance Use Disorder Patient Records	Revises § 2.1 to more closely reflect the authority granted in 42 U.S.C. § 290dd-2(g). Adds a reference to § 290dd-2(b)(2)(C) related to the issuance of court orders authorizing disclosures of Part 2 records.[1]		
2.2 Purpose and Effect	Amends paragraph (b) of § 2.2 to reflect that § 2.3(b) compels disclosures to the secretary that are necessary for enforcement of this rule, using language adapted at 45 C.F.R. § 164.502(a)(2)(ii) (Privacy Rule). Adds a new paragraph (b)(3) to prohibit any limits on a patient's right to request restrictions on use of records for treatment, payment, or health care operations (TPO) or a covered entity's choice to obtain consent to use or disclose records for TPO purposes, as provided in the Privacy Rule.[2]	The proposed paragraphs would provide that nothing in this part 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.[3]	HHS requests comments on all proposed changes to this section.[4]
2.3 **Current:** Criminal Penalty for Violation **Proposed New Title:**	Amends the heading and replaces Title 18 U.S.C. enforcement with references to the HIPAA enforcement authorities in the Social Security Act at sections 1176 (civil enforcement, including the CMP tiers established by the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009) and 1177	Section 2.3 of 42 C.F.R. part 2 currently requires that any person who violates any provision of the Part 2 regulations be criminally fined in accordance with the Title 18 U.S.C. As amended by the CARES Act, 42 U.S.C. § 290dd-2(f) applies the provisions of §§ 1176 and 1177 of the Social Security Act to a Part 2 program for a violation of 42 C.F.R. part 2 in the same	HHS acknowledges that proposed § 2.3(b) may be viewed as a reduction in privacy protection, but it believes that the exclusive application to investigations and prosecution of programs and holders of records affords an overall benefit without harming patient confidentiality when the proposed additional protections in §§ 2.66 and 2.67 are applied. HHS has limited the proposed safe harbor to investigative agencies that unknowingly obtain Part 2

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Civil and criminal penalties for violations.	(criminal penalties), as implemented in the Enforcement Rule; HHS would have civil enforcement authority. Creates a limitation on civil or criminal liability under Part 2 for investigative agencies that act with reasonable diligence before making a demand for records in the course of an investigation or prosecution of a Part 2 program or person holding the record, provided that certain conditions are met.[5]	manner as they apply to a covered entity for a violation of part C of Title XI of the Social Security Act. Therefore, HHS proposes to replace Title 18 criminal enforcement with civil and criminal penalties under §§ 1176 and 1177 of the Social Security Act (42 U.S.C. §§ 1320d-5, 1320d-6), respectively, as implemented in the Enforcement Rule; HHS would then have civil enforcement authority per the proposed revisions. Specifically, HHS proposes to rename § 2.3 as "Civil and criminal penalties for violations" and reorganize § 2.3 into section paragraphs 2.3(a), (b), and (c). Proposed § 2.3(a) would incorporate the penalty provisions of 42 U.S.C. § 290dd-2(f), which apply the civil and criminal penalties of §§ 1176 and 1177 of the Social Security Act, respectively, to violations of Part 2. Proposed section § 2.3(b) is outlined below. Proposed § 2.3(c) would specify that the Enforcement Rule 118 shall apply to violations of Part 2 in the same manner as they apply to covered entities and business associates for violations of part C of Title XI of the Social Security Act and its implementing regulations with respect to protected health information (PHI). To address concerns about potential liability for Part 2 violations arising from investigators who, in good faith, unknowingly receive Part 2 records, HHS proposes at § 2.3(b) to create a limitation on civil or criminal liability for persons acting on behalf of investigative agencies if	records and relies on the CMP tiers to allow appropriate flexibility when a Part 2 program has unknowingly violated Part 2. However, HHS solicits comments on 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. As mentioned above, HHS also solicits comments on the impact of this proposed safe harbor to patient privacy and access to SUD treatment. Because proposed § 2.3(c) would also specify that the Enforcement Rule118 shall apply to violations of Part 2 in the same manner as they apply to covered entities and business associates for violations of part C of Title XI of the Social Security Act and its implementing regulations with respect to PHI, this proposal could implement the potential application of civil and criminal penalties to violations of this part. HHS requests comment on the likely benefits and costs of these proposed changes.[7]

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		they unknowingly receive Part 2 records without first obtaining the required court order while investigating or prosecuting a Part 2 program or other person holding Part 2 records (or their employees or agents). Such a safe harbor, as proposed, 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. This revision is intended to address the increase in investigative agencies' potential liability for violating Part 2 due to the expanded application of HIPAA/HITECH Act civil and criminal penalties to violations of Part 2, as well as an increase in the need for investigation and prosecution of bad actors in accordance with the intensity and duration of the opioid overdose epidemic.[6]	
2.4 **Current:** Reports of violations **Proposed New Title:** Complaints and violations	Revises § 2.4(a) to require a Part 2 program to have a process to receive complaints concerning the program's compliance with Part 2 regulations. Revises § 2.4(b) to provide that a program may not intimidate, threaten, coerce, discriminate against, or take other retaliatory action against any patient for the exercise of any right established by, or for participation in, any process provided for under Part 2, including the filing of a complaint. Adds § 2.4(c) to prohibit a program from requiring patients to waive their right to file a complaint as a condition	Paragraphs (a) and (b) of this section currently provide that reports of violations of the Part 2 regulations and reports of any violation by an opioid treatment program (OTP) may be directed to a U.S. attorney and to SAMHSA. Section 290dd-2(f), as amended by the CARES Act, grants civil enforcement authority to HHS, which exercises HIPAA enforcement authority. To implement the change from U.S. attorney enforcement, HHS proposes to retitling "Reports of violations" with "Complaints of violations" and replacing provisions about directing reports of Part 2 violations to a U.S. attorney's office and to SAMHSA with filing complaints of potential violations with a Part 2 program to HHS. HHS notes that	HHS requests comment about potential unintended negative consequences on programs or patients of these proposed changes.[10]

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	of the provision of treatment, payment, enrollment, or eligibility for any program subject to Part 2.[8]	SAMHSA continues to regulate OTPs and may receive reports of alleged violations by OTPs of federal opioid treatment standards, which include privacy and confidentiality requirements. Changes to § 2.4 would align Part 2 and Privacy Rule provisions concerning complaints as follows: § 2.4(a) aligns with 45 C.F.R. § 164.530(d), Complaints to the covered entity; § 2.4(b) and the Privacy Rule provision at 45 C.F.R. § 164.530(g), Refraining from intimidating or retaliatory acts; and § 2.4(c) and the Privacy Rule provision at 45 C.F.R. § 164.530(h), Waiver of rights. Part 2 programs that are also covered entities already have these administrative requirements in place, but programs that are not covered entities would need to adopt new policies and procedures.[9]	
2.11 Definitions	Adds new terms and definitions, and revises others, to align defined terms with HIPAA regulatory terms at 45 C.F.R. parts 160–164 with those adopted in the CARES Act: Breach, Business associate, Covered entity, Health care operations, HIPAA, HIPAA regulations, Payment, Person, Public health authority, Treatment, Unsecured protected health information, and Use. Creates the following new defined terms: Intermediary, Investigative agency, and Unsecured record.	Most of these terms and definitions would be added or modified by referencing existing HIPAA regulatory terms at 45 C.F.R. parts 160 and 164. Several other definitions would be modified for clarity and consistency, as described below, including the replacement of “individual or entity” with “person” throughout in conformance with the specific definition for “person” as set out in this section. Although HHS requests comment on all proposals to add new or modify existing definitions to this part, comments are solicited with regard to specific concerns or considerations as noted by HHS in its commentary. (Wholly new definitions are referenced and	Although many of the terms and definitions added and modified are already existing regulatory terms, HHS is seeking specific comments for the following terms: Regarding the definition of “person,” to further the alignment of Part 2 and the HIPAA Rules and provide clarity for programs and entities that must comply with both sets of requirements, HHS proposes to replace the Part 2 definition of “person” with the HIPAA definition at 45 C.F.R. § 160.103. As an extension of this clarification, HHS also proposes to replace the term “individual” with “patient” when the regulation refers to someone who is the subject of Part 2 records, to use the term “person” when it refers to someone who is not the subject of the records at issue, and to modify the definition of “patient” in Part 2

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	Modifies the definitions of: Informant, Part 2 program director, Patient, Program, Records, Third-party payer, Treating provider relationship, and Qualified service organization.	summarized below, as are substantially modified definitions for which HHS has expressly solicited comments.) *HIPAA regulations.* The proposed definition is based on the statutory definition added by the CARES Act and has the same meaning as "HIPAA Rules." *Intermediary.* The current rule uses the term intermediary in § 2.13(d)(2) without providing a definition; HHS proposes to establish a definition of intermediary. Examples of an intermediary include, but are not limited to, a health information exchange (HIE), a research institution that is providing treatment, an accountable care organization, or a care management organization. In contrast, a research institution that is not providing treatment or a health app that is providing individual patients with access to their records would not be considered an intermediary. Member participants of an intermediary refers to health care provider practices or health-related organizations, not individual health plan subscribers or workforce members who share access to the same electronic health record (EHR) system. 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 the	to include an "individual" as that term is used in the HIPAA Rules. HHS believes that this combination of modifications would promote the understanding of both Part 2 and the HIPAA Rules and requests comment on whether this or other approaches would provide more clarity. Regarding the definition of "record," HHS is considering whether to create a separate and discreet new definition similar to psychotherapy notes that are specific to the notes of SUD counseling sessions by a Part 2 program professional. Such notes would be Part 2 records, but they 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. HHS solicits comments on the benefits and burdens of creating such 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. Under consideration is a definition such as this: SUD counseling notes means notes recorded (in any medium) by a Part 2 program provider who is a SUD or mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session and that are separated from the rest of the patient's record. SUD counseling notes exclude medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date.

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		intermediary's members (as previously defined) who has a treating provider relationship with the patient. The term intermediary is based on the function of the person—receiving records and disclosing them to other providers as a key element of its role—rather than on a title or category of an organization or business. For example, an EHR vendor that enables entities at two different health systems to share records likely would be an intermediary. That same vendor would not be an intermediary when used by employees in different departments of a hospital to access the same patient's records. Where an intermediary is also a business associate under the HIPAA Rules, it would be subject to the requirements of both an intermediary and a business associate. *Investigative agency.* HHS proposes to create a new definition for "investigative agency" to describe those government agencies with responsibilities for investigating and prosecuting Part 2 programs and persons holding Part 2 records, HHS proposes to define an investigative agency as "A state or federal administrative, regulatory, supervisory, and investigative, law enforcement, or prosecutorial agency having jurisdiction over the activities of a part 2 program or other person holding part 2 records." By creating a definition of investigative agency, HHS intends to establish a limitation on liability for such agencies in certain circumstances when a court order is	Regarding "third-party payer," HHS welcomes comments on the number and type of third-party payers that would not be considered health plans. Regarding "unsecured record," HHS believes this proposal is necessary to implement the newly required breach notification standards for Part 2 records and requests comment on this approach.

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		otherwise required by these regulations (see section 2.3, herein). *Person.* The term "person" is defined in order to conform the use of the references to "person" and "individual." *Qualified service organization.* HHS 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 circumstances when Part 2 records also meet the definition of PHI (to facilitate the implementation of the CARES Act with respect to disclosures to QSOs). 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. This definition is proposed in conjunction with a proposal to modify § 2.12, Applicability, to clarify that QSOs also use Part 2 records received from programs to work "on behalf of" the program. *Records.* The definition of records specifies the scope of information that Part 2 protects. HHS offers clarification here about how the definition of Part 2 records operates in relation to the HIPAA definitions of PHI, designated record set, and psychotherapy notes. These issues are	

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		most pertinent with respect to the right individuals have to access their records under the HIPAA Rules; Part 2 has not contained a parallel patient right of access to records. However, the Privacy Rule right of access requirements specifically excludes psychotherapy notes. If SUD treatment is provided by a mental health professional that is a Part 2 program and a covered entity, and the provider creates notes of counseling sessions that are kept separate from the individual's medical record, those notes would be psychotherapy notes as well as Part 2 records. In this case, the individual would not have a Privacy Rule right of access to those records, but a provider may voluntarily provide access upon request by the individual patient. Additionally, psychotherapy notes created by a Part 2 program that is a covered entity could only be disclosed with a separate written authorization or consent. *Third-party payer.* The term "third-party payer" refers to an entity with a contractual obligation to pay for a patient's Part 2 services and includes some health plans, which by definition are covered entities. The current regulation, at § 2.12, limits disclosures by third-party payers to a shorter list of purposes than the Privacy Rule allows for health plans. HHS proposes to exclude covered entities from the definition of third-party payer to facilitate implementation of 42 U.S.C. § 290dd-	

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		2(b)(1)(B), as amended by the CARES Act, which enacted a permission for certain recipients of Part 2 records to redisclose them according to the HIPAA standards. HHS believes that this change would continue the application of Part 2 restrictions on disclosure in a way that would carry out the intent of the CARES Act and preserve privacy protections that apply to payers that are not covered entities.	
2.13 Confidentiality Restrictions and Safeguards	Removes § 2.13(d), "List of disclosures," and redesignates that content to § 2.24. Proposes wording changes to §§ 2.13 (a)–(c).[11]	HHS's proposal to redesignate § 2.13(d) as § 2.24 would move the section toward the end of Subpart B – General Provisions, to be grouped with the newly proposed §§ 2.25 and 2.26 about patient rights and disclosure.[12] HHS's proposed change to the heading is intended to distinguish the right to a list of disclosures made by intermediaries from the proposed new right to an accounting of disclosures made by a Part 2 program.[13]	HHS solicits comment on the extent to which Part 2 programs look to the HIPAA Security Rule as a guide for safeguarding Part 2 electronic records. HHS also requests comment on whether it should modify Part 2 to apply the same or similar safeguard requirements to electronic Part 2 records as the Security Rule applies to electronic PHI or whether other safeguards should be applied to electronic Part 2 records.[14]
2.14 Minor Patients	Clarifies that requirements related to consent given by minor patients would apply to both uses and disclosures of records (aligns with HIPAA Privacy Rule). Changes the verb "judges" to "determines" in subsection (c).[15]	Wording changes distinguish between a program director's evaluation regarding a minor's decision-making capacity and an adjudication of incompetence made by a court that could trigger a disclosure to the minor's parents, which is addressed in § 2.15(c). Simply stated, this proposed change "would clarify that a program director may clinically evaluate whether a minor has decision making capacity, but not issue a legal judgment to that effect." Aligns requirements regarding obtaining appropriate consent in relation to Part 2 records of a minor with HIPAA Privacy Rule	

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		regarding use or disclosure, including for TPO purposes.[16]	
2.15 **Current:** Incompetent and Deceased Patients **Proposed New Title:** Patients Who Lack Capacity and Deceased Patients	Confirms that confidentiality requirements apply to both uses and disclosures of patients who lack capacity to make health care decisions and deceased patients. Replaces the term "incompetence" by referring to patients who lack capacity to make health care decisions. Clarifies that an adjudication that a patient lacks capacity is made by a court. Adds health plans to the list of entities to which a program may disclose records without consent to obtain payment during a period when the patient lacks capacity to make health care decisions but has not been adjudicated by a court as lacking capacity.[17]	Addresses who may consent to a disclosure of records when a patient lacks capacity to make health care decisions or is deceased. Replaces outdated references to "incompetence" and instead refers to a lack of capacity to make health care decisions. This is not intended as a substantive change, but would replace a term that may be considered derogatory. Section (a)(1) of this section refers to lack of capacity to make health care decisions as adjudicated by a court, while paragraph (a)(2) refers to lack of capacity to make health care decisions that is not adjudicated and to add health plans to the list of entities to which a program may disclose records without consent to obtain payment during a period when the patient has an unadjudicated inability to make decisions.[18]	
2.16 **Current:** Security for Records **Proposed New Title:** Security for records and notification of breaches	Aligns with the Privacy Rule's de-identification standard and Breach Notification Rule at 45 C.F.R. part 164, subpart D. Specifically, with regard to de-identification, section (a)(1)(v) references the Privacy Rule's de-identification standard at 45 C.F.R. § 164.514(b). With regard to the Breach Notification Rule, proposed changes establish and implement minimum requirements for policies and procedures for notification of breaches	These changes more closely align this provision with the Privacy Rule's de-identification standard and increase the alignment of regulatory requirements for Part 2 with the Privacy Rule and Breach Notification Rule by establishing analogous requirements for Part 2 programs, specifically: (1) written policies and procedures to address breaches and document actions taken in response to a breach; (2) notification of the secretary, affected patients, and, in some cases, the	With regard to de-identification, HHS requests comment on: • The extent to which Part 2 programs render patient identifying information de-identified under current provisions in a manner that differs from the Privacy Rule's de-identification standard, such that conforming Part 2 requirements to the Privacy Rule standard would create unintended adverse consequences for Part 2 programs or patients.

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	of unsecured Part 2 records consistent with the requirements of 45 C.F.R. part 160 and subpart D of part 164. With regard to the definition of "lawful holder," HHS proposes to determine the extent of the duty and ability of a particular person to "reasonably protect against unauthorized uses" and against "reasonably anticipated threats or hazards" based on the facts and circumstances, due to the variety of persons that could receive Part 2 records based on a valid written Part 2 consent.[19]	media; (3) obligations to mitigate harm to affected patients resulting from a breach; and (4) timely resolution of the causes of a breach.[20] Note that HHS considered adopting only the first sentence of the HIPAA definition of "breach" in the introductory text of the paragraph and not the remainder of the definition, recognizing that the HIPAA definition, which includes exclusions from the term "breach," does not offer a parallel level of protection to Part 2 records as is intended by its overall structure of requiring consent for most disclosures. "However, due to the amount of overlap between the types of entities that must comply with both Part 2 and the HIPAA Rules, . . . [HHS] decided to adopt the HIPAA breach definition in its entirety." Additionally, because "Congress was aware of the Breach Notification Rule when it passed the CARES Act, . . . [HHS] assumes that Congress intended to apply the full scope of the definition to Part 2 records. . . . [HHS] welcomes comments on any unintended negative consequences of this approach and how any alternative approaches could be implemented consistent with Congressional intent."[21] HHS also considered expanding the exception for reporting suspected child abuse and neglect to include reporting suspected abuse and neglect *of adults*, which would be consistent with the Privacy Rule's permission to report abuse, neglect, or domestic violence at 45 C.F.R. §	• 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, so that HIPAA Rules continue to apply. With regard to the definition of and requirements on "lawful holders," HHS requests comments on: • The assumptions and examples of persons who are "lawful holders" under the existing regulation but from whom it would be inappropriate to hold liable for compliance with the administrative requirements for protecting Part 2 records they have received or providing breach notification, such as a patient's family member. • Whether it would be helpful to create a regulatory definition of "lawful holder" and what persons such definition should encompass. With regard to the definition of "breach" and breach notification requirements, HHS requests comments on: • The estimated burden of notification. • Potential regulatory flexibilities for Part 2 programs to minimize burdens during their initial implementation of the policies and procedures required by the breach notification proposal. • The characteristics of programs to which any suggested flexibilities should apply.[23] Note that HHS also considered "further harmonizing" Part 2 and HIPAA by applying the Security Rule, or components of it, to Part 2 programs and other lawful holders with respect to electronic Part 2 records, but because the CARES Act did not make the Security

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		164.512(c). HHS ultimately concluded, however, that such expansion would exceed Part 2's statutory authority.[22]	Rule applicable to Part 2 programs, it believed imposing Security Rule compliance on entities that are not covered entities or business associates would exceed its statutory authority. HHS requests comments on this interpretation and, from Part 2 programs that are not covered entities, whether they look to the Security Rule generally for guidance on protecting electronic Part 2 records or otherwise voluntarily attempt to follow the requirements of the Security Rule, and if so, what their experience has been, including any implementation costs. HHS also requests comments on whether Part 2 security provisions should be modified to incorporate additional or different safeguards consistent with the Security Rule.[24]
2.19 Disposition of Records by Discontinued Programs	Proposes to create a third exception to the general requirement that a Part 2 program must remove patient identifying information or destroy the records when a program discontinues services or is acquired by another program. Currently, the law provides an exception when patient consent is obtained or another law requires retention of the records, and this new third exception clarifies that these provisions do not apply to transfers, retrocessions, and reassumptions of Part 2 programs pursuant to the Indian Self-Determination and Education Assistance Act to facilitate the responsibilities established by certain federal laws.[25]	Without this provision, program records would be destroyed if patient consent is unavailable at the time services are transferred, which could occur without sufficient opportunity to seek consent from all current or former patients.[26]	
2.20	Adds "use" to clarify that this section applies to both uses and disclosures under Part 2 and state law.[27]		HHS requests comment on the assumption that, to the extent state laws address SUD records, Part 2 programs generally are able to comply with Part 2 and

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Relationship to State Laws			state law, and examples of any circumstances in which a state law compels a use or disclosure that is prohibited by Part 2, such that Part 2 preempts such state law.[28]
2.22 Notice to patients of federal confidentiality requirements	To further align Part 2 with the Privacy Rule, HHS proposes numerous changes that will substantially restructure the Part 2 confidentiality notice (Patient Notice) requirements at § 2.22 and mirror certain HIPAA NPP content and other requirements at 45 C.F.R. § 164.520. Of note are the following changes: • Require Part 2 programs to include in the Patient Notice statements regarding patients' rights with respect to Part 2 records. • Require Part 2 programs to promptly revise and distribute its Patient Notice when there has been a material change and provide that, except when required by law, such material change may not be implemented prior to the effective date of the Patient Notice. • Require Part 2 programs to provide the Patient Notice to anyone who requests it and provide it to a patient no later than the date of the first service delivery, including where first service is delivered electronically after the compliance date for the Patient Notice (which will be 22	HHS states the proposed modifications would restructure § 2.22 to substantially mirror and address the same key elements of the HIPAA NPP, such as a required header, uses and disclosures, individual rights, and duties of Part 2 programs. As the HIPAA Rules and Part 2 apply to different, but often overlapping, sets of regulated entities, and because the NPP currently offers more robust notice requirements than the Patient Notice, HHS states the proposed changes to modify § 2.22 would provide the same information to individuals under the Privacy Rule as to patients of Part 2 programs. Additionally, HHS proposes to modify § 2.22 by incorporating most of the notice requirements in the HIPAA NPP at 45 C.F.R. § 164.520 and excluding those that are nonapplicable or pose special privacy risks, as well as separately addressing certain provisions that have special requirements or differences between application to covered entities and Part 2 programs.[30]	HHS requests comment on each Patient Notice requirements proposal, including information on how incorporating NPP elements into the Patient Notice requirements would increase or alleviate burdens for Part 2 programs. HHS seeks comment on ways to make the proposed notices easier to understand, 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. HHS specifically requests comment from legal, clinical, privacy, and civil rights experts on this matter.[31]

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	months after the effective date of a final rule).[29]		
New Proposed Rule: 2.24 Requirements for intermediaries	Move and revise provisions previously located at § 2.13(d) to a new rule § 2.24 entitled "Requirements for intermediaries" to clarify the responsibilities of recipients of records received from an intermediary under a consent with a general designation to provide to a patient upon request a list of persons to which his or her records have been disclosed and increase the time period to which this applies from the prior two to three years.[32]		HHS requests comments on: • The proposed reorganization and clarification of requirements for entities that facilitate HIE and whether there is a continued need for these requirements in light of the accounting of disclosures proposed in §2.25. • 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.[33]
New Proposed Rule: 2.25 Accounting of disclosures	Add a right to an accounting of: (i) disclosures made with consent under § 2.31 consistent with the standard in the Privacy Rule at 45 C.F.R. § 164.528, and (ii) for disclosures for TPO made from an EHR system during the three years prior to the date on which the accounting is requested. HHS proposes to toll the effective date for Part 2 programs until the effective date of a Privacy Rule final rule addressing the accounting of disclosures standard for TPO.[34]		HHS seeks comments on its proposals: • To align the accounting of disclosures requirements of the Privacy Rule and Part 2 by incorporating a general requirement for an accounting of disclosures and a limited requirement with respect to TPO disclosures. • To toll the effective date of the accounting of disclosures proposals until the effective date of the Privacy Rule accounting provision. HHS also seeks the following information: • Data from Part 2 programs that are also HIPAA-covered entities or business associates on the number and type of requests annually for an accounting of disclosures. • Whether and how frequently they receive requests for an accounting of disclosures for TPO. • To what extent covered entities are providing an accounting of disclosures for TPO through an EHR based solely on the HITECH Act statutory requirement.

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			• The staff time and other costs involved in responding to an individual's request for an accounting of disclosures.[35]
New Proposed Rule: 2.26 Right to request privacy protection for records	Add a patient right: (i) to request restrictions on disclosures of records otherwise permitted to be disclosed for TPO purposes, and (ii) to require restrictions on disclosures to health plans for payment or health care operations for services paid in full by the patient[36]		HHS seeks comments on: • The extent to which covered entities currently receive requests from patients to restrict disclosures of information for TPO purposes. • How covered entities document such requests. • The procedures and mechanisms used by covered entities to ensure compliance with patient requests to which they have agreed or that are required by law[37]
2.31 Consent requirements	To further align Part 2 with the Privacy Rule, HHS proposes numerous changes to the consent requirements in paragraph (a), including: • Identity of the discloser. • Description of the information to be disclosed, which can include (i) "for treatment, payment, and health care operations" when a patient provides a single consent for such future uses and disclosures, or (ii) a statement consenting to use for fundraising for the benefit of the program if applicable. • Designation of the recipient. • Purpose of the disclosure. • Right to revoke consent. • Expiration of consent. To accommodate TPO written consents, HHS proposes to permit a recipient to be a class of persons. In addition, for a single consent for all	HHS notes that, while its goal is to align certain consent requirements and language with the Privacy Rule, nothing prevents the Part 2 program from imposing additional consent requirements. In regard to revocation of consent, Part 2 programs would need to ensure that any ongoing or automatic disclosure mechanisms are halted upon revocation of consent. However, similar to HIPAA, HHS notes that 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 record for TPO or redisclosing the record as permitted by the Privacy Rule. As to oral revocations, HHS reaffirms that a Part 2 program still may accept an oral revocation of consent, which	HHS requests comments as follows: • Whether there are other changes that it should make to further align Part 2 consent requirements with the Privacy Rule. • Whether and to what extent the HHS should require Part 2 programs to inform requestors when a consent exists for disclosure and the scope of such consent. • The extent to which Part 2 programs accept or rely on oral revocations of consent, and if so, whether and how this is documented or tracked. • The extent to which Part 2 programs segment out Part 2 records considered "SUD counseling notes" and whether HHS should propose special protection for SUD counseling notes similar to the protection granted to psychotherapy notes in the Privacy Rule by requiring a separate written consent for their disclosure. • How entities that facilitate HIEs (i.e., intermediaries) would affect the implementation of proposed changes to consent for TPO. • Regarding HHS's assumption that its approach to consent requirements in the proposed rule

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	future uses and disclosures for TPO, HHS proposes to add that the recipient may be described as "my treating providers, health plans, third-party payers, and people helping to operate this program" or a similar statement. HHS proposes to eliminate the current requirement of a statement in the consent of the patient's right to a list of disclosures made by an intermediary. HHS proposes a new provision requiring that if the recipient of Part 2 information or records for TPO is a Part 2 program, covered entity, or business associate, the written consent must include a statement that the patient's record (or information contained in the record) may be redisclosed in accordance with the permissions contained in the HIPAA Privacy Rule, except for uses and disclosures for civil, criminal, administrative, and legislative proceedings against the patient, and the consequences if the patient refuses to sign the consent.[38]	HHS recommends be documented in the patient's record. Unlike HIPAA, HHS does not propose to require a consent provision that informs patients of the ability, under certain circumstances, to condition treatment on signing a consent for the use or disclosure of a Part 2 record since Part 2 does not prohibit the conditioning of treatment. Thus, 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. In regard to when a consent is considered "written," HHS reaffirms SAMHSA's previous guidance concerning signatures and further clarifies that, where HHS has issued regulations adopting electronic standards to be used for patient consent management and Part 2 programs have implemented such standards, the information conveyed using those standards would constitute a "written" patient consent where the individual provides all of the information required for a valid patient consent under § 2.31.[39]	remains consistent with that of SAMHSA's prior expressed guidance.[40] .
2.32 **Current:** Prohibition on re-disclosure	HHS proposes to change the section name to reflect that this section is solely related to notice requirements, as other Part 2 provisions address prohibitions on redisclosure.	In regard to the inclusion of the language "civil, criminal, administrative, or legislative proceedings" in the proposed rule, HHS notes its intention that "proceedings" be interpreted broadly to encompass	HHS requests comment on the proposed approach to the notice to accompany a disclosure, including: • Whether the simplified notice statement in paragraph (a)(2) is sufficient to inform recipients of Part 2 records.

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Proposed New Title: Notice to accompany disclosure	As proposed, this section would continue to permit either a detailed or simplified statement when providing the required notice. Most notably, HHS proposes to modify the detailed statement to: • Expand the language to reflect prohibited use and disclosure of Part 2 records, as well as testimony that describes the information the Part 2 records, in certain proceedings against the patient, unless otherwise permitted by another Part 2 provision. • Include additional exceptions to the prohibition on further use or disclosure, including an exception for covered entities and business associates who receive Part 2 records for TPO based on a patient's consent and entities that receive Part 2 records from a covered entity or business associate as permitted under the Privacy Rule (although the legal proceedings prohibition would still apply to covered entities and business associates that receive Part 2 records).[41]	investigations as in the current regulatory text.[42]	• Whether the revised detailed notice statement should include different elements. • Whether the proposed changes are likely to reduce data segregation and positively impact the ability to provide treatment and perform other activities, including, more specifically, whether different or 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.[43]
2.33 **Current**:	Of note, HHS proposes to revise redisclosure permissions for recipients of Part 2 records pursuant to a written consent as follows:	HHS states its view that the expanded ability to use and disclose Part 2 records through the proposed changes would facilitate greater integration of SUD	HHS seeks comments on the following: • Whether the terms "contractors, subcontractors, and legal representatives" should be defined and, if so, what definitions would appropriately retain

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Disclosures permitted with written consent **Proposed New Title:** Uses and disclosures permitted with written consent	• Permit a Part 2 program, covered entity, or business associate that receives Part 2 records pursuant to a written consent for TPO to redisclose the records in any manner permitted by the Privacy Rule, except for certain proceedings against the patient. • State that a Part 2 program that is not a covered entity or business associate and receives Part 2 records pursuant to a patient consent given once for all future TPO activities may only further use or disclose the records consistent with the consent. • Permit a lawful holder that is not a covered entity, business associate, or Part 2 program and receives Part 2 records for payment or health care operations to further use or disclose the records for payment and health care operations to its contractors, subcontractors, or legal representatives as needed to carry out the activities in the consent. HHS's proposed revisions also include removal of the list of examples of permissible payment and health care operations activities and clarification that the requirement for a written contract or comparable instrument containing certain provisions in § 2.33(c) applies to lawful holders other	treatment information with other PHI and improve communication and care coordination between providers and with other elements of the health care system, such as sharing claims information with alternative payment model providers for population health management, and enhance SUD diagnosis and treatment. HHS further notes that the proposed changes would facilitate the exchange of Part 2 records between Part 2 programs and reduce burdens on such exchanges by allowing a written consent to be given once for all future TPO uses and disclosures. HHS notes that only redisclosures for legal proceedings by covered entities or business associates would be subject to the more stringent Part 2 restrictions. In regard to the proposed change to § 2.33(c), HHS notes its proposed exclusion of covered entities and business associates from those requirements is due to the Privacy Rule requirements for business associate agreements. HHS further notes in commentary that a lawful holder under this provision would not be permitted to redisclose Part 2 records it receives for treatment purposes without an additional written consent from the patient.[45]	the existing accepted understanding of the business relationships consistent with HHS's intent. • 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 other types of consent. • If HHS should require Part 2 programs to provide a copy of the written patient consent when disclosing records. • If HHS should require that Part 2 programs, covered entities, and business associates 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 recipients or to the secretary for purposes of investigating compliance with Part 2 and the extent to which programs are already doing this and whether such requirements would be useful to recipients of Part 2 records or impose a burden on programs. • Ways to increase coordination among Part 2 programs or recipients of Part 2 records and providers of other health care services and with the health information technology developer and HIE communities to protect privacy for Part 2 records within EHRs. • Whether HHS should 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.

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	than covered entities and business associates.[44]		• How the proposed revisions to § 2.33 might affect the future data segregation practices of Part 2 programs and recipients of Part 2 records.[46]
2.35 **Current:** Disclosures to elements of the criminal justice system which have referred patients **Proposed New Title:** Disclosures to elements of the criminal justice system which have referred patients	HHS proposes in part to clarify that disclosures of information under this section are from Part 2 records.[47]		HHS seeks comments on whether the term "persons" reflects the terminology of those within the criminal justice system who refer patients to a Part 2 program or whether the alternative term "personnel" would be more accurate.[48]
2.52 **Current:** Research **Proposed New Title:** Scientific research	Of note, HHS proposes to replace the requirements to render Part 2 data in research reports nonidentifiable with the Privacy Rule's de-identification standard in 45 C.F.R. § 164.514.[49]		HHS seeks comments on the following: • Whether any Part 2 programs conduct research using their own Part 2 records. • The application of the HIPAA de-identification standard to Part 2 records disclosed for research, including any unintended adverse consequences that may result from this proposed change.[50]
2.53 **Current:**	Adds new paragraph (h), which would permit:	This new provision would clarify that Part 2 programs, covered entities, and business associates are permitted to disclose Part 2 records pursuant to a consent for all future	HHS seeks comment on: • Whether the new redisclosure permission for Part 2 programs, covered entities, and business

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Audit and evaluation **Proposed New Title:** Management audits, financial audits, and program evaluation	• Disclosures by a Part 2 program, covered entity, or business associate for audits and evaluations under paragraph (c) and to quality assurance entities under paragraph (d) in accordance with a consent that includes "health care operations." • Redisclosures by the recipient of such records as permitted under the HIPAA Privacy Rule, if the recipient is a Part 2 program, covered entity, or business associate.[51]	TPO uses and disclosures when a requesting entity is seeking records for activities described in paragraphs (c) or (d) of § 2.53. Proposed paragraph (h) would leave intact existing disclosure permissions and requirements for audit and evaluation activities without consent, including health care oversight activities, such as described in paragraph (e). HHS proposes this approach because it believes there is no basis to fully align the Part 2 audit and evaluation provisions with the Privacy Rule, given that the CARES Act consent provisions specifically incorporated only uses and disclosures for TPO purposes, not for health oversight activities.[52]	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. • HHS requests comment on its interpretation of the CARES Act as applied to health oversight activities and any anticipated benefits or costs of treating some audit and evaluation activities under Part 2 differently than others based on whether the activities would constitute health care operations or health oversight activities.[53]
New Proposed Rule: 2.54 Disclosures for public health	New section added to permit disclosure of records without patient consent to public health authorities, provided that the records disclosed are de-identified according to the Privacy Rule's standards.[54]	This change is proposed in conjunction with HHS's proposed definitions for "public health authority" as described above. Further, the proposed change should not be construed as extending the protections of Part 2 to de-identified information, as such information is outside the scope of § 2.12(a). Thus, once Part 2 records are de-identified for disclosure to public health authorities, Part 2 no longer applies to the de-identified records.[55]	HHS seeks comment on any benefits or costs that may result from this proposed change.[56]
2.62 Order not applicable to records	Replaced the term "qualified personnel" with a reference to the criteria in § 2.52(a)(1) that defines such persons as a:	The term "qualified personnel" has a precise meaning, but it does not have a regulatory definition within 42 C.F.R. part 2 and is used only once within the regulation. For greater clarity, HHS proposes to refer	

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disclosed without consent to researchers, auditors, and evaluators	• Person designated as director or managing director or person otherwise vested with authority to act as chief executive officer or their designee of a Part 2 program. • Other lawful holder of Part 2 data.[57]	instead to "persons who meet the criteria specified in § 2.52(a)(1)(i)–(iii) of this part" and, later in the paragraph, to "such persons."[58]	
2.63 Confidential communications	Clarified forums to specify 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 his or her records or testimony that relays information in his or her records as evidence.[59]		
2.64 **Current:** Procedures and criteria for orders authorizing disclosures for noncriminal purposes **Proposed New Title:** Procedures and criteria for orders	Expands the types of forums where restrictions on use and disclosure of records in civil proceedings against patients apply to expressly include administrative and legislative proceedings. Restricts the use of testimony conveying information in a record in civil proceedings against patients, absent consent or a court order. Adds the word "only" to clarify the extent of the limitation under paragraph (e) of § 2.64, which sets forth limitations for court orders	A court order under this section (or any section within subpart E) would be limited to the circumstances specified in § 2.63. Section 3221(e) of the CARES Act expanded privacy protections by prohibiting the use of Part 2 records for these purposes, or disclosure or use of testimony relaying the contents of a patient's records. When disclosure or use of Part 2 records or testimony relaying information in a record is sought in a nonjudicial proceeding, the application would be filed separately in court.[61]	

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authorizing uses and disclosures for noncriminal purposes	authorizing the disclosure of patient records in noncriminal proceedings, limiting such disclosures to "only" the portions of the patient's record that are essential to fulfill the purpose of the order.[60]		
2.65 **Current:** Procedures and criteria for orders authorizing disclosure and use of records to criminally investigate or prosecute patients **Proposed New Title:** Procedures and criteria for orders authorizing disclosure and use of records to criminally investigate or prosecute patients	Expands the types of forums where restrictions on use and disclosure of records in criminal proceedings against patients apply to expressly include administrative and legislative proceedings. Restricts the use of testimony conveying information in a record in criminal proceedings against patients, absent consent or a court order. The proposed modification to § 2.65(e)(1) would limit uses and disclosures to those parts of a patient's records or testimony relaying the information in those records that are essential to fulfill the objective of the order. Likewise, the proposed modification to § 2.65(e)(2) would limit disclosures to those law enforcement and prosecutorial officials who are responsible for, or are conducting, the investigation or prosecution, and limit their use of the records or testimony to investigation and prosecution of the extremely serious or suspected crime specified in the application and as limited by § 2.63.[62]	Parallels the proposed changes to § 2.64, discussed above regarding testimony relaying the contents of a patient's record. In addition to criminal prosecutions brought as part of the judicial process, criminal investigations may be carried out by executive agencies and legislative bodies, and the CARES Act has widened the confidentiality protections for patients in all of these forums where there may be a risk of exposure and liability. The proposed modification to § 2.65(e)(1) would limit uses and disclosures to those parts of a patient's records or testimony relaying the information in those records that are essential to fulfill the objective of the order. Likewise, the proposed modification to § 2.65(e)(2) would limit disclosures to those law enforcement and prosecutorial officials who are responsible for, or are conducting, the investigation or prosecution, and it would limit their use of the records or testimony to investigation and prosecution of the extremely serious or suspected crime specified in the application and as limited by § 2.63.[63]	

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2.66 **Current:** Procedures and criteria for orders authorizing disclosure and use of records to investigate or prosecute a Part 2 program or the person holding the records **Proposed New Title:** Procedures and criteria for orders authorizing use and disclosure to investigate or prosecute a Part 2 program or the person holding the records	Creates requirements for investigative agencies to follow in the event they discover in good faith that they received Part 2 records during an investigation or prosecution of a Part 2 program or the person holding the records before seeking a court order[64]	Specifically, HHS would require an investigative agency (other than one proceeding under § 2.53(e)) 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 nonretrievable within a reasonable period of time, but not more than 120 days from discovery. 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. HHS proposes in paragraph (b) to provide an option for substitute notice by publication when it is impracticable under	

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		the circumstances to provide individual notification of the opportunity to seek revocation or amendment of a court order issued under § 2.66. Additionally, HHS proposes to reorganize paragraph (c) by expressly incorporating the provisions from § 2.64(d) that would require an applicant to show a court the good-cause requirement and criteria, as well as adding the proposed § 2.3(b) requirements as elements of good cause for investigative agencies that apply for a court order under proposed § 2.66(a)(3)(ii).[65]	
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	Adds new criteria for issuance of a court order in instances where an application is submitted after the placement of an undercover agent or informant has already occurred, requiring an investigative agency to satisfy the conditions at § 2.3(b). Clarifies that the good-cause criteria for a court order in paragraph (c)(2) includes circumstances when obtaining the evidence another way would "yield incomplete evidence." Creates 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 at proposed §		

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	2.3(b) before applying for a court order for Part 2 records after discovering that it unknowingly had received such records.[66]		
2.68 **New Proposed Rule:** Report to the Secretary	Creates new requirements for investigative agencies to file annual reports about the instances in which they applied for a court order after receipt of Part 2 records or placement of an undercover agent or informant as provided in §§ 2.66 and 2.67. Such reports would be due within 60 days following the end of the calendar year.[67]	The report would also include the number of instances in which such applications were denied due to findings by the court of violations of Part 2.[68]	
45 C.F.R. § 164.520 Notice of privacy practices for protected health information	HHS proposes the following changes to update the NPP requirements of 45 C.F.R. § 164.520 and incorporate provisions specific to covered entities using and disclosing Part 2 records. Notably, HHS proposes the following: • Expressly state that covered entities have an obligation to provide patients with adequate notice of the uses and disclosures of Part 2 records and patient rights and covered entity's duties regarding the same. • Remove the *"Exception for Inmates"* provision. • Revise the NPP content requirements to include, among other changes: ○ Provide notice that Part 2 records or testimony	As required by § 3221(i) of the CARES Act, HHS proposes changes to 45 C.F.R. §164.520 to ensure adequate notice is given to patients who are the subject of these records.[70] HHS states that the proposed changes would further align the Patient Notice requirements for Part 2 records with NPP requirements with respect to PHI.[71] HHS makes the distinction that under the proposed rule any covered entity that uses or discloses Part 2 records would be subject to the notice requirements of § 2.22 in addition to the NPP requirements in 45 C.F.R. § 164.520. However, Part 2 programs that are not covered entities and not subject to HIPAA would only be	HHS requests comments 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. HHS specifically requests comment from legal, clinical, privacy, and civil rights experts on this matter.[75] HHS requests comments on the burden the statutory required implementations will place on regulated entities.[76]

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	relaying the content of such records shall not be used or disclosed in certain proceedings against the individual without written consent or court order. ○ Provide notice that a covered entity may use or disclose the individual's Part 2 records for fundraising on behalf of the covered entity only with the written consent of the individual. ○ Require a covered entity, when providing notice about the right of access, to include notice about the right to inspect and obtain a copy of PHI, the right to do so at limited cost or free of charge, and the right to direct a covered health care provider to transmit an electronic copy of PHI in an EHR to a third party. ○ Require a covered entity to provide notice of the right to discuss the NPP with a designated contact person identified by the covered entity. ○ Expand the requirement that a covered entity provide individuals with	obligated to comply with § 2.22.[72] With respect to the proposed removal of the "*Exception for Inmates*," HHS no longer believes it is appropriate to withhold notice from an incarcerated individual with respect to their health information privacy rights and a covered entity's practices. This proposal would ensure that regulated entities provide an NPP to inmates consistent with what is provided to other individuals and retains the limitation on the right of access due to security concerns.[73] With respect to the proposal that covered entities may use or disclose the individual's Part 2 records for fundraising on behalf of the covered entity only with the written consent of the individual, HHS believes fundraising is far enough outside an individual's reasonable expectation of how their Part 2 records will be used or disclosed that entities should obtain written consent.[74]	

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	notice of the covered entity's legal duties and privacy practices to information beyond that of PHI (i.e., to Part 2 records). • Require a covered entity's NPP to include the email address for a designated person available to answer questions about the covered entity's privacy practices. • A new provision permitting a covered entity to provide information, in its NPP, regarding how an individual who seeks to direct PHI to a third party, when the PHI is not in an EHR or is in a nonelectronic format, can instead obtain a copy of PHI directly under 45 C.F.R. § 164.524 and send the copy to the third party themselves or request the covered entity to send a copy of the PHI to a third party using a valid authorization under 45 C.F.R. § 164.508. • Remove the existing requirement for a covered entity to obtain a written acknowledgement of receipt of the NPP. • Prohibit construing the permissions for Organized Health Care Arrangements to disclose PHI between participants as negating covered entity obligations or patient rights related to Part 2 records.[69]		

Endnotes

K&L GATES

[1] Confidentiality of Substance Use Disorder (SUD) Patient Records, 87 Fed. Reg. 74,216, 74,226 (proposed Dec. 2, 2022).
[2] *Id.*
[3] *Id.*
[4] *Id.*
[5] *Id.* at 74,227–28.
[6] *Id.*
[7] *Id.*
[8] *Id.* at 74,228.
[9] *Id.*
[10] *Id.*
[11] *Id.* at 74,232–33.
[12] *Id.*
[13] *Id.* at 74,233.
[14] *Id.*
[15] *Id.*
[16] *Id.* at 74,233, 74,262.
[17] *Id.* at 74,233.
[18] *Id.*
[19] *Id.* at 74,233–34.
[20] *Id.*
[21] *Id.* at 74,265–66.
[22] *Id.* at 74,266–67.
[23] *Id.* at 74,233–34.
[24] *Id.* at 74,267.
[25] *Id.* at 74,234.
[26] *Id.*
[27] *Id.* at 74,234–35.
[28] *Id.* at 74,235.
[29] *Id.* at 74,236–37.
[30] *Id.* at 74,235.
[31] *Id.* at 74,248.
[32] *Id.* at 74,239.
[33] *Id.* at 74,248.
[34] *Id.* at 74,239.
[35] *Id.*

[36] *Id.*
[37] *Id.* at 74,240.
[38] *Id.* at 74,240–41.
[39] *Id.*
[40] Id. at 74,240–41, 74,248.
[41] *Id.* at 74,241–42.
[42] *Id.* at 74,242.
[43] *Id.* at 74,242, 74,248.
[44] *Id.* at 74,242–43.
[45] *Id.* at 74,242.
[46] *Id.* at 74,242–43.
[47] *Id.* at 74,243.
[48] *Id.*
[49] *Id.*
[50] *Id.* at 74,243, 74,249.
[51] *Id.* at 74,243–44.
[52] *Id.*
[53] *Id.*
[54] *Id.* at 74,244–45.
[55] *Id.* at 74,245.
[56] *Id.* at 74,244–45.
[57] *Id.* at 74,245.
[58] *Id.*
[59] *Id.*
[60] *Id.*
[61] *Id.*
[62] *Id.* at 74,245–46.
[63] *Id.*
[64] *Id.* at 74,246.
[65] *Id.*
[66] *Id.* at 74,247.
[67] *Id.*
[68] *Id.*
[69] *Id.* at 74,237–38.
[70] *Id.* at 74,237.
[71] *Id.*
[72] *Id.* at 74,236.
[73] *Id.* at 74,237.

[74] *Id.* at 74,238.
[75] *Id.* at 74,248.
[76] *Id.* at 74,238.