October 25, 2019

Elinore F. McCance-Katz, M.D., Ph.D.
Assistant Secretary
Substance Abuse and Mental Health Services Administration
Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

Re: Confidentiality of Substance Use Disorder Patient Records Proposed Rule (SAMHSA 4162-20)

Dear Dr. McCance-Katz:

The Healthcare Leadership Council (HLC) appreciates the opportunity to comment on (SAMHSA's) Confidentiality of Substance Use Disorder Patient Records Notice of Proposed Rulemaking (Proposed Rule).

HLC is a coalition of chief executives from all disciplines within American healthcare. It is the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century healthcare system that makes affordable high-quality care accessible to all Americans. Members of HLC – hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, laboratories, biotech firms, health product distributors, post-acute care providers, home care providers, and information technology companies – advocate for measures to increase the quality and efficiency of healthcare through a patient-centered approach.

HLC remains committed to aligning 42 CFR Part 2 (Part 2) with the Health Insurance Portability and Accountability Act (HIPAA) for the purposes of treatment, payment, and healthcare operations (TPO) to enable the appropriate exchange of necessary information for treatment and care coordination of individuals with substance use disorders (SUD). For the last 20 years, the HIPAA Privacy and Security Rules have engendered public trust and have been effective in protecting identifiable health information, including SUD information, collected by HIPAA covered entities.

We are pleased to see SAMHSA's proposals to update and clarify Part 2 regulations as part of the U.S. Department of Health and Human Services' (HHS) *Regulatory Sprint to Coordinated Care*. HLC offers the following comments on the Proposed Rule, as well

as broader policy changes that we believe are necessary and within SAMHSA's statutory authority.

Applicability and Re-Disclosure

HLC appreciates SAMHSA's efforts to facilitate coordination of care activities by non-Part 2 providers by clarifying the applicability of Part 2 to non-Part 2 providers and by affirming the ability of non-Part 2 providers to segregate records received from Part 2 programs to avoid rendering their own independent record keeping subject to Part 2. We believe that this clarification can reduce the burden on behalf of non-Part 2 providers and increase the potential for improved coordination of care for SUD patients. However, we ask SAMHSA for further clarification and guidance on the implementation of the proposed changes so that providers can assure compliance with the regulations. Additionally, SAMHSA should clarify whether the proposed changes apply to entities that receive information from Part 2 providers for non-treatment purposes such as health plans, business associates, and healthcare clearinghouses.

Consent Requirements

The Proposed Rule seeks to clarify that patients may consent to disclosures of Part 2 information to entities without a treating provider relationship and eliminates the requirement that written consent to disclosure contain the name of the specific individual as the recipient of the Part 2 record. HLC supports these changes and concurs that this change would reduce delays in patients receiving non-medical services and benefits which often address broader social determinants of health (e.g. housing, food insecurity, social support). We recommend that the final rule include additional categories or examples of non-medical services and benefits to clarify the entities to which this provision applies.

Disclosures Permitted with Written Consent

The Proposed Rule codifies a list of permissible activities that allow re-disclosures by lawful holders of Part 2 records to contractors, subcontractors, and legal representatives consistent with the purpose of the patient's original consent through which the Part 2 provider disclosed the Part 2 record to the lawful holder, for the purpose of *payment* and *health care operations*. Additionally, the Proposed Rule states that the list of permissible activities is not intended to cover *case management* or *care coordination* which SAMHSA interprets falls under "treatment, diagnosis, and referral."

As mentioned above, HLC supports aligning Part 2 with HIPAA for the purposes of TPO. We believe that SAMHSA has the statutory authority to align Part 2 more closely with HIPAA for the purposes of TPO. As outlined, 42 USC § 290dd-2 (the Confidentiality Statute) allows the Secretary of HHS to revise Part 2 regulations. The Confidentiality Statute states that the Secretary *"shall prescribe regulations to carry out the purposes of [Part 2]. Such regulations may contain such* ***definitions****, and may provide for such safeguards and procedures, including procedures and criteria for the*

issuance and scope of orders under subsection (b)(2)(C), ***as in the judgment of the Secretary are necessary or proper*** *to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith."* [1] Indeed, in the 2018 final rule (83 FR 241) SAMHSA determined that it has the authority to define *payment* and *health care operations* activities in 42 C.F.R. § 2.33(b), however *treatment* was not included in those activities. As granted by this previously exercised authority, we ask SAMHSA to reconsider its current interpretation of *care coordination* and *case management*.

HLC urges that SAMHSA include *care coordination* and *case management* under the definition of *health care operations* to align with HIPAA's Privacy Rule. We believe that this change would further reduce barriers to coordinated care by alleviating complex and multiple patient consent requirements while concurrently protecting patient privacy. Aligning Part 2 with HIPAA for the purposes of TPO will allow for more timely and accurate flow of SUD patient information to care coordinators and case managers who play an integral role in a patient's care.

Medical Emergencies

The Proposed Rule seeks to broaden the bona fide medical emergencies exception to include declared emergencies due to natural disasters that disrupt treatment facilities and service. HLC agrees that natural disasters can disrupt usual consent-based procedures and cut off access to a patient's usual provider, therefore we support this change as it can ensure patient access to urgently needed treatment to avoid adverse medical consequences.

Research

The Proposed Rule seeks to align Part 2 with HIPAA with regard to broadening the research exception to individuals or entities not covered by HIPAA or the Common Rule. HLC supports this change as it could allow researchers to conduct additional scientific and public health research on SUD care and SUD populations to bring further understanding in this area and to derive additional solutions to address the opioid crisis.

Audit and Evaluation

The Proposed Rule seeks to clarify and provides examples of permitted disclosures for audits and/or program evaluation without patient consent. HLC supports clarification of these provisions as they can resolve potential confusion and reduce administrative burdens.

Proposal for Education of Key Stakeholders

The steps taken by the Proposed Rule are important to clarify a complex and often misunderstood regulatory framework. It has been our experience that perception

[1] 42 U.S.C. §290dd-2(g).

routinely is not directly connected with reality about what the current version of Part 2 regulations state. The proposals you have put forward are an important step toward clarifying the current parameters of this rule. However, we urge SAMHSA to investigate the feasibility of undertaking a strategic education effort with interested parties to better familiarize stakeholders throughout the healthcare system of their rights and responsibilities under the ultimate final version of this proposal. We recommend this include patients, healthcare providers, substance abuse program administrators, law enforcement entities, and social service organizations.

Conclusion

While we are pleased to see SAMHSA's proposals to update Part 2, we ask that SAMHSA consider additional modifications within its authority to more closely align Part 2 with HIPAA. The details of SAMHSA's authority to make the modifications cited above and additional changes are enclosed in a legal memorandum prepared by Epstein Becker & Green, P.C. on behalf of The Association for Behavioral Health and Wellness. Thank you for your attention to this important matter. Should you have any questions, please contact Tina Grande at 202.449.3433 or tgrande@hlc.org.

Sincerely,

Mary R. Grealy
President

Enclosure: Legal Memorandum

ABHW
Advancing Health Care Policy
for Mental Health and Addiction

MEMORANDUM

To: The Association for Behavioral Health and Wellness

From: Epstein Becker & Green, P.C.

Date: October 21, 2019

Re: SAMHSA's Legal Authority to Expand the Scope of the Part 2 Regulations

This memorandum discusses efforts by the United States Department of Health and Human Services ("**HHS**"), Substance Abuse and Mental Health Services Administration ("**SAMHSA**") over the past several years to revise 42 C.F.R. Part 2 (the "**Part 2 Regulations**") in order to facilitate better coordination of care in treating people with substance use disorders ("**SUDs**") while maintaining confidentiality protections for SUD patient records ("**Part 2 Information**"). These efforts include the proposed revisions in the recently published 42 C.F.R. Part 2 Proposed Rule (the "**2019 Proposed Rule**").[1]

Despite these efforts, the legal basis for the Part 2 Regulations provides SAMHSA with broader authority than the Agency has as yet exercised and this authority would allow SAMHSA to make additional changes to the Part 2 Regulations in order to better achieve its stated goals. Specifically, under its current statutory authority at 42 U.S.C. § 290dd-2 (the "**Confidentiality Statute**"), SAMHSA could revise the regulatory restrictions on the disclosure and redisclosure of Part 2 Information in order to better align the Part 2 Regulations with the Health Insurance Portability and Accountability Act ("**HIPAA**") Privacy Rule. Implementing such revisions would enable SAMHSA to ensure effective compliance with the Part 2 confidentiality requirements, improve safeguards for information exchanged between Part 2 Programs and "qualified service organizations" ("**QSOs**"), and remove barriers to effective

[1] 84 Fed. Reg. 44,568 (Aug. 26, 2019).

case management and care coordination for patients with SUDs, things the Agency has yet to accomplish through its recent regulatory efforts.

Herein, we outline the specific additional changes to the Part 2 Regulations that SAMHSA could make under its current statutory authority, as described in the Confidentiality Statute. These additional changes include: (1) allowing for the disclosure and redisclosure of Part 2 Information for purposes of treatment, payment, and health care operations ("**TPO**"), as those terms are defined in the HIPAA Privacy Rule; (2) allowing for the disclosure and redisclosure of Part 2 Information for purposes of case management and care coordination under the definitions of either "health care operations" or QSOs; and/or (3) aligning the requirements for QSO agreements ("**QSOAs**") with the standards for Business Associate Agreements ("**BAAs**").

I. SAMHSA's Authority

The existing Confidentiality Statute authorizes the Secretary of HHS ("**the Secretary**") to promulgate regulations defining the ***extent, circumstances and purposes*** for which Part 2 Information may be ***disclosed with consent***. Specifically, the Confidentiality Statute states:

> The content of any record referred to in subsection (a) of this section may be disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed ***under regulations*** prescribed pursuant to subsection (g) of this section.[2]

The Confidentiality Statute also gives the Secretary the authority to prescribe regulations that, ***in the judgement of the Secretary***, "***are necessary or proper*** to effectuate the purposes of [Part 2], to prevent circumvention or evasion thereof, or to facilitate compliance therewith."[3]

Accordingly, SAMHSA, acting on behalf of the Secretary, has the statutory authority to promulgate regulations to effectuate, and facilitate compliance with, the Part 2 confidentiality requirements. The Confidentiality Statute does not dictate how

[2] 42 U.S.C. §290dd-2(b)(1) (emphasis added).

[3] 42 U.S.C. §290dd-2(g) (emphasis added).

patient consent be provided, the specific types of information that can or cannot be addressed through patient consent, or the purposes for which such information can be disclosed or redisclosed. Instead, Congress left these decisions to the discretion of the Secretary (through SAMHSA) to address through rulemaking. Indeed, in establishing the original written consent requirements and prohibitions on redisclosure, the Department of Health, Education and Welfare ("HEW", the predecessor to HHS), noted that this was "an exercise of the general rulemaking authority in subsection (g) of the authorizing legislation".[4] Further, in trying "to provide a reasonable protection against unauthorized disclosure of information disclosed with consent", HEW acknowledged the "difficulty" in determining how to apply the Part 2 Regulations to entities "whose records are not otherwise affected by this part" without raising "serious problems of legality, administrative feasibility, and fairness".[5] Accordingly, HEW made determinations on how to balance these concerns, and maintain the confidentiality of Part 2 Information, by implementing regulations related to the requirements for written consent and restrictions on redisclosure because Congress did not otherwise speak to these issues in the Confidentiality Statute.

The Confidentiality Statute also does not restrict the Secretary's ability to revise the Part 2 Regulations over time, as circumstances change. Rather, the Confidentiality Statute directs the Secretary to promulgate regulations as are "necessary and proper" in order to effectuate the purposes of Part 2, prevent circumvention or evasion of Part 2, or facilitate compliance with Part 2. Indeed, as the health care market, electronic health information systems and other aspects of health coverage and treatment continue to evolve, it is imperative for SAMHSA to ensure that the Part 2 Regulations similarly evolve in order to meet Congress's directive in the Confidentiality Statute.

In fact, under the Administrative Procedure Act, an agency may show that there are good reasons for a new policy which is reflected by a change in existing regulations.[6] In doing so, the agency need not demonstrate to a court's satisfaction that the reasons for the new policy are better than the reasons for the old one. It suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency believes it to be better, which the conscious change

[4] 40 Fed. Reg. 20,532 (May 9, 1975).

[5] *Id.*

[6] 5 U.S.C. §551 et seq.

of course adequately indicates.[7] Specifically, the U.S. Supreme Court has held that an agency does not need to blindly follow prior statutory interpretation or regulatory provisions. Here, SAMHSA does not need to maintain the existing restrictions under the Part 2 Regulations related to consent and/or redisclosure which have been identified as unduly burdensome and onerous, given that there are good reasons to implement new policies that would be permissible under the statute.

II. Disclosure and Redisclosure of Part 2 Information for Purposes of TPO

Lacking restrictive language, the Confidentiality Statute provides SAMHSA with the authority to better align the Part 2 Regulations with the HIPAA Privacy Rule by allowing for uses and disclosures of Part 2 Information with patient consent for purposes of treatment, payment and health care operations – TPO.[8]

Prior to 2018, the Part 2 Regulations provided for the disclosure of Part 2 Information solely subject to ***specific consent***, meaning that the consent had to identify the specific person or entity to whom the patient's records may be disclosed, the purpose of the disclosure, and the amount and kind of information to be disclosed.[9] In its January 3, 2018 final rule (the "**2018 Final Rule**"), [10] and in an effort to provide flexibility to those holding Part 2 Information, SAMHSA provided for disclosure of patients' records with ***general consent***. Specifically, SAMHSA identified circumstances under which lawful

[7] *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009).

[8] The existing statutory authority at 42 U.S.C. §290dd-2 allows for the promulgation of regulations that describe the extent, circumstances and purposes for which substance abuse treatment records may be disclosed with consent. Specifically, 42 U.S.C. §290dd-2(b)(1) states: "The content of any record referred to in subsection (a) of this section may be disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsection (g) of this section."

[9] *See e.g.*, 21 C.F.R §401.22, as originally defined in interpretive regulations issued by the Special Action Office for Drug Abuse Prevention in 1972 at 37 Fed. Reg. 24,637 (Nov. 17, 1972); 21 C.F.R §1401.21, as originally defined by the Special Action Office for Drug Abuse Prevention in 1973 at 38 Fed. Reg. 33,747 (Dec. 6, 1973); 42 C.F.R. §2.31, as defined in the 1975 Final Rule implementing regulations under 42 C.F.R. Part 2 at 40 Fed. Reg. 27,802 (Jul. 1, 1975); and 42 C.F.R. §2.31, as defined in the 1987 Final Rule implementing changes to the Part 2 Regulations at 52 Fed. Reg. 21,810 (Jun. 9, 1987).

[10] 83 Fed. Reg. 239 (Jan. 3, 2018).

holders of Part 2 Information and their legal representatives, contractors, and subcontractors could use and disclose patients' records subject to ***general consent***, providing more flexibility in the scope of individuals/entities that can receive Part 2 Information without being specifically listed on the consent form. However, SAMHSA restricted the purposes for which such Part 2 Information could be disclosed under general consent to be for ***purposes of payment and health care operations***. According to SAMHSA in the preamble of the 2018 Final Rule, SAMHSA stated its belief that "it is important to maintain patient choice in disclosing information to health care providers with whom patients have direct contact", and thereby limited the disclosures allowed for under general consent to only those for purposes of payment and health care operations and explicitly omitted disclosures for treatment and related activities under general consent.[11] Importantly, in finalizing this policy, SAMHSA did not state that its authority to allow for disclosures for treatment and related activities under general consent is limited by the Confidentiality Statute, because it is not so limited. On the flip side, in response to public comments related to allowing for disclosure to third parties (including lawful holders, contractors, subcontractors and legal representatives) under general consent, SAMHSA specifically stated that the Confidentiality Statute "authorizes SAMHSA to promulgate regulations to effectuate the confidentiality provisions governing substance use disorder patient records" and that "[t]he part 2 rule's applicability to third parties is a reasonable exercise of SAMHSA's statutory authority".[12] Accordingly, SAMHSA has chosen to exercise its authority to extend who is able to receive certain Part 2 Information subject to general consent, but SAMHSA has not extended the exercise of its authority to the type of information that can be disclosed to these third parties.

In choosing this approach, SAMHSA has created a complicated construct where certain Part 2 Information regarding an individual patient (e.g., treatment-related information) may only be disclosed with "specific consent" while other SUD information about that same patient (e.g., information related to payment and health care operations activities, as defined by SAMHSA) may be disclosed with "general consent". This dual construct is not required by the Confidentiality Statute. Instead, this is an approach that SAMHSA created and that it determined to be necessary to protect the confidentiality of Part 2 Information. However, in creating this dual construct, SAMHSA has created

[11] *Id*. at 243.

[12] *Id*. at 247.

more confusion with respect to the protection of Part 2 Information, thereby impeding rather than facilitating compliance with Part 2 (as required by the Confidentiality Statute).

The terms of the Confidentiality Statute are clear in prohibiting the use and disclosure of Part 2 Information for purposes of TPO ***without*** patient consent. However, SAMHSA has broad authority under the Confidentiality Statute to define the process for a patient to give consent and to articulate the purposes for which Part 2 Information can be disclosed. Thus, SAMHSA could allow patients to authorize, using general consent, disclosure for purposes of TPO (as those terms are defined in the HIPAA Privacy Rule). This would promote consistency and ease administrative burden for those entities that are subject to both Part 2 and HIPAA, by using the same construct for disclosures related to TPO for both Part 2 and non-Part 2 information.

III. Disclosure and Redisclosure of Part 2 Information for Purposes of Case Management and/or Care Coordination

A major concern of SAMHSA's current regulatory approach is the disconnect between the Part 2 Regulations and HIPAA with respect to disclosure and redisclosure of an individual's Part 2 Information for case management and/or care coordination. Indeed, SAMHSA noted that "[w]hen the regulations were written, substance abuse treatment was primarily conducted by specialty treatment providers, and as a result, the impact on coordination of care was not raised as a core issue."[13] However, even the first interpretive guidelines issued with respect to the Confidentiality Statute noted that "[w]hile the legislative history of section 408 [of the Drug Abuse Office and Treatment Act of 1972] makes clear the intent of Congress that patient records should not be used to the patients' disadvantage, from the Act read as a whole the intention is equally clear to encourage [] social and occupational rehabilitation …"[14] and the guidelines allowed for a patient to consent to the disclosure of his or her Part 2 Information for such purposes.

As described above, in the 2018 Final Rule, SAMHSA identified circumstances under which lawful holders of Part 2 Information and their legal representatives, contractors, and subcontractors may use and disclose patient records with ***general consent*** for purposes of payment and health care operations. SAMHSA

[13] 79 Fed. Reg. 26,930 (May 12, 2014).

[14] 37 Fed. Reg. 24,636 (Nov. 17, 1972).

determined that it had the authority to define payment and health care operations activities in 42 C.F.R. §2.33(b), but SAMHSA explicitly omitted treatment-related activities from those definitions. Instead, SAMHSA has chosen to maintain that ***specific consent*** is required for disclosures related to treatment, such as information about SUD patient diagnosis, treatment, or referral for treatment. Further, SAMHSA has chosen to redefine what "health care operations" are with respect to the disclosure of Part 2 Information. SAMHSA's approach to defining "health care operations" in a manner that is different from the HIPAA definition of "health care operations", i.e., to specifically exclude any activities included in the HIPAA definition of "health care operations" that SAMHSA considers to be related to treatment (such as case management and care coordination), was not required by the Confidentiality Statute and SAMHSA has the current authority to revise the Part 2 Regulations to alleviate the difficulties that have arisen from its current regulatory approach.

As discussed above, the most straightforward approach to resolving the concerns around case management and care coordination would be for SAMHSA to use its current statutory authority to allow for disclosures for TPO purposes (as those terms are defined in the HIPAA Privacy Rule) pursuant to the patient's general consent under 42 C.F.R. §2.33(b). In the alternative, SAMHSA could pursue one of the two options outlined below. Specifically, SAMHSA's current statutory authority would support SAMHSA revising the Part 2 Regulations to change the definition of "health care operations" under Part 2 to match the definition of "health care operations" included in the HIPAA Privacy Rule. Alternatively, SAMHSA's current statutory authority would support SAMHSA revising the definition of QSOs to support the disclosure of Part 2 Information for case management and care coordination purposes.

a. Option to Revise the Definition of "Health Care Operations"

The definition of "health care operations" under the HIPAA Privacy Rule encompasses such activities as case management and care coordination, which are currently excluded from SAMHSA's definition of "health care operations."

SAMHSA acknowledged, in the preamble to the 2018 Final Rule, that its definition of "health care operations" differs from the HIPAA Privacy Rule's definition of "health care operations." This is because it is SAMHSA's "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" and "[f]or 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."[15] However, in establishing the new definition of "health care operations", SAMHSA failed to reference HHS's position, as stated in the preamble to the HIPAA Privacy Rule, that there are distinctions between care coordination activities that are defined as "treatment"[16] and care coordination activities that are defined as "health care operations".[17] For example, HHS stated that "population-based activities related to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives, and related functions [] ***do not entail direct patient care***."[18] Further, HHS stated that "[a]ctivities often referred to as risk assessment, disease and case management are treatment activities ***only to the extent*** that they are services provided to a particular patient by a health care provider; ***population based analyses or records review for the purposes of treatment protocol development or modification are health care operations, not treatment activities***."[19]

Given that SAMHSA has the statutory authority to define the extent, circumstances and purposes for which Part 2 Information may be disclosed with general consent, in a manner that facilitates compliance with the Part 2 confidentiality requirements, SAMHSA could rely on the HIPAA Privacy Rule's definition of "health care operations" and still maintain its established position that care coordination activities with "a patient treatment component",[20] as defined in the

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[15] *Id*. at 243.

[16] "Treatment" is defined in the HIPAA Privacy Rule as "the provision, ***coordination***, ***or management of health care and related services*** by one or more health care providers, including the ***coordination or management of health care*** by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another." 45 C.F.R. §164.501 (emphasis added).

[17] "Health care operations" is defined in the HIPAA Privacy Rule to include "[c]onducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities; patient safety activities (as defined in 42 CFR 3.20); population-based activities relating to improving health or reducing health care costs, protocol development, ***case management and care coordination***, contacting of health care providers and patients with information about treatment alternatives; and ***related functions that do not include treatment***; …". 45 C.F.R. §164.501 (emphasis added).

[18] 65 Fed. Reg. 82,490 (Dec. 28, 2000) (emphasis added).

[19] *Id*. at 82,498 (emphasis added).

[20] *See* 82 Fed. Reg. 6,066 (Jan. 18, 2017).

HIPAA Privacy Rule, should be subject to specific consent. Although under this option SAMHSA would not be using the full extent of its statutory authority to allow for disclosures for TPO purposes pursuant to the patient's general consent, this option would still allow for better alignment of the Part 2 Regulations with the HIPAA Privacy Rule. Specifically, this revision to the definition of "health care operations" included in the Part 2 Regulations would allow for better care coordination for patients with SUDs under the purview of the Part 2 consent provisions, while also promoting consistency in the definition of "health care operations" for those entities that are subject to both Part 2 and HIPAA, thereby easing the administrative burden that those entities would otherwise face if they have to continue to distinguish which definition of "health care operations" applies to various patient records.

b. Option to Revise the Definition of QSOs

In order to facilitate the operational needs of Part 2 Programs, the Part 2 Regulations promulgated by HEW in 1975 allowed for the disclosure of Part 2 Information to QSOs without the need for patient consent.[21] In general, QSOs are entities that provide business and other support services to Part 2 Programs. The exception to patient consent requirements for such entities was created by regulation and is not specifically required by the Confidentiality Statute.

In the 1975 final rule, HEW originally defined QSOs at §2.11(n) as:

> a service organization which has entered into a written agreement with a program pursuant to which the service organization—(1) acknowledges that in receiving, storing, processing, or otherwise dealing with any information from the program about patients in the program, it is fully bound by the provisions of this part; (2) undertakes to institute appropriate procedures for safeguarding such information, with particular reference to patient identifying information; and (3) undertakes to resist in judicial proceedings any efforts to obtain access to information pertaining to patients otherwise than as expressly provided for in this part.[22]

[21] *See* 40 Fed. Reg. 20,522 (May 9, 1975); 40 Fed. Reg. 27,802 (Jul. 1, 1975).

[22] 40 Fed. Reg. at 27,805.

Further, the final rule clarified in §2.11(p) that "[t]he following types of communications ***do not constitute disclosures of records***: … Communications between a program and a [QSO] of ***information needed by the organization to perform its services*** to the program."[23]

The final rule also stated the following with respect to communications between a Part 2 Program and a QSO:

> Section 2.11(p) is intended to clarify the status of communications which are carried on within a program or between a program and ***persons or organizations which are assisting it in providing patient care***. ***The authorizing legislation was not intended to prohibit programs from carrying on accepted practices in terms of obtaining specialized services from outside organizations.*** In conjunction with the definition of qualified service organizations, set forth in §2.11(n), the provisions of §2.11(p) should prevent the development of abuses in this area.[24]

Accordingly, HEW created the concept of QSOs via rulemaking, and implemented safeguards to allow for such entities to continue "***accepted practices***" to assist Part 2 Programs in ***providing patient care*** in the Part 2 Regulations.

SAMHSA has revised the definition of a QSO over time, as changes in the market have evolved, so that the definition reflects the types of services that QSOs currently provide to Part 2 Programs. In its January 18, 2017 final rule (the "**2017 Final Rule**"), SAMHSA revised the definition of a QSO to include population health management in the list of examples of services a QSO may provide.[25] Accordingly, the current definition of a QSO defines the services that a QSO may provide to include "data processing, bill collecting, dosage preparation, laboratory analyses, or legal, accounting, ***population health management***, medical staffing, or other professional services, or services to prevent or treat child abuse or neglect, including training on nutrition and child care and individual and group therapy".[26]

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[23] *Id*. (emphasis added).

[24] *Id*. at 27,806 (emphasis added).

[25] 82 Fed. Reg. 6,066 (Jan. 18, 2017).

[26] 42 C.F.R. §2.11 (emphasis added).

Given that QSOs were created ***through regulation*** rather than through legislation, SAMHSA has the authority to further refine ***through rulemaking*** how such entities are defined and the services that they are permitted to provide for Part 2 Programs. In particular, SAMHSA could refine the definition of QSOs in the Part 2 Regulations to allow for QSOs to provide services to both Part 2 Programs and legal holders of Part 2 Information pursuant to a QSOA. Further, SAMHSA could refine the definition of QSOs to include case management and/or care coordination in the list of services a QSO may provide. Such revisions would allow for the disclosure of Part 2 Information between a Part 2 Program, or legal holders of Part 2 Information, and a QSO for purposes of care management and/or care coordination services furnished by the QSO. SAMHSA has previously considered making such a change.[27]

IV. Aligning the Requirements for QSOAs with the Standards for BAAs

As discussed above, given that QSOs were created through regulations rather than through legislation, SAMHSA has the authority to further refine through rulemaking how such entities operate in order to require better protections for the Part 2 Information utilized by a QSO. In particular, SAMHSA could refine the Part 2 Regulations in a number of ways to better align the Part 2 Regulations with the HIPAA Privacy Rule. For example, SAMHSA could revise the requirements for QSOAs as follows:

(1) Allow QSOAs to be multi-party agreements for the multi-directional sharing of information covered under the Part 2 Regulations. The multi-party agreement could establish a baseline of collective responsibilities for ensuring privacy of the disclosed information while enabling better care coordination and population health management.

(2) Align the requirements for a QSOA with the requirements for a BAA under HIPAA. A business associate is a person other than a member of the covered entity's workforce who performs a function or activity on

[27] "SAMHSA is analyzing the regulations to identify options for allowing Part 2 data to flow to health care entities for the purpose of care coordination and population management while maintaining patient protections. One potential solution includes expanding the definition of a qualified service organization (QSO; § 2.11) to explicitly include care coordination services and to allow a QSO Agreement (QSOA) to be executed between an entity that stores Part 2 information, such as a payer or an ACO that is not itself a Part 2 program, and a service provider." 79 Fed. Reg. 26,931 (May 12, 2014).

> behalf of a covered entity involving the use or disclosure of protected health information ("**PHI**"). The HIPAA Privacy Rule states that "[a] covered entity may disclose [PHI] to a business associate and may allow a business associate to create, receive, maintain, or transmit [PHI] on its behalf, if the covered entity obtains satisfactory assurance that the business associate will appropriately safeguard the information." [28] Further, "[a] business associate may disclose [PHI] to a business associate that is a subcontractor and may allow the subcontractor to create, receive, maintain, or transmit [PHI] on its behalf, if the business associate obtains satisfactory assurances … that the subcontractor will appropriately safeguard the information."[29]

Based on HEW's original construct that QSOs are allowed to continue "accepted practices" to assist in the provision of patient care, SAMHSA has the authority to revise the manner in which QSOAs are used, to expand the ability of QSOs to provide case management and/or care coordination services, in line with how business associates are utilized under the HIPAA Privacy Rule. The standards for BAAs are well-established and robust, and applying these standards to QSOAs would bolster the protections afforded to Part 2 Information utilized by a QSO to perform services for a Part 2 Program.

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[28] 45 C.F.R. §164.502(e)(1).

[29] 45 C.F.R. §164.502(e)(2).