MEMORANDUM

To: National Association of ACOs

From: Dentons US LLP

Date: February 2, 2018

Subject: New SAMHSA Rulemaking and Its Potential Impact on Accountable Care Organizations

On January 3, 2018. the Substance Abuse and Mental Health Services Administration ("SAMHSA"), part of the U.S. Department of Health and Human Services ("HHS"), issued a final rule updating Confidentiality of Alcohol and Drug Abuse Patient Records regulations found at 42 C.F.R. Part 2 ("Part 2").[1] Part 2 limits the use and disclosure of patient identifying information obtained by federally-assisted substance use disorder programs ("Covered Information").[2] The final rule, which will become effective on February 2, 2018, marks the first substantive update to Part 2 since 1987.[3]

SAMHSA issued the new rule to respond to "significant changes" that have occurred within the U.S. health care system since 1987, including the development of integrated care models, electronic systems for the management and exchange of patient information, and reimbursement models that focus on performance metrics.[4]

The final rule makes several notable changes to Part 2, including (1) adding an abbreviated notice option to the prohibition on re-disclosure, (2) clarifying requirements for contractors, subcontractors, and legal representatives to use or disclose Covered Information, including the creation of new contractual requirements, and (3) expanding the type of entities whose Covered Information may be subject to audit and evaluation, as well as the parties who may perform such audits and evaluations. These changes, as well as their potential impact on accountable care organizations ("ACOs"), are discussed in more detail below.

Abbreviated Notice of Prohibition on Re-Disclosure

Under Part 2, any disclosure of Covered Information made with the patient's written consent must be accompanied with a written notice that re-disclosure is prohibited unless further disclosure is expressly permitted in the patient's written consent or otherwise permitted under Part 2.[5] Prior to the final rule, the notice originally required by Part 2 was rather lengthy, consisting of approximately 140 words (or 900 characters, with spaces).[6]

Under the final rule, Part 2 is revised to permit federally-assisted substance use disorder programs and other lawful holders of Covered Information to provide an abbreviated notice regarding Part

[1] 83 Fed. Reg. 239 (Jan 3, 2018).
[2] 42 C.F.R. §§ 2.2(a), 2.12.
[3] 83 Fed. Reg. at 239.
[4] 82 Fed. Reg. 6053 (Jan. 18, 2017).
[5] 42 CFR § 2.32(a).
[6] *See id.*

2's prohibition on re-disclosure.[7] SAMHSA provided the abbreviated notice option to address concerns about providing notice through electronic health record systems. Specifically, many electronic health record systems have a standard maximum character limit of 80 characters in the free text that may be used to transmit the notice required by Part 2.[8] As previously noted, the original notice required under Part 2 far exceeded this limit.

Contractors, Subcontractors, and Legal Representatives

As the health care industry has evolved, many lawful holders of Confidential Information have come to rely on agents and contractors to provide operational services such as independent auditing, legal services, claims processing, plan pricing , and other administrative functions. These services often require access to health data, including Covered Information.[9]

Prior to the final rule, Part 2 stated that a federally-assisted substance use disorder program may disclose Covered Information pursuant to a patient's written consent to individuals or entities identified in the consent.[10] While SAMHSA permitted contracted agents of individuals/entities to be treated as the individual/entity for purposes of the consent, many industry stakeholders expressed confusion about the application of Part 2 to contractors and subcontractors.[11]

To provide greater clarity, SAMHSA added new regulatory text to address the use and disclosure of Confidential Information by contractors, subcontractors, and legal representatives. Under the final rule, if a patient consents to a disclosure of their Covered Information for "payment" and/or "health care operations activities," the lawful holder of the Covered Information may further disclose the Covered Information as necessary for contractors, subcontractors, or legal representatives to carry out "payment" and/or "health care operations activities" on behalf of the lawful holder.[12] In the preamble to the final rule, SAMHSA provided several examples of payment and health care operations activities, including, *e.g.*, billing and claims management, clinical professional support service, patient safety activities, training, and business management and general administrative activities.[13] SAMHSA emphasized that these examples were meant to be illustrative, not exhaustive.[14]

SAMHSA also emphasized that payment and health care operations activities are *not* intended to encompass activities related to a patient's diagnosis, treatment, or referral for treatment, such as, *e.g.*, care coordination or care management.[15] It is noteworthy that SAMSHSA's definition of "health care operations" is different from that under HIPAA'S privacy rule in which "health care operations" is defined to include care coordination and care management. SAMHSA's rationale for this exclusion was that patients should have a choice about disclosing Covered Information to health care providers with whom they have direct contact.[16]

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[7] 83 Fed. Reg. at 240. The abbreviated notice states, "42 CFR part 2 prohibits unauthorized disclosure of these records." *Id.* at 251 (adding 42 C.F.R. § 2.32(a)(2)).
[8] 83 Fed. Reg. at 240.
[9] 82 Fed. Reg. at 6056.
[10] 42 C.F.R. § 2.33.
[11] 82 Fed. Reg. at 6056 ("We have previously clarified in responses to particular questions that contracted agents of individuals and/or entities may be treated as the individual/entity. Questions raised by commenters during this rulemaking have, however, highlighted varying interpretations of the current (1987) rule's restrictions on lawful holders and their contractors' and subcontractors' use and disclosure of part 2-covered data for purposes of carrying out payment, health care operations, and other health care related activities.")
[12] 83 Fed. Reg. at 251 (adding 42 C.F.R. § 2.33(b)).
[13] 83 Fed. Reg. at 243.
[14] *Id.*
[15] *Id.*
[16] *Id.*

Notably, the final rule also adds new regulatory provisions requiring a lawful holder of Covered Information to include specific provisions in its contracts with contractors, subcontractors, and legal representatives, if the lawful holder intends to engage any such party to carry out payment or health care operations that require the use or disclosure of Covered Information.[17] This provision is consistent with the HIPAA privacy rule's requirements for Business Associate Agreements. The contract must provide that the contractor, subcontractor, or legal representative is fully bound by Part 2, and require that the contractor, subcontractor, or legal representative implement appropriate safeguards to prevent unauthorized uses and disclosures of Covered Information and report any unauthorized uses, disclosures of breaches of Covered Information to the lawful holder.[18] The contractor, subcontractor, or legal representative also is required to limit its disclosures of Covered Information to the minimum necessary to perform its duties and not re-disclose Covered Information to a third party unless that third party is an agent who will only re-disclose the Covered Information back to the contractor or lawful holder.[19] SAMSHA declined to provide specific contractual language that lawful holders could use to meet these requirements, on the grounds of permitting flexibility in contract structuring.[20]

To permit law holders time to bring their contracts into compliance, SAMSA is delaying the compliance date of this contract requirement by two years, until February 1, 2020.[21] Moreover, SAMSHA stated that compliance with these contractual requirements is not required if lawful holders choose not to re-disclose Covered Information to contractors, subcontractors, or legal representatives.[22]

Audit and Evaluation Activities

The final rule also expands the type of entities whose Covered Information may be subject to audit and evaluation, as well as the parties who may perform such audits and evaluations.

Prior to the final rule, Part 2 permitted Covered Information held by federally-assisted substance use disorder programs to be accessed as part of an audit or evaluation performed on behalf of (1) a federal, state, or local government agency that provided financial assistance to such programs or that regulated such programs or (2) third-party payers or quality improvement organizations performing a utilization or quality control review.[23] SAMSHA revised Part 2 to provide that Covered Information held by other lawful holders also may be accessed as part of an audit or evaluation performed on behalf of (1) a federal, state, or local government agency that provides financial assistance to the lawful holder or regulates it or (2) third-party payers or quality improvement organizations performing a utilization or quality control review.[24]

Significantly, this expansion appears to allow ACOs to access Covered Information as part of an audit or evaluation. In the preamble to the final rule, SAMHSA suggested that, under the revised Part 2 regulations, an ACO could, *e.g.*, "evaluate the impact of integrated care on several participating behavioral health care programs' quality of care."[25]

The final rule also revised Part 2 to explicitly state that audits and evaluations could be performed by contractors, subcontractors, and legal representatives on behalf of third-party payers or quality improvement organizations.[26]

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[17] *Id.* at 251 (adding 42 C.F.R. § 2.33(c)).
[18] 83 Fed. Reg. at 251.
[19] *Id.*
[20] 83 Fed. Reg. at 245.
[21] *Id.* at 239, 244.
[22] *Id.* at 244.
[23] 42 C.F.R. § 2.53(a)(1), (b)(2).
[24] 83 Fed. Reg. at 252 (revising 42 C.F.R. § 2.53(a)(1), (b)(2)).
[25] 83 Fed. Reg. at 246.
[26] 83 Fed. Reg. at 252 (revising 42 C.F.R. § 2.53(a)(1)(ii), (b)(2)(ii)).

Potential Impact on ACOs

Many of the changes to Part 2 appear to reduce administrative burdens on ACOs and provide greater access to Covered Information as required for integrated care models. As previously noted, the changes to the Part 2 audit and evaluation regulations would appear to give ACOs greater access to Covered Information to assess, *e.g.*, quality of care and cost efficiencies. Moreover, the new abbreviated notice provisions in Part 2 should facilitate ACO's disclosure of Covered Information through electronic health record systems (by making notice therein easier to provide).

On the other hand, the new contractual requirements in Part 2 appear to create new compliance hurdles for ACOs and other lawful holders of Covered Information. ACOs would be well advised to review their relationships with contractors, subcontractors, and legal representatives to determine whether re-disclosure of Covered Information is anticipated and, if so, to revise the relevant services agreement to include the provisions now required under Part 2. ACOs may also wish to develop a template Part 2 agreement or addendum (akin to a HIPAA business associate agreement) that could be attached to services agreements on a go-forward basis.

It is also worth noting that this is not the last opportunity for ACOs and other stakeholders to provide input on Part 2 regulations. SAMSHA stated that it is contemplating future rulemaking for Part 2.[27] SAMSHA also stated that, as required by the 21st Century Cures Act, it would be convening a stakeholder meeting prior to March 21, 2018 to determine the effects of Part 2 on patient care, health outcomes, and patient privacy.[28] ACOs may wish to consider recommendations regarding Part 2 to make in anticipation of this meeting.

[27] *Id.*
[28] 83 Fed. Reg. at 248.