SAMHSA Releases Supplemental Final Rule Regarding Disclosures of Substance Use Disorder Treatment Information

Melissa A. Soliz, Coppersmith Brockelman PLC
January 10, 2018

On Wednesday, January 3, the Substance Abuse and Mental Health Services Administration ("SAMHSA") issued a Supplemental Final Rule ("SFR"), which amended the federal Confidentiality of Substance Use Disorder Patient Records regulations at 42 C.F.R. Part 2 ("Part 2 Regulations"). The SFR goes into effect on February 2, 2018, with the exception of new contract requirements that have a compliance date of February 2, 2020. This paper provides a brief summary of the SFR and a chart comparing the changes together with explanatory guidance from the preamble.

The Current Part 2 Regulations

Under the existing Part 2 Regulations, which were recently updated effective March 21, 2017, a federally-assisted substance use disorder program (called a "Part 2 program") and other "lawful holders" of information from a Part 2 program that identifies an individual as having or having had a substance use disorder (called "Part 2 information") generally could be released only with an individual's express, written consent. Even disclosures related to payment, treatment, or health care operations require consent, unlike the Health Insurance Portability and Accountability Act and its implementing regulations ("HIPAA"). Moreover, each disclosure made pursuant to an individual's consent is required to be accompanied by a lengthy notice of prohibition on re-disclosure. There are few exceptions to the consent requirement under the Part 2 Regulations.

One exception under the current Part 2 Regulations is for disclosures by Part 2 programs to contractors, called Qualified Service Organizations ("QSOs"), which provide services to the Part 2 program to assist in payment and health care operations functions. (Services may include activities such as data processing, bill collecting, dosage preparation, laboratory analyses, legal, accounting, population health management, medical staffing, or other professional services, and services to prevent or treat child abuse or neglect, including training on nutrition and child care and individual and group therapy.) SAMHSA clarified in the preamble to the 2017 revisions to the Part 2 Regulations that if the services provided by the QSO include a "treatment component," such as care coordination or medical management services, then Part 2 information may be shared only with the prior written consent of the patient or as otherwise permitted under the part 2 statute, regulations, or guidance. If, however, the services provided by the QSO support payment and health care operations functions, the Part 2 program may disclose Part 2 information to the QSO that is necessary for the QSO to provide services to the Part 2 program, provided that there is a written contract in place (called a Qualified Service Organization Agreement or "QSOA"). Under a QSOA, the QSO acknowledges that it is fully bound by the Part 2 Regulations, and if necessary, will resist in judicial proceedings any efforts to obtain access to Part 2 information except as permitted by the Part 2 Regulations. Other SAMHSA guidance further permits a QSO to disclose Part 2 information to its "contract agents" (an undefined term), so long as the disclosure is limited to the Part 2 information necessary for providing the services described in the QSOA, and the agent only further discloses the information back to the QSO or to the Part 2 program from which the information originated.

Another exception to the consent requirement is for disclosures by Part 2 programs to an individual or entity performing an audit or evaluation of the Part 2 program, if certain requirements are met.

The current Part 2 Regulations also regulate "lawful holders" of Part 2 information. A lawful holder is an individual or entity, other than a Part 2 program, who has received Part 2 information as the result of a part 2-compliant consent (with a prohibition on re-disclosure notice) or as otherwise permitted under the Part 2 Regulations. The current Part 2 Regulations are silent on whether "lawful holders" may disclose Part 2 information to their contractors without individual consent.

Changes under the 2018 Supplemental Final Rule

In the SFR, SAMHSA addresses the circumstances under which lawful holders may use and disclose Part 2 information without individual consent to their contractors and for audit and evaluation purposes:

- Disclosures to Contractors for Payment or Health Care Operations. The SFR allows lawful holders that receive Part 2 information pursuant to an individual's written consent to re-disclose the Part 2 information to their contractors. But there are limits: (1) the disclosure may be for payment and health care operations purposes only (not for treatment, case management or care coordination); and (2) the consent form authorizing the disclosure to the lawful holder must include "payment and health care operations" as one purpose for the disclosure to the lawful holder. (This exception is different from the exception permitting disclosures from Part 2 programs to QSOs.) There are also certain contractual requirements that must be in place between the lawful holder and its contractor by February 2, 2020.

- Disclosures for Audit and Evaluation. The SFR also allows lawful holders to disclose Part 2 information under the audit and evaluation exception. If the disclosure under this exception is to an individual or entity for a Medicare, Medicaid, or CHIP audit or evaluation, the receiving individual or entity may further re-disclose the Part 2 information to its contractors for purposes of carrying out the audit or evaluation.

Additionally, SAMHSA now permits use of an abbreviated notice of the prohibition on re-disclosure. Under the SFR, an abbreviated notice that is 80 characters long may be used in any instance where the notice is required. SAMHSA is making this change because 80 characters fits into the standard free-text space within EHR systems. The abbreviated notice in the SFR reads ''Federal law/42 CFR part 2 prohibits unauthorized disclosure of these records.''

The chart below compares the text of the current Part 2 Regulations to the SFR and includes the most pertinent guidance from the preamble on the meaning of these changes.

SUMMARY OF SIGNIFICANT CHANGES MADE TO 42 CFR PART 2 BY THE SUPPLEMENTAL FINAL RULE (83 Fed. Reg. 239 (January 3, 2018))*

Coppersmith Brockelman PLC

January 10, 2018

Subject	**42 C.F.R. Part 2 (2017)**	**Supplemental Final Rule (2018)**: additions underlined; deletions strikethrough	**Relevant Guidance from the Preamble of the Supplemental Final Rule**
Effective & Compliance Dates	Currently in effect	Effective Date: The final rule is effective February 2, 2018. Compliance Date: The compliance date is February 2, 2018; however, lawful holders have two years from the effective date (*i.e.*, February 2, 2020) to bring their contracts into compliance with 42 C.F.R. § 2.33(c) to cover disclosures between lawful holders and their contractors, subcontractors, and legal representatives for payment and health care operations where the patient has consented to disclosures to the lawful holder for these purposes.	". . . [C]ontracts may include statements about required compliance with 42 CFR part 2; however, no specific language beyond this concept is required by the rule. This rule provides up to two years from the effective date to comply with this section. Because part 2 programs and other lawful holders can modify their contracts during the normal renegotiation of contracts as existing contracts expire or, if such contracts are not regularly updated, can make such changes up to two years from this final rule's effective date, new regulatory language required by § 2.33(c), as revised, should impose a minimal burden." 83 Fed. Reg. at 250.
Notice of Prohibition on Re-Disclosures	**§ 2.32 Prohibition on re-disclosure.** (a) Notice to accompany disclosure. Each disclosure made with the patient's written consent must be accompanied by the following written statement: This information has been disclosed to you from records protected by federal confidentiality rules (42 CFR part 2). The federal rules prohibit you from making any further disclosure of information in this record that identifies a patient as having or having had a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person unless further disclosure is expressly permitted by the written consent of the individual whose information is being disclosed or as otherwise permitted by 42 CFR part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose (see §2.31). The federal rules	**§ 2.32 Prohibition on re-disclosure.** (a) Notice to accompany disclosure. Each disclosure made with the patient's written consent must be accompanied by one of the following written statements: (1) This information has been disclosed to you from records protected by federal confidentiality rules (42 CFR part 2). The federal rules prohibit you from making any further disclosure of information in this record that identifies a patient as having or having had a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person unless further disclosure is expressly permitted by the written consent of the individual whose information is being disclosed or as otherwise permitted by 42 CFR part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose (see § 2.31). The federal rules restrict any use of the information to investigate or prosecute with regard to a crime any patient with a substance use disorder, except as provided at §§ 2.12(c)(5) and 2.65; or	"SAMHSA has adopted an abbreviated notice that is 80 characters long to fit in standard free-text space within health care electronic systems." 83 Fed. Reg. at 240. "SAMHSA decided, consistent with its proposal, to allow use of an abbreviated notice in any instance in which a notice is required under the regulations. Recognizing concerns expressed by commenters that an abbreviated notice could be insufficient to convey understanding of part 2 requirements, SAMHSA encourages part 2 programs and other lawful holders using the abbreviated notice to discuss the requirements with those to whom they disclose patient identifying information." 83 Fed. Reg. at 240.

*This document was prepared for educational purposes and is not intended to provide legal advice. It does not address all of the changes made to 42 CFR Part 2 by the Supplemental Final Rule or all of the commentary relating to the changes. To access the Supplemental Final Rule in its entirety, go to: https://www.gpo.gov/fdsys/pkg/FR-2018-01-03/pdf/2017-28400.pdf.

Subject	42 C.F.R. Part 2 (2017)	Supplemental Final Rule (2018): additions underlined; deletions strikethrough	Relevant Guidance from the Preamble of the Supplemental Final Rule
	restrict any use of the information to investigate or prosecute with regard to a crime any patient with a substance use disorder, except as provided at §§2.12(c)(5) and 2.65. (b) [Reserved]	(2) 42 CFR part 2 prohibits unauthorized disclosure of these records. (b) [Reserved]	
Disclosures permitted with written consent – payment and health care operations	**§ 2.33 Disclosures permitted with written consent.** If a patient consents to a disclosure of their records under § 2.31, a program may disclose those records in accordance with that consent to any person identified in the consent, except that disclosures to central registries and in connection with criminal justice referrals must meet the requirements of §§ 2.34 and 2.35, respectively.	**§ 2.33 Disclosures permitted with written consent.** (a) If a patient consents to a disclosure of their records under § 2.31, a part 2 program may disclose those records in accordance with that consent to any person or category of persons identified or generally designated in the consent, except that disclosures to central registries and in connection with criminal justice referrals must meet the requirements of §§ 2.34 and 2.35, respectively. (b) If a patient consents to a disclosure of their records under § 2.31 for payment and/or health care operations activities, a lawful holder who receives such records under the terms of the written consent may further disclose those records as may be necessary for its contractors, subcontractors, or legal representatives to carry out payment and/or health care operations on behalf of such lawful holder. Disclosures to contractors, subcontractors, and legal representatives to carry out other purposes such as substance use disorder patient diagnosis, treatment, or referral for treatment are not permitted under this section. In accordance with § 2.13(a), disclosures under this section must be limited to that information which is necessary to carry out the stated purpose of the disclosure. (c) Lawful holders who wish to disclose patient identifying information pursuant to paragraph (b) of this section must have in place a written contract or comparable legal instrument with the contractor or voluntary legal representative, which provides	**Purpose/Intent** "SAMHSA recognizes the legitimate needs of lawful holders of patient identifying information to disclose that information to their contractors, subcontractors, and legal representatives ***for purposes of payment and health care operations*** as long as the core protections of 42 CFR part 2 are maintained." 83 Fed. Reg. at 242 (emphasis added). ". . . [I]t is not SAMHSA's intent to apply part 2 to contractors and subcontractors in a manner similar to what was accomplished under the HIPAA Privacy and Security Rules for Business Associates in accordance with, respectively, sections 13404(a) and 13401(a) of the HITECH Act, 42 U.S.C. 17934(a), 17931(a). SAMHSA has attempted to align part 2 with HIPAA in this final rule to the extent such changes are permissible under 42 U.S.C. 290dd–2.. . . At the same time, Part 2 and its authorizing statute are separate and distinct from HIPAA, the HITECH Act, and their implementing regulations. Because of its targeted population, part 2 and its authorizing statute provides more stringent federal protections than other health privacy laws, including the HIPAA Rules, in order to encourage individuals with substance use disorders to seek treatment." 83 Fed. Reg. at 242. "SAMHSA declines to implement the suggested alternative approaches [*e.g.*, allowing lawful holders to contract with QSOs and revising the QSO definition to align with the HIPAA business associate concept]. SAMHSA agrees there are similarities between contractors under § 2.33(b) and QSOs. However, SAMHSA did not propose in the SNPRM to revise the provision on QSOs." 83 Fed. Reg. at 242.

Subject	**42 C.F.R. Part 2 (2017)**	**Supplemental Final Rule (2018)**: additions underlined; deletions strikethrough	**Relevant Guidance from the Preamble of the Supplemental Final Rule**
		that the contractor, subcontractor, or voluntary legal representative is fully bound by the provisions of part 2 upon receipt of the patient identifying information. In making any such disclosures, the lawful holder must furnish such recipients with the notice required under § 2.32; require such recipients to implement appropriate safeguards to prevent unauthorized uses and disclosures; and require such recipients to report any unauthorized uses, disclosures, or breaches of patient identifying information to the lawful holder. The lawful holder may only disclose information to the contractor or subcontractor or voluntary legal representative that is necessary for the contractor or subcontractor or voluntary legal representative to perform its duties under the contract or comparable legal instrument. Contracts may not permit a contractor or subcontractor or voluntary legal representative to re-disclose information to a third party unless that third party is a contract agent of the contractor or subcontractor, helping them provide services described in the contract, and only as long as the agent only further discloses the information back to the contractor or lawful holder from which the information originated.	**Examples of Permissible Disclosures to Contractors** "Examples of permissible activities under § 2.33(b) that SAMHSA considers to be payment and health care operations activities include: • Billing, claims management, collections activities, obtaining payment under a contract for reinsurance, claims filing and related health care data processing; • Clinical professional support services (*e.g.*, quality assessment and improvement initiatives; utilization review and management services); • Patient safety activities; • Activities pertaining to: o The training of student trainees and health care professionals; o The assessment of practitioner competencies; o The assessment of provider and/or health plan performance; and o Training of non-health care professionals; • Accreditation, certification, licensing, or credentialing activities; • Underwriting, enrollment, premium rating, and other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits, and ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care; • Third-party liability coverage; • Activities related to addressing fraud, waste and abuse; • Conducting or arranging for medical review, legal services, and auditing functions; • Business planning and development, such as conducting cost management and planning-related analyses related to managing and operating, including formulary development and administration, development or improvement of methods of payment or coverage policies; • Business management and general administrative activities, including management activities relating to implementation of and compliance with the requirements of this or other statutes or regulations; • Customer services, including the provision of data analyses for policy holders, plan sponsors, or other customers;

Subject	**42 C.F.R. Part 2 (2017)**	**Supplemental Final Rule (2018)**: additions underlined; deletions strikethrough	**Relevant Guidance from the Preamble of the Supplemental Final Rule**
			• Resolution of internal grievances; • The sale, transfer, merger, consolidation, or dissolution of an organization; • Determinations of eligibility or coverage (*e.g.* coordination of benefit services or the determination of cost sharing amounts), and adjudication or subrogation of health benefit claims; • Risk adjusting amounts due based on enrollee health status and demographic characteristics; • Review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges." 83 Fed. Reg. at 243. ". . . [T]his list of activities is being included in the preamble, rather than in regulatory text, in order to make clear that it is ***an illustrative rather than exhaustive list of the types of payment and health care operations activities that would be acceptable to SAMHSA.*** By removing the list from the regulatory text, SAMHSA intends for other appropriate payment and health care operations activities to be permitted under § 2.33 as the health care system continues to evolve." 83 Fed. Reg. at 241 (emphasis added). **Prohibited Disclosures to Contractors** "SAMHSA maintains its position that the payment and health care operations activities referenced in § 2.33 and listed in the preamble are not intended to encompass substance use disorder, patient diagnosis, treatment, or referral for treatment." 83 Fed. Reg. at 243. "SAMHSA believes it is important to maintain patient choice in disclosing information to health care providers with whom patients have direct contact. For this reason, the final provision in § 2.33(b) is not intended to cover care coordination or case management and disclosures to contractors, subcontractors, and legal representatives to carry out such purposes are not permitted under this section. In addition, SAMHSA added language to the

Subject	**42 C.F.R. Part 2 (2017)**	**Supplemental Final Rule (2018)**: additions underlined; deletions strikethrough	**Relevant Guidance from the Preamble of the Supplemental Final Rule**
			regulatory text in § 2.33(b) to clarify that disclosures to contractors, subcontractors and legal representatives are not permitted for activities related to a patient's diagnosis, treatment, or referral for treatment." 83 Fed. Reg. at 243. SAMSHA notes that the position articulated in this final rule differs from the HIPAA Privacy Rule, under which 'health care operations' encompasses such activities as case management and care coordination." 83 Fed. Reg. at 243. **Contractual Requirements** "SAMHSA is not specifying the exact contract language to be used. With respect to the comment regarding limiting disclosures to the minimum information necessary, § 2.13 requires that any disclosure made must be limited to that information which is necessary to carry out the purpose of the disclosure." 83 Fed. Reg. at 244. "SAMHSA declines to provide specific and detailed contract language because SAMHSA believes lawful holders need the flexibility to include language that fits within their contract structures." 83 Fed. Reg. at 245. "In the case where there is a legal representative who is required to represent the lawful holder by law, the requirement for a contract or comparable legal instrument in § 2.33(c) shall not apply." 83 Fed. Reg. at 246; *see also* 83 Fed. Reg. at 244. "Those utilizing contractors or subcontractors should then inform those parties in their contracts that information governed by part 2 requires the contractor or subcontractor to take reasonable steps to prevent unauthorized uses and disclosures and to inform the lawful holder of any breaches and/or unauthorized uses." 83 Fed. Reg. at 245.

Subject	**42 C.F.R. Part 2 (2017)**	**Supplemental Final Rule (2018)**: additions underlined; deletions strikethrough	**Relevant Guidance from the Preamble of the Supplemental Final Rule**
			Consent Form ". . . SAMHSA notes that § 2.13 requires that any disclosure made under the regulations must be limited to that information which is necessary to carry out the purpose of the disclosure. Therefore, to comply with § 2.13, lawful holders should ensure that the purpose section of the consent form is consistent with the role of or services provided by the contractor or subcontractor (*e.g.*, ''payment and health care operations'')." 83 Fed. Reg. at 244. "SAMHSA does not require that part 2 consent forms be passed along to the contractor or subcontractor." 83 Fed. Reg. at 245. **Qualified Service Organizations (QSOs)** "SAMHSA declines to eliminate the requirement that § 2.33(b) only applies to lawful holders that receive patient identifying information pursuant to a written consent. SAMHSA believes that the consent requirement for lawful holders that fall under § 2.33(b) must be maintained and that § 2.33(b) should not apply to QSOs." 83 Fed. Reg. at 246. **Miscellaneous** "Under § 2.33, lawful holders, contractors and their subcontractors are responsible for providing a prohibition on re-disclosure notice (§ 2.32) if they re-disclose patient identifying information to their contractors in order to meet the requirements of § 2.33. If other entities access the information as permitted by the lawful holder (because the other entities that gain access to the information via the cloud are contractors with the lawful holder (§ 2.33) and not the cloud services provider), or to fulfill the requirements on the written consent (§ 2.31), then the lawful holder (not the cloud service provider) is responsible for ensuring that a notice of the prohibition on redisclosure is conveyed to those entities, along with the information." 83 Fed. Reg. at 245.

Subject	**42 C.F.R. Part 2 (2017)**	**Supplemental Final Rule (2018)**: additions underlined; deletions strikethrough	**Relevant Guidance from the Preamble of the Supplemental Final Rule**
			". . . [T]he information can be disclosed directly to the contractor or subcontractor and does not need to first be disclosed to the lawful holder (*i.e.*, recipient named on the consent form) and then subsequently redisclosed, as long as the information is being used for the purposes of payment and health care operations. This is because contractors, legal representatives, and subcontractors are acting on behalf of the lawful holders based on contracts, legal agreements or mandates in law." 83 Fed. Reg. at 246. "SAMHSA did not propose to define 'contractors' and 'subcontractors' in its proposed rule and declines to do so now in the final rule." 83 Fed. Reg. at 246.
Audit & Evaluation	**§ 2.53 Audit and evaluation.** (a) Records not copied or removed. If patient records are not downloaded, copied or removed from the part 2 program premises or forwarded electronically to another electronic system or device, patient identifying information, as defined in § 2.11, may be disclosed in the course of a review of records on the part 2 program premises to any individual or entity who agrees in writing to comply with the limitations on re-disclosure and use in paragraph (d) of this section and who: (1) Performs the audit or evaluation on behalf of: (i) Any federal, state, or local government agency which provides financial assistance to the part 2 program or is authorized by law to regulate its activities; or (ii) Any individual or entity who provides financial assistance to the part 2 program, which is a third-party payer covering patients in the part 2 program, or which is a quality	**§ 2.53 Audit and evaluation.** (a) Records not copied or removed. If patient records are not downloaded, copied or removed from the premises of a part 2 program ~~premises~~ or other lawful holder, or forwarded electronically to another electronic system or device, patient identifying information, as defined in § 2.11, may be disclosed in the course of a review of records on the premises of a part 2 program ~~premises~~ or other lawful holder to any individual or entity who agrees in writing to comply with the limitations on re-disclosure and use in paragraph (d) of this section and who: (1) Performs the audit or evaluation on behalf of: (i) Any federal, state, or local governmental agency that ~~which~~ provides financial assistance to a ~~the~~ part 2 program or other lawful holder, or is authorized by law to regulate ~~its~~ the activities of the part 2 program or other lawful holder; (ii) Any individual or entity which provides financial assistance to the part 2 program or other lawful holder, which is a third-party payer covering patients in the part 2 program,	". . . [I]n the SNPRM, SAMHSA proposed regulatory changes to clarify that audits and evaluations may be performed on behalf of federal, state, and local governments providing financial assistance to, or regulating the activities of, lawful holders as well as part 2 programs. . . . In addition, SAMHSA proposed regulatory revisions to: Specify that audits and evaluations may be performed by contractors, subcontractors, or legal representatives on behalf of a third-party payers or a quality improvement organizations; and state that if disclosures are made under this section for a Medicare, Medicaid, or CHIP audit or evaluation, including a civil investigation or administrative remedy, further disclosures may be made to contractors, subcontractors, or legal representatives to carry out the audit or evaluation. SAMHSA is now finalizing these requirements." 83 Fed. Reg. at 246. ". . . [I]f a government agency is auditing or evaluating a lawful holder, which it regulates, the agency may receive the patient identifying information necessary for that audit or evaluation directly from the lawful holder." 83 Fed. Reg. at 247.

Subject	42 C.F.R. Part 2 (2017)	**Supplemental Final Rule (2018)**: additions underlined; deletions strikethrough	Relevant Guidance from the Preamble of the Supplemental Final Rule
	improvement organization performing a utilization or quality control review; or (2) Is determined by the part 2 program to be qualified to conduct an audit or evaluation of the part 2 program. (b) Copying, removing, downloading, or forwarding patient records. Records containing patient identifying information, as defined in § 2.11, may be copied or removed from a part 2 program premises or downloaded or forwarded to another electronic system or device from the part 2 program's electronic records by any individual or entity who: (1) Agrees in writing to: (i) Maintain and destroy the patient identifying information in a manner consistent with the policies and procedures established under § 2.16; (ii) Retain records in compliance with applicable federal, state, and local record retention laws; and (iii) Comply with the limitations on disclosure and use in paragraph (d) of this section; and (2) Performs the audit or evaluation on behalf of: (i) Any federal, state, or local government agency which provides financial assistance to the part 2 program or is authorized by law to regulate its activities; or (ii) Any individual or entity who provides financial assistance to the part 2 program, which is a third-party payer covering patients in the part 2 program, or which is a quality improvement organization performing a utilization or quality control review. (c) Medicare, Medicaid, Children's Health Insurance Program (CHIP), or related audit or evaluation.	or which is a quality improvement organization performing a utilization or quality control review, or such individual's or entity's or quality improvement organization's contractors, subcontractors, or legal representatives. (2) Is determined by the part 2 program or other lawful holder to be qualified to conduct an audit or evaluation of the part 2 program or other lawful holder. (b) Copying, removing, downloading, or forwarding patient records. Records containing patient identifying information, as defined in § 2.11, may be copied or removed from ~~a~~ the premises of a part 2 program ~~premises~~ or other lawful holder or downloaded or forwarded to another electronic system or device from the part 2 program's or other lawful holder's electronic records by any individual or entity who: (1) Agrees in writing to: (i) Maintain and destroy the patient identifying information in a manner consistent with the policies and procedures established under § 2.16; (ii) Retain records in compliance with applicable federal, state, and local record retention laws; and (iii) Comply with the limitations on disclosure and use in paragraph (d) of this section; and (2) Performs the audit or evaluation on behalf of: (i) Any federal, state, or local governmental agency that ~~which~~ provides financial assistance to the part 2 program or other lawful holder, or is authorized by law to regulate ~~its~~ the activities of the part 2 program or other lawful holder; or (ii) Any individual or entity ~~who~~ which provides financial assistance to the part 2 program or other lawful holder, which is a third-party payer covering patients in the part 2 program, or which is a quality improvement organization performing a utilization or quality control review, or such individual's or	

Subject	**42 C.F.R. Part 2 (2017)**	**Supplemental Final Rule (2018)**: additions underlined; deletions strikethrough	**Relevant Guidance from the Preamble of the Supplemental Final Rule**
	(1) Patient identifying information, as defined in § 2.11, may be disclosed under paragraph (c) of this section to any individual or entity for the purpose of conducting a Medicare, Medicaid, or CHIP audit or evaluation, including an audit or evaluation necessary to meet the requirements for a Centers for Medicare & Medicaid Services (CMS)-regulated accountable care organization (CMS-regulated ACO) or similar CMS-regulated organization (including a CMS-regulated Qualified Entity (QE)), if the individual or entity agrees in writing to comply with the following: (i) Maintain and destroy the patient identifying information in a manner consistent with the policies and procedures established under § 2.16; (ii) Retain records in compliance with applicable federal, state, and local record retention laws; and (iii) Comply with the limitations on disclosure and use in paragraph (d) of this section. (2) A Medicare, Medicaid, or CHIP audit or evaluation under this section includes a civil or administrative investigation of a part 2 program by any federal, state, or local government agency with oversight responsibilities for Medicare, Medicaid, or CHIP and includes administrative enforcement, against the part 2 program by the government agency, of any remedy authorized by law to be imposed as a result of the findings of the investigation. (3) An audit or evaluation necessary to meet the requirements for a CMS-regulated ACO or similar CMS-regulated organization (including a CMS-regulated QE) must be conducted in accordance with the following:	<u>entity's or quality improvement organization's contractors, subcontractors, or legal representatives</u>. (c) Medicare, Medicaid, Children's Health Insurance Program (CHIP), or related audit or evaluation. (1) Patient identifying information, as defined in § 2.11, may be disclosed under paragraph (c) of this section to any individual or entity for the purpose of conducting a Medicare, Medicaid, or CHIP audit or evaluation, including an audit or evaluation necessary to meet the requirements for a Centers for Medicare & Medicaid Services (CMS)-regulated accountable care organization (CMS-regulated ACO) or similar CMS-regulated organization (including a CMS-regulated Qualified Entity (QE)), if the individual or entity agrees in writing to comply with the following: (i) Maintain and destroy the patient identifying information in a manner consistent with the policies and procedures established under § 2.16; (ii) Retain records in compliance with applicable federal, state, and local record retention laws; and (iii) Comply with the limitations on disclosure and use in paragraph (d) of this section. (2) A Medicare, Medicaid, or CHIP audit or evaluation under this section includes a civil or administrative investigation of a part 2 program by any federal, state, or local government agency with oversight responsibilities for Medicare, Medicaid, or CHIP and includes administrative enforcement, against the part 2 program by the government agency, of any remedy authorized by law to be imposed as a result of the findings of the investigation. (3) An audit or evaluation necessary to meet the requirements for a CMS-regulated ACO or similar CMS-regulated	

Subject	**42 C.F.R. Part 2 (2017)**	**Supplemental Final Rule (2018)**: additions underlined; deletions strikethrough	**Relevant Guidance from the Preamble of the Supplemental Final Rule**
	(i) A CMS-regulated ACO or similar CMS-regulated organization (including a CMS-regulated QE) must: (A) Have in place administrative and/or clinical systems; and (B) Have in place a leadership and management structure, including a governing body and chief executive officer with responsibility for oversight of the organization's management and for ensuring compliance with and adherence to the terms and conditions of the Participation Agreement or similar documentation with CMS; and (ii) A CMS-regulated ACO or similar CMS-regulated organization (including a CMS-regulated QE) must have a signed Participation Agreement or similar documentation with CMS, which provides that the CMS-regulated ACO or similar CMS-regulated organization (including a CMS-regulated QE): (A) Is subject to periodic evaluations by CMS or its agents, or is required by CMS to evaluate participants in the CMS-regulated ACO or similar CMS-regulated organization (including a CMS-regulated QE) relative to CMS-defined or approved quality and/or cost measures; (B) Must designate an executive who has the authority to legally bind the organization to ensure compliance with 42 U.S.C. 290dd-2 and this part and the terms and conditions of the Participation Agreement in order to receive patient identifying information from CMS or its agents;	organization (including a CMS-regulated QE) must be conducted in accordance with the following: (i) A CMS-regulated ACO or similar CMS-regulated organization (including a CMS-regulated QE) must: (A) Have in place administrative and/or clinical systems; and (B) Have in place a leadership and management structure, including a governing body and chief executive officer with responsibility for oversight of the organization's management and for ensuring compliance with and adherence to the terms and conditions of the Participation Agreement or similar documentation with CMS; and (ii) A CMS-regulated ACO or similar CMS-regulated organization (including a CMS-regulated QE) must have a signed Participation Agreement or similar documentation with CMS, which provides that the CMS-regulated ACO or similar CMS-regulated organization (including a CMS-regulated QE): (A) Is subject to periodic evaluations by CMS or its agents, or is required by CMS to evaluate participants in the CMS-regulated ACO or similar CMS-regulated organization (including a CMS-regulated QE) relative to CMS-defined or approved quality and/or cost measures; (B) Must designate an executive who has the authority to legally bind the organization to ensure compliance with 42 U.S.C. 290dd-2 and this part and the terms and conditions of the Participation Agreement in order to receive patient identifying information from CMS or its agents; (C) Agrees to comply with all applicable provisions of 42 U.S.C. 290dd-2 and this part;	

Subject	**42 C.F.R. Part 2 (2017)**	**Supplemental Final Rule (2018)**: additions underlined; deletions strikethrough	**Relevant Guidance from the Preamble of the Supplemental Final Rule**
	(C) Agrees to comply with all applicable provisions of 42 U.S.C. 290dd-2 and this part; (D) Must ensure that any audit or evaluation involving patient identifying information occurs in a confidential and controlled setting approved by the designated executive; (E) Must ensure that any communications or reports or other documents resulting from an audit or evaluation under this section do not allow for the direct or indirect identification (e.g., through the use of codes) of a patient as having or having had a substance use disorder; and (F) Must establish policies and procedures to protect the confidentiality of the patient identifying information consistent with this part, the terms and conditions of the Participation Agreement, and the requirements set forth in paragraph (c)(1) of this section. (4) Program, as defined in §2.11, includes an employee of, or provider of medical services under the program when the employee or provider is the subject of a civil investigation or administrative remedy, as those terms are used in paragraph (c)(2) of this section. (5) If a disclosure to an individual or entity is authorized under this section for a Medicare, Medicaid, or CHIP audit or evaluation, including a civil investigation or administrative remedy, as those terms are used in paragraph (c)(2) of this section, then a quality improvement organization which obtains the information under paragraph (a) or (b) of this section may disclose the information to that individual or entity but only for the purpose	(D) Must ensure that any audit or evaluation involving patient identifying information occurs in a confidential and controlled setting approved by the designated executive; (E) Must ensure that any communications or reports or other documents resulting from an audit or evaluation under this section do not allow for the direct or indirect identification (e.g., through the use of codes) of a patient as having or having had a substance use disorder; and (F) Must establish policies and procedures to protect the confidentiality of the patient identifying information consistent with this part, the terms and conditions of the Participation Agreement, and the requirements set forth in paragraph (c)(1) of this section. (4) Program, as defined in §2.11, includes an employee of, or provider of medical services under the program when the employee or provider is the subject of a civil investigation or administrative remedy, as those terms are used in paragraph (c)(2) of this section. (5) If a disclosure to an individual or entity is authorized under this section for a Medicare, Medicaid, or CHIP audit or evaluation, including a civil investigation or administrative remedy, as those terms are used in paragraph (c)(2) of this section, ~~then~~ the individual or entity may further disclose the patient identifying information that is received for such purposes to its contractor(s), subcontractor(s), or legal representative(s), to carry out the audit or evaluation, and a quality improvement organization which obtains ~~the~~ such information under paragraph (a) or (b) of this section may disclose the information to that individual or entity (or, to such individual's or entity's contractors, subcontractors, or legal representatives, but only for the purposes of this section ~~conducting a Medicare, Medicaid, or CHIP audit or evaluation~~).	

Subject	**42 C.F.R. Part 2 (2017)**	**Supplemental Final Rule (2018)**: additions underlined; deletions strikethrough	**Relevant Guidance from the Preamble of the Supplemental Final Rule**
	of conducting a Medicare, Medicaid, or CHIP audit or evaluation. (6) The provisions of this paragraph do not authorize the part 2 program, the federal, state, or local government agency, or any other individual or entity to disclose or use patient identifying information obtained during the audit or evaluation for any purposes other than those necessary to complete the audit or evaluation as specified in paragraph (c) of this section. (d) Limitations on disclosure and use. Except as provided in paragraph (c) of this section, patient identifying information disclosed under this section may be disclosed only back to the program from which it was obtained and used only to carry out an audit or evaluation purpose or to investigate or prosecute criminal or other activities, as authorized by a court order entered under § 2.66.	(6) The provisions of this paragraph do not authorize the part 2 program, the federal, state, or local government agency, or any other individual or entity to disclose or use patient identifying information obtained during the audit or evaluation for any purposes other than those necessary to complete the audit or evaluation as specified in paragraph (c) of this section. (d) Limitations on disclosure and use. Except as provided in paragraph (c) of this section, patient identifying information disclosed under this section may be disclosed only back to the <u>part 2</u> program <u>or other lawful holder</u> from which it was obtained and <u>may be</u> used only to carry out an audit or evaluation purpose or to investigate or prosecute criminal or other activities, as authorized by a court order entered under § 2.66.	