Partnership to Amend 42 CFR Part 2 Meeting at OMB
August 1, 2019

Organizations and individuals

- America's Health Insurance Plans (AHIP)- Jeanette Thornton
- American Hospital Association (AHA)- Priscilla Ross, Kristina Weger
- American Psychiatric Association (APA)- Michelle Dirst
- Association for Behavioral Health and Wellness (ABHW)- Pamela Greenberg and Kate Romanow
- Hazelden Betty Ford Foundation- Emily Piper
- Mental Health America (MHA)- Madeline Reinert
- National Association of Medicaid Directors (NAMD)- Jack Rollins
- National Alliance on Mental Illness (NAMI)- Andrew Sperling
- Netsmart- Al Guida
- National Governors Association (NGA)- Maribel Ramos

PARTNERSHIP TO AMEND 42 CFR PART 2

A COALITION OF NEARLY 50 HEALTH CARE STAKEHOLDERS COMMITTED TO ALIGNING 42 CFR PART 2 (PART 2) WITH HIPAA FOR TREATMENT, PAYMENT, AND HEALTH CARE OPERATIONS (TPO) TO ALLOW APPROPRIATE ACCESS TO PATIENT INFORMATION THAT IS ESSENTIAL FOR PROVIDING WHOLE-PERSON CARE.

The undersigned organizations agree on the following:

- Part 2 provisions are not compatible with the way health care is delivered currently.
- Access to a patient's entire medical record, including addiction records, ensures that health care professionals have all the information necessary for safe, effective, high quality treatment and care coordination that addresses all of a patient's health needs.
- Failure to integrate services and supports can lead to risks and dangers to individual patients, such as contraindicated prescription medicines and problems related to medication adherence.
- Obtaining multiple consents from a patient is challenging and creates barriers to whole-person, integrated approaches to care that have proven to produce the best outcomes for our patients.
- Part 2 requirements should be aligned fully with the HIPAA requirements that allow the use and disclosure of patient information for **treatment, payment, and health care operations (TPO).**
- Health care professionals, insurers, and others who receive basic health information through a health information exchange or a shared electronic health record should not use this information to discriminate against patients regarding quality of care, payment of covered services, or access to care.
- Part 2 information should not be disclosed for non-treatment purposes to law enforcement, employers, divorce attorneys, or others seeking to use the information against the patient, which the HIPAA privacy framework already easily accommodates. Existing penalties for unauthorized release and use of confidential medical information should apply.
- In the 116th Congress, we support H.R. 2062, the Overdose Prevention and Patient Safety Act (OPPS Act) and S. 1012, the Protecting Jessica Grubb's Legacy Act. Both bills align Part 2 with HIPAA for the purposes of TPO, while strengthening protections against the use of addiction records in criminal proceedings.

Academy of Managed Care Pharmacy · Alliance of Community Health Plans · American Association on Health and Disability · American Dance Therapy Association · American Health Information Management Association · American Hospital Association · American Psychiatric Association · American Society of Addiction Medicine · American Society of Anesthesiologists · America's Essential Hospitals · America's Health Insurance Plans · AMGA · Association for Ambulatory Behavioral Healthcare · Association for Behavioral Health and Wellness · Association for Community Affiliated Plans · Association of Clinicians for the Underserved · Blue Cross Blue Shield Association · The Catholic Health Association of the United States · Centerstone · College of Healthcare Information Management Executives · Confidentiality Coalition · Corporation for Supportive Housing · Employee Assistance Professionals Association · Global Alliance for Behavioral Health and Social Justice · Hazelden Betty Ford Foundation · Healthcare Leadership Council · InfoMC · The Joint Commission · The Kennedy Forum · Medicaid Health Plans of America · Mental Health America · National Alliance on Mental Illness · National Association for Behavioral Healthcare · National Association for Rural Mental Health · National Association of ACOs · National Association of Addiction Treatment Providers · National Association of Counties · National Association of County Behavioral Health and Development Disability Directors · National Association of State Mental Health Program Directors · National Rural Health Association · Netsmart · OCHIN · Opioid Safety Alliance · Otsuka America Pharmaceutical, Inc. · Patient-Centered Primary Care Collaborative · Pharmaceutical Care Management Association · Premier Healthcare Alliance · Smiths Medical · Strategic Health Information Exchange Coalition

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June 1, 2019

EPSTEIN
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MEMORANDUM

To: Pamela Greenberg
Association for Behavioral Health and Wellness

From: Epstein Becker & Green, P.C.

Date: March 26, 2019

Re: Modifications to 42 C.F.R. Part 2 to Align More Closely with HIPAA

Pursuant to your request, we have reviewed the memorandum you provided that was drafted by Gerald (Jud) E. DeLoss, Gozdecki Del Giudice on March 13, 2019 (the "DeLoss Memorandum") identifying certain revisions that the United States Department of Health and Human Services ("HHS"), Substance Abuse and Mental Health Services Administration ("SAMHSA") could make to 42 C.F.R. Part 2 (the "Part 2 Regulations") to allow for less restrictive disclosure and redisclosure of substance use disorder patient records ("Part 2 Information") for treatment, payment, and health care operations purposes through the use of a generalized consent or an "opt out" process. Herein, we outline additional changes to the Part 2 Regulations, beyond those identified in the DeLoss Memorandum, which we believe HHS/SAMHSA also could make under its current statutory authority at 42 U.S.C. § 290dd-2 (the "Confidentiality Statute"). These additional changes include (1) allowing for the disclosure and redisclosure of Part 2 Information for purposes of case management and/or care coordination under the definitions of either "health care operations" or "qualified service organizations" ("QSOs"); and (2) aligning the requirements for QSO agreements ("QSOAs") with the standards for Business Associate Agreements ("BAAs"). The purpose of these additional changes would be to better align the Part 2 Regulations with the Health Insurance Portability and Accountability Act ("HIPAA") Privacy Rule in order to ensure effective compliance with the Part 2 confidentiality requirements, to improve safeguards for information exchanged between Part 2 Programs and QSOs, and to remove barriers to effective case management and care coordination for patients with substance use disorders.

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."[1] Further, the Confidentiality Statute gives the Secretary the authority to prescribe regulations that, ***in the judgement of the***

[1] 42 U.S.C. §290dd-2(b)(1).

Secretary, "*are necessary or proper* to effectuate the purposes of [Part 2], to prevent circumvention or evasion thereof, or to facilitate compliance therewith."[2]

Accordingly, SAMHSA, acting on behalf of the Secretary, has the statutory authority to promulgate regulations to effectuate the purposes of, and facilitate compliance with, the Part 2 confidentiality requirements. We discuss below ways in which SAMHSA could revise the Part 2 Regulations through rulemaking in order to (1) allow for the disclosure and redisclosure of Part 2 Information for purposes of case management and/or care coordination by revising the definitions of either "health care operations" or "QSOs", and (2) to align the requirements for QSOAs with the standards for BAAs in order to improve safeguards for information exchanged between Part 2 Programs and QSOs.

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

a. Option 1: Revise the Definition of "Health Care Operations"

In its January 3, 2018 final rule making changes to the Part 2 Regulations,[3] SAMHSA identified circumstances under which lawful holders of covered records and their legal representatives, contractors, and subcontractors may use and disclose patient identifying information with general consent for purposes of payment and health care operations. SAMHSA determined that it had the authority to define payment and health care operations activities but explicitly omitted treatment and related activities from that definition. SAMHSA specified that the categories of payment and health care operations activities referenced in 42 C.F.R. §2.33 and listed in the preamble of the final rule were not intended to encompass substance use disorder patient diagnosis, treatment, or referral for treatment. SAMHSA chose to expressly exclude case management and care coordination from the categories of "payment and health care operations", as referenced in 42 C.F.R. §2.33 and listed in the preamble of the final rule. In making this decision, SAMHSA emphasized the importance of maintaining patient choice, by collecting specific prospective consent to disclose information to health care providers with whom patients have direct contact. Therefore, SAMHSA determined that disclosures to contractors, subcontractors, and legal representatives are not permitted with only general consent for activities related to a patient's diagnosis, treatment, or referral for treatment, to include case management and care coordination.

In adopting changes in the final rule to allow for use and disclosure of Part 2 Information with general consent for purposes of payment and health care operations, SAMHSA acknowledged in the preamble that it was not adopting the HIPAA Privacy Rule's definition of "health care operations", which includes such activities as case management and care coordination. However, SAMHSA did not mention the distinction that HHS made under the HIPAA Privacy Rule between elements of care coordination that are considered "treatment"[4] and those that are considered

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[2] 42 U.S.C. §290dd-2(g).

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

[4] "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*

"health care operations."[5] For example, in the regulations adopting the HIPAA Privacy Rule, 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."[6] 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."[7]

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 has the authority to further refine the definition of payment and health care operations activities, as referenced in 42 C.F.R. §2.33 and listed in the preamble of the final rule, without the need for an amendment to the Confidentiality Statute. SAMHSA could maintain its established position that "care coordination has a patient treatment component",[8] while still allowing for better alignment of the Part 2 Regulations with the HIPAA Privacy Rule by relying on the HIPAA Privacy Rule's definition of "health care operations", which already incorporates a distinction between case management and care coordination services that constitute "health care operations" versus such services that constitute "treatment".[9] This would allow for better care coordination for patients with substance use disorders 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 face when having to determine which definition of "health care operations" applies in various circumstances.

b. Option 2: Revision to the Definition of QSOs

The Part 2 Regulations promulgated by the Department of Health, Education and Welfare ("HEW", the predecessor to HHS) in 1975 allowed for the disclosure of Part 2 Information to

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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.

[5] "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.

[6] 65 Fed. Reg. 82,490 (Dec. 28, 2000).

[7] *Id.* at 82,498.

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

[9] While SAMHSA has declined to do so in the past, SAMHSA could use the same statutory authority described above to allow for the use and disclosure of treatment, payment, and health care operations, in line with the HIPAA Privacy Rule, under the general consent provisions.

QSOs without the need for patient consent.[10] The exception for such entities was created by regulation and is not specifically delineated by the Confidentiality Statute.

> In the 1975 final rule, HEW originally defined QSOs at §2.11(n) as follows:
>
> > 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.[11]

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."[12]

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.[13]

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

The current definition of a QSO has evolved to more specifically define the types of services that a QSO provides to a Part 2 Program. In its January 18, 2017 final rule making changes to the Part 2 Regulations, SAMHSA revised the definition of a QSO to include population health management in the list of examples of services a QSO may provide.[14] 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

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

[11] 40 Fed. Reg. at 27,805.

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

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

[14] 82 Fed. Reg. 6,066 (Jan. 18, 2017).

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".[15]

Given that QSOs were created through regulations 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 explicitly include case management and/or care coordination services in such definition. Such a revision would allow for the disclosure of Part 2 Information between a Part 2 Program and a QSO for purposes of care management and/or care coordination services furnished by the QSO for the Part 2 Program. SAMHSA has previously considered making such a change,[16] and could do so again by distinguishing between case management and care coordination services that are more akin to "population health management" versus such services that constitute "treatment".

III. 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 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."[17] Further, "[a] business associate may disclose [PHI] to a business associate that is a subcontractor and may allow the

[15] 42 C.F.R. §2.11.

[16] "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).

[17] 45 C.F.R. §164.502(e)(1).

> 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."[18]

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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[18] 45 C.F.R. §164.502(e)(2).

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Legal Analysis of 42 U.S.C. § 290dd-2 and Ability to Modify 42 C.F.R. Part 2 to Align More Closely with HIPAA

Gerald (Jud) E. DeLoss
Gozdecki Del Giudice
Chicago, IL

March 13, 2019

We have conducted research to determine whether, based on existing statutory language, legislative history, and Congressional intent, 42 U.S.C. § 290dd-2 ("Confidentiality Statute"), the United States Department of Health and Human Services ("HHS"), Substance Abuse and Mental Health Services Administration ("SAMHSA") could amend 42 C.F.R. Part 2 ("Part 2") to allow for less restrictive disclosure and redisclosure of substance use disorder patient records ("Part 2 Information") without amending the Confidentiality Statute. Specifically, whether, based on the existing language of the Confidentiality Statute, HHS/SAMHSA could amend Part 2 to allow patients to execute a general consent to permit disclosure and redisclosure of Part 2 Information for treatment, payment, and health care operations purposes, as each of those terms is defined under the Health Insurance Portability and Accountability Act of 1996 and the regulations promulgated thereunder ("HIPAA"). This proposal would be similar to that proposed under H.R. 6082, the Overdose Prevention and Patient Safety Act or similar legislation that is expected to be introduced during this session ("H.R. 6082").[1] H.R. 6082 would have permitted the disclosure of Part 2 Information to HIPAA covered entities or Part 2 programs for treatment, payment, and health care operations, without a consent executed by the patient.

I. SHORT ANSWER

We believe that HHS/SAMHSA could amend Part 2 to permit the exchange of Part 2 Information for treatment, payment, and health care operations purposes among Part 2 programs and HIPAA covered entities. This modification to Part 2 would be similar to that proposed under H.R. 6082 and could be carried out by HHS/SAMHSA without an amendment to the Confidentiality Statute. While HIPAA permits the disclosure of protected health information for treatment, payment, and health care operations purposes without a consent or authorization, the Confidentiality Statute currently requires a consent in most cases for those purposes. We believe that the Confidentiality Statute would not prohibit HHS/SAMHSA from amending Part 2 to align more closely with HIPAA by allowing the patient to execute either: (1) a consent that would "opt out" the patient from the ability of Part 2 programs or HIPAA covered entities to share Part 2 information for treatment, payment, and health care operations purposes; or (2) a generalized consent that would authorize both disclosures and redisclosures of Part 2 Information for

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[1] H.R.6082 - Overdose Prevention and Patient Safety Act, 115th Congress (2017-2018).

treatment, payment, and health care operations purposes to HIPAA covered entities and Part 2 programs.

Currently, Part 2 imposes a barrier to the sharing of Part 2 Information primarily as a result of the stringent consent provision requiring the recipient(s) to be identified in detail as well as the prohibition against redisclosure of Part 2 Information without specific consent. Based upon our review of the Confidentiality Statute and its legislative history, we do not believe that these specific restrictions contained in Part 2 are mandated by the Confidentiality Statute. As such, we believe that HHS/SAMHSA may be able to amend Part 2 to modify or remove the restrictions thereby reducing or removing barriers for Part 2 programs and HIPAA covered entities to share Part 2 Information for treatment, payment, and health care operations purposes.

Congress has expressed its intent, as set forth in the Committee Reports described below, that Part 2 Information only be disclosed as provided under the Confidentiality Statute. The Confidentiality Statute does not expressly impose a redisclosure prohibition and does not specify the unique criteria of a valid consent to the extent or degree that Part 2 currently requires. HHS/SAMHSA, and not Congress, has imposed different and more stringent requirements over time without an express requirement to do so set forth in the Confidentiality Statute. Part 2 could be modified to remove these agency-imposed restrictions based upon HHS/SAMHSA's interpretation and application of the Confidentiality Statute. This action would be consistent with federal agency law that allows an agency, such as HHS/SAMHSA, to change its longstanding policy as long as the new policy is permissible under the statute, there are good reasons for the policy change, and the agency believes the new policy to be better.

II. ANALYSIS

The current version of the Confidentiality Statute provides as follows:

> Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to substance abuse education, prevention, training, treatment, rehabilitation, or research, which is conducted, regulated, or directly or indirectly, assisted by any department or agency of the United States shall, except as provided in subsection (e) of this section, be confidential and be disclosed only for the purposes and under the circumstances expressly authorized by subsection (b) of this section.[2]

Under the Confidentiality Statute, the content of any such record may be disclosed in accordance with the prior written consent of the patient but only to such extent, under such circumstances,

[2] 42 U.S.C. § 290dd-2(a).

and for such purposes as may be allowed under regulations issued by HHS/SAMHSA.[3] The Confidentiality Statute allows HHS/SAMHSA to:

> [P]rescribe regulations to carry out the purposes of this section ... 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) of this section, ***as in the judgment of the Secretary*** are necessary or proper to effectuate the purposes of this section...[4]

Currently, Part 2 imposes stringent requirements for consents. As written, the consent criteria impose a requirement that the names of the recipients be individually listed.[5] However, as will be discussed further below, HHS/SAMHSA recently modified this provision (without any amendment to the Confidentiality Statute) to allow for disclosures via a general designation of an individual or entity participant(s) or class of participants who have a treating provider relationship with the patient.[6]

In addition, currently Part 2 prohibits redisclosure of Part 2 Information absent specific patient consent to that redisclosure. HHS/SAMHSA has stated that one consent may authorize disclosure to an initial recipient and redisclosure to an additional recipient(s) if so indicated in the consent.[7] This interpretation was adopted by HHS/SAMHSA in 1987, when Part 2 was modified (without amendment to the Confidentiality Statute).

In order to determine whether Congress intended to mandate the consent criteria and specifically prohibit redisclosure of Part 2 Information as set forth in Part 2, we researched and conducted an extensive analysis of the legislative history of the Confidentiality Statute back to its origins in the 1970s. Except as noted below, but for a few changes in the scope of the Confidentiality Statute (such as covering "substance abuse", "alcoholism", and then "substance use disorders"), and allowing HHS/SAMHSA to promulgate regulations to carry out the intent of the Confidentiality Statute (early 1970s), there have been few new statutory restrictions or expansions of the scope of disclosure of Part 2 Information.

A. Legislative History of 42 U.S.C. § 290dd-2 and Congressional Intent.

The Confidentiality Statute itself contains no express prohibition on redisclosure of substance use disorder records and there are no specific requirements set forth relating to the type of or elements of a consent. Below we provide a summary of the earlier versions of the Confidentiality

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[3] 42 U.S.C. § 290dd-2(b)(1).
[4] 42 U.S.C. § 290dd-2(g), (emphasis added).
[5] 42 C.F.R. § 2.31(a)(4)(i).
[6] 42 C.F.R. § 2.31(a)(4)(iii)(3).
[7] 52 Fed. Reg. 21,651, 21,800 (June 9, 1987).

Statute, from 1970 to 1998 and relevant substantive modifications, if any. There have not been any substantive changes to the Confidentiality Statute relating to Part 2 information since 1998, which is the version that is currently in effect.

1970 and 1972

The Confidentiality Statute was originally authorized by the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 and the Drug Abuse Prevention, Treatment, and Rehabilitation Act of 1972.[8] These two laws were consolidated in 1992 in the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act.[9] The statute, codified at 42 U.S.C. § 290dd-2, required the Secretary to promulgate regulations that: (1) require the written consent of the patient to disclose SUD treatment records; and (2) prevent, absent a court order, SUD treatment records from being acquired and used by law enforcement to investigate or prosecute a patient.

In 1972, the Drug Abuse Office and Treatment Act of 1972[10], Section 408, applied to "drug abuse prevention functions" and allowed disclosures of the "records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any drug abuse prevention program" only under two circumstances if the patient gave consent. A patient could consent to the release of records to: "(A) medical personnel for the purpose of diagnosis or treatment of the patient, and (B) to governmental personnel for the purpose of obtaining benefits to which the patient is entitled."[11]

Congress issued a House Committee Report on January 26, 1972 which is illustrative of intent with respect to disclosure of Part 2 Information under the governing statute. Specifically, the House Committee Report stated:

> The conferees wish to stress their conviction that the strictest adherence to the provisions of [the Confidentiality Statute] is absolutely essential to the success of all drug abuse prevention programs. Every patient and former patient must be assured that his right to privacy will be protected. Without that assurance, fear of public disclosure of drug abuse or of records that will attach for life will discourage thousands from seeking the treatment they must have if this tragic national problem is to be overcome. Every person having control over or access to patients' records must

[8] 42 U.S.C. Ch. 60: Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation program, in 21.
[9] Public Law 102-321 dated July 10, 1992, § 543.
[10] *See* Public Law 92-255 dated March 21, 1972, § 408.
[11] *See* § 408(b)(1)(A)-(B).

> understand that disclosure is permitted only under the circumstances and conditions set forth in this section.[12]

The statute, as in effect in 1972, did not specify the elements of a valid consent. Congress did not express an intent as to the type of or elements of a valid consent. Congress did state that every person having control or access to patients' records must understand that disclosure is only permitted as specified in the Confidentiality Statute. We interpret this comment to indicate that disclosures under the Confidentiality Statute would only be permitted pursuant to the statutory requirement then imposed under the Confidentiality Statute, which permitted a patient to consent to disclosure of Part 2 Information to medical personnel and to governmental personnel.

1974

In 1974, Congress changed the wording of the Confidentiality Statute such that the statute now protected "any records of the identity, diagnosis, prognosis, or treatment of any patient maintained in connection with the performance of any program or activity relating to alcoholism or alcohol abuse education, training, treatment, rehabilitation, or research..."[13] The Confidentiality Statute, as written in 1974, required that these records "be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b) of this section." (which included a requirement of patient consent).[14] Further, in the 1974 version of the Confidentiality Statute, Congress expanded the scope and permitted disclosure of such records if the patient gave prior written consent ... but only to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsection (g)..."[15] Congress thereby granted HHS/SAMHSA new authority to promulgate regulations for the disclosure of Part 2 Information.

The 1974 version of the Confidentiality Statute is almost identical in all other aspects to the current version except that the outlined prohibitions did not apply to any exchange of records "within the Armed Forces" in subsection (e)(1) and (2), and specified a monetary penalty for violation in subsection (f).[16]

A Senate Report issued on June 13, 1973 ("Senate Report") confirms that the Congressional intent has remained the same as in 1972. Specifically, the Senate Report states:

> [R]ecords of clients in any federally conducted, regulated, or assisted alcoholism program are to be confidential and may be disclosed only under the circumstances and for the purposes stated in this section. Under regulations authorized by the section,

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[12] H.R. Rep. 92-775 at 2072.
[13] *See* Public Law 93-282 (1974).
[14] Public Law 93-282 (1974).
[15] Public Law 93-282 (1974).
[16] Public Law 93-282 (1974).

> disclosure without this consent is permitted only to medical personnel to the extent necessary in a bona fide medical emergency, to qualified personnel for research, management, and evaluation of programs with no disclosure of patients' identities in the resulting reports, and when authorized by an appropriate order of a court granted after application ...[17]

Like the House Report of 1972, there was no reference in the Confidentiality Statute or in the Senate Report about the type(s) of consent that must be given. Such matters were left to the discretion of HHS/SAMHSA pursuant to regulations. The Senate Report confirmed that Part 2 Information could be disclosed with either patient consent or an appropriate court order. Redisclosure of Part 2 Information was not addressed.

1992

In 1992, the Confidentiality Statute consolidated separate statutory requirements for alcoholism and substance abuse into one statute. It was re-codified to § 290dd-2 and the Confidentiality Statute now encompassed "substance abuse" education, prevention, training, treatment, rehabilitation, or research and "alcoholism or alcohol abuse." The Confidentiality Statute remained virtually identical to today's version. In 1992 two House Conference Reports,[18] were issued but contained no additional insights into Congress's view on redisclosures or consent requirements.

Again, the Confidentiality Statute contained no references to redisclosures or specific consent requirements. Such matters were left to the discretion of HHS/SAMHSA and, if necessary, could be addressed pursuant to regulations.

1998

Finally, in 1998, there was a very minor change to the Confidentiality Statute, specifically deleting the "Armed Forces" language from section (e).[19] The Senate Report[20] that was issued, did not provide any relevant insight into Congressional intent.

In summary, based on the legislative history of the Confidentiality Statute and the Committee Reports which indicate Congressional intent, we did not find any substantive restrictions or prohibitions on sharing of Part 2 Information using either an "opt out" consent or a generalized consent permitting disclosure and redisclosure of Part 2 Information for treatment, payment, and health care operations. Additionally, we did not find any statutory basis which would restrict or prohibit HHS/SAMHSA from allowing either an "opt out" consent or a general consent form to

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[17] S. Rep. 93-208, 3058 (1973).
[18] H.R. Conf. Rep. 102-546 and H.R. Conf. Rep. 102-871.
[19] 42 U.S.C. § 290dd-3.
[20] S. Rep. 105, 220.

be used for both disclosures and redisclosures. As noted by the National Association of Medicaid Directors: "nothing in 42 U.S.C. § 290dd-2 dictates the particular form or content of such consent".[21]

B. HHS/SAMHSA has Previously Modified Part 2 to Allow for Greater Sharing of Part 2 Information.

In 2017, HHS/SAMHSA issued a final Part 2 regulation (the "Amended Rule") to permit disclosure and redisclosure of Part 2 Information pursuant to a consent with a general designation for treatment purposes within health information exchanges ("HIE"), accountable care organizations ("ACO"), other integrated care settings, and research organizations.[22] The disclosure and redisclosure process was permitted pursuant to a specialized consent that referenced the intermediary – the entity that acted on behalf of the HIE, ACO, integrated care setting, or research organization – coupled with a "general designation of an individual or entity participant(s) or class of participants that must be limited to a participant(s) who has a treating provider relationship with the patient whose information is being disclosed."[23] Under the Amended Rule, the intermediary could redisclose Part 2 Information to participants with a treating provider relationship without a separate consent and without specifying the name or identity of the participant. The participant was also permitted to share the Part 2 Information with the intermediary. The Amended Rule was issued without any modification to the Confidentiality Statute.

SAMHSA/HHS' issuance of the Amended Rule supports our conclusion that there is no explicit restriction in the Confidentiality Statute that would prohibit HHS/SAMHSA from further modifying Part 2 to allow the sharing of Part 2 Information among Part 2 programs and HIPAA covered entities for treatment, payment, and health care operations purposes. In fact, HHS/SAMHSA has changed its policy on redisclosure of substance use disorder records over time without any changes in the authorizing statute. For example, in 1974, Part 2 also allowed redisclosure in a few circumstances. Specifically, the regulation provided that:

> [W]henever information from patient records is needed by any person, such information must be obtained directly from the program maintaining such records and not from another person to whom disclosure thereof has been made, ***except*** where the initial disclosure was ***intentionally and expressly made for the purpose of redisclosure*** ... or the information is no longer available from the program and redisclosure is not prohibited by any other provision of this part.[24]

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[21] National Association of Medicaid Directors (NAMD), Re: SAMHSA 4162-20: Confidentiality of Substance Use Disorder Patient Record. April 11, 2016.
[22] 82 Fed. Reg. 6052 (January 18, 2017).
[23] 42 C.F.R. § 2.31(a)(4)(iii)(3)(B)(3).
[24] 42 C.F.R. § 2.32(c) (1974) (Emphasis added).

The relevant provision indicates that HHS/SAMHSA previously acknowledged the ability of a patient to consent to both the disclosure of Part 2 Information with the intent and expression of that intent to allow for redisclosure pursuant to one consent. This section of the regulations is no longer set forth in current Part 2 but it represents the authority of HHS/SAMHSA to allow for redisclosure of Part 2 Information without additional consent in accordance with and under the authority granted to that agency under the Confidentiality Statute.

C. H.R. 6082 and the HIPAA Process for Sharing of Information.

HIPAA allows for the disclosure of protected health information ("PHI") for treatment, payment, and health care operations without consent or authorization[25] and does not generally prohibit subsequent redisclosures of that PHI by the recipient. While HIPAA does not require an authorization or consent to be utilized for disclosures for treatment, payment, and health care operations, the Confidentiality Statute generally does require a consent to be executed for Part 2 Information to be disclosed for those purposes.

H.R. 6082 adopts the definitions of treatment[26], payment[27], and health care operations[28] as defined under HIPAA and provides that information can be shared for those purposes but only to Part 2 programs and to HIPAA covered entities. HIPAA defines covered entities as health care providers that engage in electronic transactions, health plans, and health care clearinghouses.[29] H.R. 6082 also adopts this definition and permits disclosures and redisclosures to recipients that are considered Part 2 programs or HIPAA covered entities, without consent.

Though HIPAA does not require a consent to share information for treatment, payment, and health care operations, the authorization process used for other types of disclosures is relevant here. The elements of a proper authorization under HIPAA include the ability to reference a class of persons authorized to make the disclosure and recipients who may receive the information, rather than individually identifying each and every individual or entity that can or will receive or disclose the information.[30] Thus, contrary to Part 2's requirement that each individual or entity be identified and listed in a consent, HIPAA provides that the disclosing parties and recipient(s) can be generally referenced, such as by "any health plan, physician, health care professional, hospital, clinic, laboratory, pharmacy, medical facility, or other health care provider that has provided payment, treatment or services to me or on my behalf" or by an authorization permitting disclosures by "all medical sources."[31] The authorization process utilized under HIPAA permits the disclosure by classes of disclosing parties to classes of

[25] 45 C.F.R. § 164.506(a) and 45 C.F.R. § 164.508.
[26] 45 C.F.R. § 164.501.
[27] 45 C.F.R. § 164.501.
[28] 45 C.F.R. § 164.501.
[29] 45 C.F.R. § 164.501.
[30] 45 C.F.R. §§ 164.508(c)(1)(ii) and (iii).
[31] *See*, https://www.hhs.gov/hipaa/for-professionals/faq/473/may-a-valid-authorization-list-categories-of-persons-who-may-use-protected-information/index.html.

recipients, which also allows for disclosure and redisclosure by and among the same classes and parties. This process is akin to that spelled out under H.R. 6082 which would allow for exchange (disclosure and redisclosure) among Part 2 programs and HIPAA covered entities for treatment, payment, and health care operations purposes. This general designation is also similar to the consent process spelled out in the Amended Rule, as described above, although the Amended Rule would only permit disclosure for treatment purposes to a narrow class of recipients.

D. Federal Agency Law Would Allow for HHS/SAMHSA to Modify Part 2 Regulations to Reflect the Need for a Less Restrictive Flow of Information.

Under the Administrative Procedure Act, 5 U. S. C. § 551 *et seq.*, an agency must show that there are good reasons for a new policy which is reflected by a change in existing regulations. However, it 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 of course adequately indicates. *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009).

Under federal agency law, the U.S. Supreme Court has held an agency would not need to blindly follow prior statutory interpretation or regulatory provisions. Here, HHS/SAMHSA would not need to continue to comply with prior Part 2 restrictions relating to consent and/or redisclosure which have been identified as unduly burdensome and onerous. In fact, the preamble to the Amended Rule issued earlier in 2017[32] specifically references the numerous obstacles that the existing regulation imposed to the sharing of information for important and legitimate purposes including coordinating medical care, integrating behavioral health and medical health, and allowing for greater flexibility within new health care models.[33] These and other valid purposes would support a change by HHS/SAMHSA in the existing Part 2 regulations to allow for sharing of Part 2 Information for treatment, payment, and health care operations purposes between and among Part 2 programs and HIPAA covered entities.

III. POTENTIAL CONSENT PROCESS

We believe that HHS/SAMHSA has the ability to modify Part 2 to permit either or both new consent processes for sharing of Part 2 Information for treatment, payment, and health care operations purposes. First, HHS/SAMHSA could permit the use of an "opt out" consent process that would grant a patient control over their information by execution of a consent that would remove the patient's Part 2 Information from the exchange by and between Part 2 programs and HIPAA covered entities. Generally, the "opt out" consent process originates with a default position that patients agree to participate in the sharing of their information. The patient is provided detailed information at intake which describes the uses and disclosures permitted and how the exchange of health information takes place. If the patient agrees with the use and

[32] 82 Fed. Reg. 6052 (January 18, 2017).
[33] 82 Fed. Reg. 6052, 6053 (January 18, 2017).

disclosure of his or her health information as specified during the intake, the patient need not do anything and the exchange of health information proceeds in accordance with applicable law as explained to him or her. In this scenario, the exchange of Part 2 Information would be limited to treatment, payment, and health care operations purposes and only by and between Part 2 programs and HIPAA covered entities. If the patient disagrees with this position, he or she may execute a consent that removes him or her from that health information exchange process or "opts" them out of the process. The use or disclosure of his or her Part 2 Information would only be permitted with consent or as otherwise permitted under Part 2.

In addition, or in the alternative, HHS/SAMHSA could authorize through regulation the use of a generalized consent that would designate a class or category of recipients similar to that which is permitted under HIPAA for the exchange of Part 2 Information for treatment, payment, and health care operations. The proposed consent process could identify the class or category of recipients to include HIPAA covered entities and Part 2 programs. This type of consent process would be similar to that set forth in H.R. 6082. While H.R. 6082 would permit disclosures and redisclosures without consent, the process described herein would still require a consent, as mandated by the Confidentiality Statute. However, this consent would permit the continued exchange of Part 2 Information by and between HIPAA covered entities and Part 2 programs with the execution of only one consent, rather than requiring a separate consent each time the Part 2 Information was disclosed by one HIPAA covered entity or Part 2 program to another.

We believe the revisions to Part 2 in 2017 under the Amended Rule that now permit the use of a general designation in the consent for treatment disclosures represents HHS/SAMHSA's authority to permit disclosures and redisclosures under Part 2 without modifying the Confidentiality Statute – as is anticipated herein.

Historically, the process for disclosing Part 2 Information, including the specific requirements for consent, have not been imposed under the Confidentiality Statute but rather, were left to be spelled out through agency regulations. With respect to redisclosure, HHS/SAMHSA has previously taken regulatory action to allow for redisclosure of Part 2 Information without relying upon or requesting a change to the Confidentiality Statute. Further, HHS/SAMHSA has recently modified the Part 2 consent provisions to allow for general designations of the class of recipients, without requiring an amendment to the Confidentiality Statute.

IV. CONCLUSION

HHS/SAMHSA has the authority to modify the Part 2 consent provisions and could do so to permit the use of either: (1) an "opt out" consent process permitting exchange of Part 2 Information by and between HIPAA covered entities and Part 2 programs for treatment, payment, and health care operations purposes; and/or (2) a general designation identifying Part 2 programs and HIPAA covered entities as the recipients of Part 2 Information and permitting disclosures and redisclosures solely for treatment, payment, and healthcare operations purposes. To our knowledge based upon our research, we believe that such processes are permissible under the Confidentiality Statute. The Confidentiality Statute allows HHS/SAMHSA to promulgate

those regulations as necessary "in the judgment of the Secretary"[34] to carry out the intent of ensuring confidentiality surrounding substance use disorder records. Based on our research of the legislative history of the Confidentiality Statute and Congressional intent, we believe that HHS/SAMHSA could relax its overly burdensome redisclosure and consent restrictions to allow for sharing of Part 2 Information for treatment, payment, and health care operations purposes with Part 2 programs and HIPAA covered entities while still effectuating Congressional intent. Finally, we believe that should HHS/SAMHSA change its current redisclosure and consent policy, it would remain in compliance with federal agency law which specifically allows an agency to change its policy as long as the new policy is permissible under the governing statute and the agency believes the new policy to be better.

Our conclusion is based upon the review of legislative materials, Committee Reports, current and prior versions of Part 2, and the wording of the Confidentiality Statute, as modified over time. Further, while our conclusion is that HHS/SAMHSA may proceed to modify Part 2 as described above, that agency is not obligated to follow these recommendations and any action taken would be pursuant to HHS/SAMHSA jurisdiction and decision-making authority. This memorandum confers no rights on any third parties and no third-party beneficiaries are intended or permitted to rely upon the conclusions herein. Any opinions in this memorandum are limited to the matters set forth herein. No opinion may be inferred or implied beyond the matters expressly stated in this memorandum and the conclusions must be read in conjunction with the assumptions, limitations, exceptions and qualifications set forth in this memorandum. We assume no obligation to update this memorandum to advise you of any changes in facts or laws subsequent to the date hereof. We reserve the right to alter our conclusion based upon additional research and new information as identified. There are no guarantees as to validity and enforceability of the conclusions expressed herein.

[34] 42 U.S.C. § 290dd-2(g).