



# 42 C.F.R. Part 2 in Retrospective: The 30-Year Journey of the Alcohol and Drug Abuse Treatment Confidentiality Regulations

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Behavioral Health Task Force

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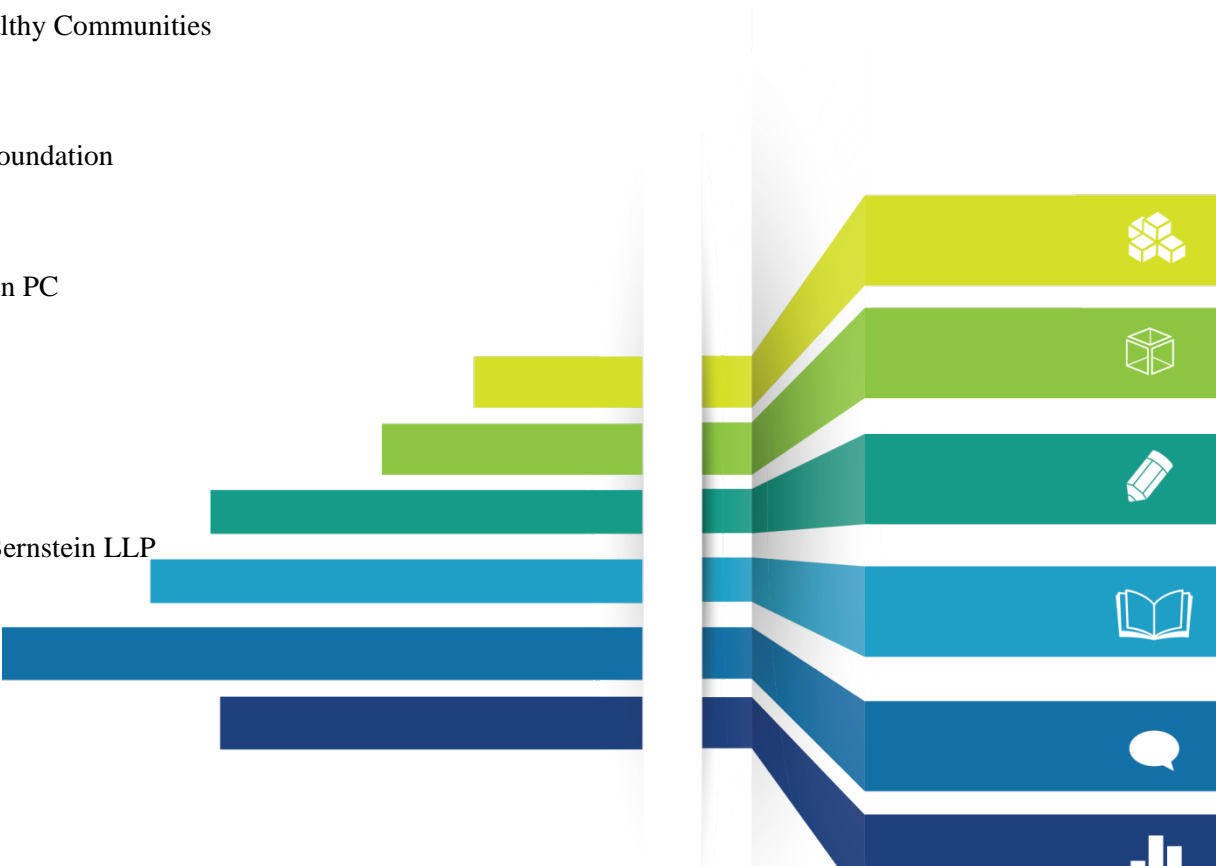
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## **I. Overview of Part 2**

### ***A. Background Information for Part 2***

In 1970 and 1972, Congress enacted the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act<sup>1</sup> and the Drug Abuse Prevention, Treatment, and Rehabilitation Act of 1972<sup>2</sup> to ensure the protection of alcohol and drug abuse records.<sup>3</sup> In combination, these acts were designed to help those who suffer from substance use disorders (SUD)<sup>4</sup> seek the necessary treatment without fear of retaliation. Stigma and a fear of prosecution by persons with SUD dissuaded many from seeking proper treatment. The two pieces of legislation sought to resolve this hurdle by expanding protection for those struggling with these disorders, including better privacy and confidentiality for those seeking treatment.

In 1975, the U.S. Department of Health, Education, and Welfare promulgated the Confidentiality of Alcohol and Drug Abuse Records regulations, located at 42 C.F.R. Part 2 (hereinafter, Part 2).<sup>5</sup> The regulations set forth the limited circumstances in which SUD patient information may be used, disclosed, and even re-disclosed. In doing so, the regulations prevent uses or disclosures other than those specifically detailed in the regulations. The basic principles of privacy and confidentiality form the foundation of Part 2.

The Part 2 regulations were updated in 1987.<sup>6</sup> They were designed to ameliorate to some degree the significant adverse impact of disclosure of SUD information related to individuals seeking treatment. Significant protection of behavioral health information, including SUD information, has developed at both federal and state levels since promulgation of and revisions to the regulations although roadblocks associated with the stigma persist. Until recently, Part 2 had not been substantively altered for nearly three decades, and many providers argued that the regulations had become outdated in

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<sup>1</sup> 42 U.S.C. § 4582 (1970).

<sup>2</sup> 21 U.S.C. § 1175 (1972).

<sup>3</sup> The current authorizing statute for the Part 2 regulations can be found at 42 U.S.C. § 290dd-2.

<sup>4</sup> “Substance,” as used in this Member Briefing, includes both alcohol and drug abuse.

<sup>5</sup> 40 Fed. Reg. 27802 (July 1, 1975).

<sup>6</sup> 52 Fed. Reg. 21798 (June 9, 1987).

the face of the Health Insurance Portability and Accountability Act (HIPAA) guidelines as the overarching protection of patient information.

Further, given the health care industry's increasing dependence on technology, Part 2 may not serve the needs of patients for continuity of care and/or integration of primary care and behavioral health services. It also may frustrate the ability of patients and providers to access some of the advantages of governmental health care programs.

The U.S. Department of Health and Human Services (HHS) Substance Abuse and Mental Health Services Administration (SAMSHA), the federal agency tasked with administration of Part 2, released proposed revisions to Part 2 on February 9, 2016 and final regulations on January 18, 2017.<sup>7</sup> The newly revised regulations provide additional support for patient privacy and strive to facilitate communication between providers and patients and third-party payers. To offer context for the recent revisions, this Member Briefing provides a detailed discussion of the Part 2 regulations prior to March 21, 2017, the effective date of the Final Rule. The Member Briefing then highlights some of the major revisions under the Final Rule.

#### *A Word About the Health Insurance Portability and Accountability Act*

The relationship between and contributions of both HIPAA and Part 2 will be the subject of a subsequent Member Briefing, but it is valuable to consider this topic briefly to provide context for evaluating the revisions to Part 2 and the attendant legal issues.

HIPAA provides broad protections for patient records by establishing baseline data privacy and security safeguards for medical information, including SUD treatment information. Likewise, the 2013 amendments to HIPAA in the Health Information Technology for Economic and Clinical Health (HITECH) Act<sup>8</sup> bolster HIPAA protections

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<sup>7</sup> The proposed revisions to Part 2 can be found at 81 Fed. Reg. 6987 (Feb. 9, 2016). The comment period on the proposed rules closed on April 11, 2016. SAMHSA published the regulations in final form on January 18, 2017, with an effective date of February 17, 2017. 82 Fed. Reg. 6052 (Jan. 18, 2017). However, President Trump and White House Chief of Staff Reince Priebus, in a memorandum dated January 20, 2017 entitled "Regulatory Freeze Pending Review," delayed the effective date to March 21, 2017. 82 Fed. Reg. 8346 (Jan. 24, 2017). See *infra* Section IV for a discussion of the Final Rule.

<sup>8</sup> HITECH was enacted in 2013 as part of the American Recovery and Investment Act of 2009. Following the enactment of the HITECH Act, the Department for Health and Human Services Office for Civil Rights

by providing significant guidance on the administration, maintenance, and transmission of electronic protected health information (ePHI). HIPAA and HITECH require that entities holding protected health information (PHI) institute broad technical and physical safeguards for all types of patient identifying information, which are applicable to paper and electronic information alike. Disclosure of such information without consent is limited to exceptions specifically included in the HIPAA regulations. Many states have incorporated the HIPAA regulations into their state health care information protection statutes.

Reviewing Part 2 and HIPAA together reveals the significant influence Part 2 had on the framework of HIPAA and its implementing regulations. Both HIPAA and Part 2 set forth requirements for safeguarding confidential information and for giving the patient the power to authorize disclosure of PHI and limiting disclosures without authorization to specific situations. However, the failure of Part 2 to remain current with the changing health care environment has resulted in two disparate sets of standards that isolate SUD treatment programs from other providers. Part 2, prior to the recently revised regulations, had become a barrier to integration of substance abuse treatment with health care decisions affecting the whole patient. Unlike HIPAA, Part 2 applies solely to SUD treatment programs considered to be federally assisted—nonprofit providers receiving federal grants or those participating in state or federal health programs such as Medicare and Medicaid. HIPAA, on the other hand, applies more broadly to nonprofits, for-profits, and providers who do not participate in federal health programs but take private insurance.

The Mental Health Parity and Addiction Equity Act of 2008<sup>9</sup> (Parity Act) expanded coverage of SUD treatment by many health plans. Patients expect to be able to access these benefits, but SUD programs and their patients are encumbered in the process of benefit determination and reimbursement by restrictions on release of information by Part 2 limitations.

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(OCR) promulgated the HIPAA Omnibus Rule adopting regulations that brought HIPAA into conformity with changes set forth in the HITECH Act.

<sup>9</sup> Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA), Pub. L. No. 110-343, 122 Stat. 3765 (enacted Oct. 3, 2008).

***B. An Introduction to the Part 2 Regulations Existing Prior to Effective Date of 2017 Final Rule***<sup>10</sup>

Part 2 applies specifically to all records relating to the identity, diagnosis, prognosis, or treatment of any patient in a federally assisted SUD program. A program covered by Part 2 is one that offers substance abuse education, treatment, or prevention and is regulated or assisted by the federal government.<sup>11</sup>

First, a “program” is defined as any “individual” or “entity” that “holds itself out as providing education, treatment or prevention to individuals in need of alcohol or drug abuse treatment.”<sup>12</sup> A general medical facility is typically not considered a program; however, a defined unit within a general facility that holds itself out as a provider of substance abuse and/or alcohol treatment services and provides those services meets the definition of a “program” under Part 2.<sup>13</sup> In addition, specific providers working in a general medical facility whose main job function is to diagnose and treat patients for substance/alcohol abuse meet the definition of “program.”<sup>14</sup>

Second, the “program” must be “federally assisted,” which means that the program: (i) is being operated by a department or agency of the United States; (ii) is operating based on the authorization of a department or agency of the United States (e.g., the program has received a license, certification, registration, or other authorization from the government); (iii) is receiving federal financial assistance or is part of an organization receiving federal financial assistance; and (iv) receives tax deductions or is operating under tax-exempt status.<sup>15</sup>

Thus, the definition of a “federally assisted program” is broad and includes: (1) a program authorized, certified, licensed, or registered by the federal government; (2) a program receiving federal funds in any form, including funds that do not directly pay for

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<sup>10</sup> The overview of the Part 2 regulations does not reflect revisions made by the Final Rule issued on January 18, 2017. All references to the Code of Federal Regulations are to the regulations prior to March 21, 2017, the effective date of the Final Rule. See *supra* note 7. The changes made by the Final Rule are discussed *infra* Section IV.

<sup>11</sup> 42 C.F.R. § 2.12.

<sup>12</sup> 42 C.F.R. § 2.11.

<sup>13</sup> *Id.*

<sup>14</sup> *Id.*

<sup>15</sup> 42 C.F.R. § 2.12(b).

SUD services; (3) any program granted tax-exempt status by the Internal Revenue Service (IRS); (4) a program allowed tax deductions by the IRS for contributions; (5) a program authorized to conduct business by the federal government, including programs certified as a Medicare provider; (6) a program authorized to conduct methadone maintenance treatment; and (7) a provider registered with the Drug Enforcement Administration; or (8) a program conducted directly by the federal government.

Except in very limited circumstances, Part 2 does not permit a federally assisted program to disclose SUD treatment records unless a patient first provides voluntary, written consent. The written consent requirement under Part 2 can be met only if the form includes ten required elements as laid out in the law.<sup>16</sup> These elements include the name or title of the individual or the name of the organization to which disclosure is to be made (commonly referred to as the “To Whom” provision), the specific purpose or need for the disclosure, a description of how much and what kind of information will be disclosed, and the date, event, or condition upon which the consent expires. Because the disclosure must be in writing, verbal consent from the patient is not sufficient to satisfy obligations of confidentiality to the patient. Additionally, Part 2 does not permit a patient to consent to authorizing disclosure to a class of organizations (e.g., health care providers that are currently involved in treatment to the patient).

As mentioned, there are exceptions to the written, voluntary consent form requirement under both HIPAA and Part 2. However, unlike HIPAA, Part 2 contains very limited exceptions to the basic prohibitions for disclosure or re-disclosure without written authorization from the patient. For example, a Part 2 program may be required to disclose SUD treatment or other patient information if the state mandates child abuse and neglect reporting,<sup>17</sup> when reporting cause of death,<sup>18</sup> or subject to a valid court order.<sup>19</sup> In addition, Part 2 permits providers to disclose in cases of medical emergency,<sup>20</sup> when reporting crimes that occur on program premises or against staff,<sup>21</sup>

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<sup>16</sup> See generally 42 C.F.R. § 2.31(a); 45 C.F.R. § 164.508(c).

<sup>17</sup> 42 C.F.R. § 2.12(c)(6); 45 C.F.R. § 164.512(b)(1)(ii).

<sup>18</sup> 42 C.F.R. § 2.15(b).

<sup>19</sup> 42 C.F.R. § 2.61.

<sup>20</sup> 45 C.F.R. § 164.506(c); 42 C.F.R. § 2.51.

<sup>21</sup> 45 C.F.R. §§ 164.502(j)(2), 164.512(f)(2); 42 C.F.R. § 2.12(c)(5).



to entities having administrative control,<sup>22</sup> to qualified service organizations,<sup>23</sup> and to outside auditors, evaluators, central registries, and researchers.<sup>24</sup> However, even permitted disclosures are restricted by Part 2, which imposes limitations on how the patient information is disclosed.<sup>25</sup> These exceptions are further discussed in Section II(E).

Part 2 even restricts the re-disclosure and use of SUD records once they have been lawfully disclosed by a SUD program. In order for a program to fulfill its statutory obligations, even with a patient's signed written consent to make the disclosure, all SUD records must be accompanied by the following written statement:

This information has been disclosed to you from records protected by Federal confidentiality rules (42 CFR Part 2). The Federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 42 CFR Part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose. The Federal rules restrict any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient.<sup>26</sup>

## **II. What Happens When HIPAA and Part 2 Come Together in the Behavioral Health Care Setting**

### ***A. Entities and Providers Subject to HIPAA and Part 2***

HIPAA applies to a "covered entity," which is: (1) a health plan; (2) a health care clearinghouse; or (3) a health care provider who electronically transmits health

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<sup>22</sup> 45 C.F.R. §§ 164.502(a)(1), 164.506(a), (c); 42 C.F.R. § 2.12(c)(3).

<sup>23</sup> 45 C.F.R. §§ 160.103, 164.504(e), (c); 42 C.F.R. § 2.12(c)(4).

<sup>24</sup> 45 C.F.R. §§ 164.501, 164.506, 164.512(i); 42 C.F.R. § 2.53(c)-(d); 42 C.F.R. § 2.52; 45 C.F.R. § 164.512(i)(1)(ii).

<sup>25</sup> For example, Part 2 permits disclosure for the purpose of audits and evaluations, but requires any person or organization conducting the audit to agree in writing that it will re-disclose the information only in certain situations.

<sup>26</sup> 42 C.F.R. § 2.32.

information in connection with a HIPAA-regulated transaction, typically an electronic transmission of PHI for billing purposes.<sup>27</sup> Some HIPAA covered entities also are subject to the requirements applicable to federally assisted drug abuse and/or alcohol treatment programs.<sup>28</sup> A provider that is subject to HIPAA and Part 2 must follow both regulations. The practical effect is that compliance with both regulations will necessarily mean adherence to the regulation with the most restrictions—likely Part 2. To identify the types of programs subject to Part 2 requires familiarity with the regulatory definitions. As discussed, a “program” is defined as any “individual” or “entity” that “holds out as providing and renders diagnoses or treatment to individuals in need of alcohol or drug abuse treatment.”<sup>29</sup> A general medical facility is typically not considered a program; however, a defined unit within a general facility that holds itself out as a provider of substance abuse and/or alcohol treatment services and provides those services meets the definition of a “program” under Part 2.<sup>30</sup> In addition, specific providers working in a general medical facility whose primary responsibility is to diagnose and treat patients for substance/alcohol abuse meet the definition of “program.”<sup>31</sup>

Moreover, the “program” must be “federally assisted,” which means that the program: (i) is being operated by a department or agency of the United States; (ii) is operating based on the authorization of a department or agency of the United States (e.g., the program has received a license, certification, registration, or other authorization from the government); (iii) is receiving federal financial assistance or is part of an organization receiving federal financial assistance; (iv) receives tax deductions or is operating under tax-exempt status.<sup>32</sup>

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<sup>27</sup> 45 C.F.R. §§ 160.102, 160.103. Each of the key terms relevant to determining HIPAA covered entity status, such as how the regulation defines a “health plan,” a “health care clearinghouse,” “provider,” and “transaction” is defined in Section 160.103 of the regulation.

<sup>28</sup> See *supra* discussion of federally assisted programs in Section I(B).

<sup>29</sup> 42 C.F.R. § 2.11.

<sup>30</sup> *Id.*

<sup>31</sup> *Id.*

<sup>32</sup> 42 C.F.R. § 2.12(b).

## ***B. What Information Is Protected by HIPAA and Part 2***

The type of information protected by HIPAA as PHI includes any health information related to an identifiable individual that is combined with a unique identifier, such as a name, social security number, date of birth, or one or more of 18 elements listed in the regulation.<sup>33</sup> HIPAA very broadly defines “health information” as:

any information, whether oral or recorded in any form or medium, that: (1) Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; ***and*** (2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual.<sup>34</sup>

Examples of information that would constitute PHI are:

- A calendar appointment in a doctor’s office listing the name of a patient and the date of the patient’s appointment; even without more, this information uniquely identifies the patient and the date of the patient’s appointment, which is information that relates to “the provision of health to the individual.”
- A verbal description by a nurse in a hospital of a patient’s health status with any identifier such as a social security number, address, or date of birth. Indeed, any unique identification such as an unusual tattoo that removes any doubt about the patient’s identity coupled with the patient’s health information is PHI.

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<sup>33</sup> 45 C.F.R. § 160.103. In addition to defining what constitutes individually identifiable information in its definition, HIPAA also lists 18 elements that, according to the regulations, would render health information de-identified if removed from data. 45 C.F.R. § 164.514(b)(2)(i). These elements are often cited as the types of identifiers that, if combined with health information, would result in PHI. But it is important to note that there may be other unique identifiers not included in this list that would satisfy the definition of PHI if combined with someone’s health information and clearly identifies the subject of the information.

<sup>34</sup> 45 C.F.R. § 160.103 (emphasis added).

- A printout of a page from the medical record of a patient receiving SUD treatment listing the patient’s medical record number and the name of the facility where the patient is being treated. In this example, the medical record number is the unique identifier and the information about the treatment facility providing care provides some insight into the type of care the patient is receiving and “relates” to the patient’s health condition.

While there may be some overlap in the types of information protected by HIPAA and Part 2, Part 2 is narrower in scope, aiming specifically at information that identifies individuals who have received treatment or are receiving treatment for substance and/or alcohol abuse.<sup>35</sup>

Part 2 establishes the confidentiality of the “[records] of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of [drug abuse and/or alcohol abuse programs].”<sup>36</sup> Analysis of the regulatory definitions of key terms used to establish what kind of information is considered confidential is helpful in determining the scope of Part 2. Specifically, “records” are “any information, whether recorded or not, relating to a patient received or acquired by a federally assisted alcohol or drug program.”<sup>37</sup> Further, the regulation defines “disclose” as “a communication of patient identifying information, the affirmative verification of another person’s communication of patient identifying information, or the communication of any information from the record of a patient who has been identified.”<sup>38</sup>

Similar to HIPAA, Part 2 defines and describes the types of information that render information about an individual’s participation in a SUD treatment program as “patient identifying information”:

the name, address, social security number, fingerprints,  
photograph, or similar information by which the identity of a

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<sup>35</sup> 42 C.F.R. §§ 2.1(a), 2.2(a).

<sup>36</sup> *Id.*

<sup>37</sup> 42 C.F.R. § 2.11.

<sup>38</sup> *Id.*

patient can be determined with reasonable accuracy and speed either directly or by reference to other publicly available information. The term does not include a number assigned to a patient by a program, if that number does not consist of, or contain numbers (such as a social security, or driver's license number) which could be used to identify a patient with reasonable accuracy and speed from sources external to the program.<sup>39</sup>

Some examples of the types of information that would be considered confidential under Part 2 include:

- A counselor in a Part 2 program is asked to confirm whether patient Jane Doe was ever admitted to the program. The mere confirmation of a patient's participation in a Part 2 program is the type of information that the regulation protects.
- The contents of an electronic medical record system in a hospital that includes patient information from the hospital's methadone treatment program are shared.
- Patient information from a drug treatment program is shared with a Health Information Exchange.

The table below summarizes similarities and differences between HIPAA and Part 2 in terms of the types of information protected and who is required to follow these regulations:

HIPAA	Part 2
Applies to a covered entity.	Applies to a federally assisted alcohol and/or drug abuse treatment program.

<sup>39</sup> *Id.*

HIPAA	Part 2
Establishes that PHI is confidential. Covered entities must do at least what HIPAA requires (i.e., HIPAA establishes a floor).	Establishes the confidentiality of patient records maintained by drug and/or alcohol abuse treatment programs. The privacy protections of Part 2 are more narrowly focused and more restrictive than HIPAA.
Protects written and verbal information.	Protects written and verbal information.
Contains a Privacy Rule and a Security Rule. The Privacy Rule addresses the disclosure of PHI and the Security Rule governs technological security of ePHI.	Addresses the privacy of substance abuse/alcohol information but does not address information security or standards for protecting electronic information in the extensive manner that HIPAA does.
Generally requires authorization prior to disclosure with exceptions.	Generally requires authorization prior to disclosure with exceptions.

**C. HIPAA Authorization Requirements**

HIPAA authorizes covered entities to release PHI with a patient authorization or pursuant to an exception, as defined in the law. Most covered entities are required to utilize a Notice of Privacy Practices to inform individuals about the legally permitted uses and disclosures of PHI by the covered entity. In all other circumstances, the individual must sign an authorization before the covered entity may disclose or use the individual’s PHI.

The HIPAA Privacy Rule sets out the elements that must be included in an authorization. To be valid, an authorization to disclose PHI must contain the following core elements:

- The name or other specific identification of the person(s), or classes of persons, authorized to make the requested use or disclosure;

- The name or other specific identification of the person(s), or class of persons, who will receive the PHI;
- A meaningful and specific description of the information to be used or disclosed;
- A description of each purpose of the requested use or disclosure (The statement “at the request of the individual” is a sufficient description of purpose when an individual initiates the authorization and does not, or elects not to, provide a statement of purpose);
- An expiration date or event that relates to the individual or the purpose of the use or disclosure; and
- The signature of the individual or personal representative and date.<sup>40</sup>

In addition to the above core elements, the authorization must also include the following required statements:

- A statement of the individual’s right to revoke the authorization in writing;
- A statement regarding the covered entity’s ability or inability to condition treatment, payment, enrollment, or eligibility for benefits on the authorization by stating either:
  - The covered entity may not condition treatment, payment, enrollment, or eligibility for benefits on obtaining the authorization, where such conditioning is prohibited by the Privacy Rule; or
  - The consequences of refusing to sign the authorization when the Privacy Rule permits such conditioning.
- A statement about the potential for information disclosed pursuant to the authorization to be subject to re-disclosure by the recipient and no longer protected by the Privacy Rule.<sup>41</sup>

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<sup>40</sup> 45 C.F.R. § 164.508(c)(1).

<sup>41</sup> 45 C.F.R. § 164.508(c)(2).

A valid authorization may contain information in addition to the required elements, so long as the additional information is consistent with the required elements. The authorization must be written in plain language and covered entities must give patients a copy of the signed authorization.<sup>42</sup>

Under the HIPAA Privacy Rule, a personal representative of the individual may execute an authorization on behalf of the individual. If the personal representative signs an authorization on behalf of an individual, then a description of such representative's authority to act for the individual also must be included in the authorization. Unless the receiving entity is a covered entity or a covered entity's business associate<sup>43</sup> under HIPAA, the Privacy Rule contains no prohibition on re-disclosure. Finally, except in limited circumstances set forth in the HIPAA Privacy Rule, an authorization for use or disclosure of PHI cannot be combined with any other document to create a compound authorization.<sup>44</sup>

#### ***D. Part 2 Consent Requirements***

Under Part 2, a release of information form is commonly referred to as a "consent." A Part 2 consent must include the following elements:

- Name or general designation of the program or person permitted to make the disclosure;
- Name or title of the individual or name of the organization to which disclosure is to be made;
- Name of the patient;
- Purpose of the disclosure;
- How much and what kind of information is to be disclosed;
- Signature of patient or personal representative;

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<sup>42</sup> 45 C.F.R. § 164.508(c)(3)-(4).

<sup>43</sup> See 45 C.F.R. § 160.103 for the definition of "business associate."

<sup>44</sup> See 45. C.F.R. § 164.508(b)(3).



- Date on which consent is signed;
- Statement that the consent is subject to revocation at any time except to the extent that the program has already acted on it; and
- Date, event, or condition upon which consent will expire if not previously revoked.

Part 2 consents may be revoked orally, unlike HIPAA authorizations, which may only be revoked in writing.<sup>45</sup>

When Part 2 programs disclose information pursuant to a consent, they must include the following prohibition on re-disclosure:

This information has been disclosed to you from records protected by Federal confidentiality rules (42 CFR Part 2). The Federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 42 CFR Part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose. The Federal rules restrict any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient.<sup>46</sup>

Persons who receive records directly from a Part 2 program and who are notified of the restrictions on re-disclosure of the records are bound by the requirements of Part 2.

A Part 2 program may disclose information about a patient to those persons in the criminal justice system who have made participation in the program a condition of the disposition of any criminal proceedings against the patient or a condition of the patient's parole or other release from custody.<sup>47</sup> The patient may authorize disclosures within the criminal justice system to individuals who have a need for the information in connection

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<sup>45</sup> 42 C.F.R. § 2.31.

<sup>46</sup> 42 C.F.R. § 2.32.

<sup>47</sup> 42 C.F.R. § 2.35(a)

with their duty to monitor the patient.<sup>48</sup> Examples of such individuals include the prosecuting attorney who is withholding charges against a patient, a court granting pretrial or post-trial release, and probation or parole officers responsible for supervision of the patient.<sup>49</sup> Under Part 2, a criminal justice system consent may be made irrevocable during the period of its intended use if the consent states:

- The period during which it remains in effect, which must be reasonable and take into account the anticipated length of the treatment;
- The type of criminal proceeding involved;
- The need for the information in connection with the final disposition of that proceeding;
- When the final disposition will occur;
- Such other factors as the program, the patient, and the criminal justice personnel who will receive the disclosure consider pertinent; *and*
- That it is revocable only upon the passage of a specified amount of time or the occurrence of a specified ascertainable event. (This time or event must be no later than the final disposition of the conditional release or other activity in connection with which the patient consent is given.)<sup>50</sup>

A person who receives patient information pursuant to a criminal justice system consent may re-disclose that information and use it only to carry out that person's official duties with respect to the patient's conditional release or other activity in connection with which the patient consent is given.<sup>51</sup>

Under Part 2, a minor must always sign the consent form for a program to release information even to his or her parent or guardian. HIPAA defers to requirements in other applicable laws regarding the use or disclosure of health information involving minors,

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<sup>48</sup> 42 C.F.R. § 2.35(a)(1).

<sup>49</sup> *Id.*

<sup>50</sup> 42 C.F.R. § 2.35(c).

<sup>51</sup> 42 C.F.R. § 2.35(d).

and thus, HIPAA does not change the requirements under Part 2 regarding minors and consent.

### ***E. Exceptions to Authorization Requirements Under HIPAA and Part 2***

As discussed, both Part 2 and the HIPAA Privacy Rule generally require written authorization or consent to disclose PHI, and both laws contain limited exceptions. In evaluating these exceptions, it is important to remember that the consent requirement is the default rule. If both Part 2 and HIPAA apply and only one law provides an exception, a consent would still be required. For example, if an exception exists under HIPAA, but that exception does not exist or does not apply under the typically more stringent standards under Part 2, the Part 2 program would still need to obtain an authorization. Several exceptions apply to both HIPAA and Part 2 restrictions. These exceptions include:

- Internal program communications;
- In response to a crime against program personnel or on program premises (or threats to commit such a crime);
- To report suspected child abuse or neglect;
- Medical emergencies;
- In response to a valid court order;
- For audit and evaluation activities;
- For research activities; and
- In a communication with a Qualified Service Organization (Part 2) or Business Associate (HIPAA).<sup>52</sup>

All of these exceptions are narrowly construed and include specific requirements.

#### *1. Internal Program Communications*

Both Part 2 and HIPAA allow for staff members within programs to communicate on a “need to know” basis. Part 2 states that a person’s employment or contracting with a program does not automatically give that person the right to receive SUD information.

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<sup>52</sup> 42 C.F.R. §§ 2.12(c)(4), 2.51, 2.52, 2.53, 2.61, 2.63; 45 C.F.R. §§ 164.512, 164.502.

Instead, the person must have a need for the information in connection with their duties that arise out of the provision of diagnosis, treatment, or referral for treatment of alcohol or drug abuse.<sup>53</sup>

Similarly, HIPAA requires programs to identify the staff persons or classes of persons within its program who need access to PHI, the categories of PHI they need access to, and any conditional limits to such access.<sup>54</sup> The program is then responsible for making reasonable efforts to limit access to PHI by such persons or classes of persons based on these determinations.<sup>55</sup>

## 2. *Crimes on Program Premises or Against Program Personnel*

In limited circumstances, Part 2 and HIPAA permit programs to disclose limited information to law enforcement officers.<sup>56</sup> Part 2 limits such disclosures to those directly related to crimes and threats to commit crimes on program premises or against program personnel. The disclosure to law enforcement must be limited to the circumstances of the incident and the patient's status, name, address, and last known location.<sup>57</sup>

## 3. *Child Abuse Reporting*

Both Part 2 and HIPAA permit programs to comply with state laws that require the reporting of child abuse and neglect.<sup>58</sup> Unlike HIPAA, however, Part 2 permits only an initial report of abuse or neglect. The Part 2 exception does not extend to follow-up requests for information or to subpoenas. In this situation, the program would either need to have an appropriate signed consent or a valid court order to release the information.

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<sup>53</sup> 42 C.F.R. § 2.12(c)(3).

<sup>54</sup> 45 C.F.R. § 164.514(d)(2)(i).

<sup>55</sup> 45 C.F.R. § 164.514(d)(2)(ii).

<sup>56</sup> See 42 C.F.R. § 2.12(c)(5); 45 C.F.R. § 164.512(f)(5).

<sup>57</sup> 42 C.F.R. § 2.12(c)(5).

<sup>58</sup> See 42 C.F.R. § 2.12(c)(6); 45 C.F.R. § 164.512(b)(1)(ii).

#### 4. *Medical Emergencies*

Both Part 2 and HIPAA allow disclosure of a patient's protected information to medical personnel for the purpose of treating a condition that:

- (1) poses an immediate threat to the health of any individual, and
- (2) requires immediate medical intervention.<sup>59</sup>

In these circumstances, a program can disclose only to the medical personnel responding to the medical emergency and only that information necessary to diagnose or treat the emergency medical condition.

Immediately following the disclosure, the program must document in the patient's records the following:

- The name and affiliation of the medical personnel to whom disclosure was made;
- The name of the individual making the disclosure;
- The date and time of the disclosure; and
- The nature of the emergency.<sup>60</sup>

#### 5. *Valid Court Orders*

Part 2 and HIPAA permit disclosure in response to a valid court order, but have different requirements for what must be contained within the order.<sup>61</sup> The Part 2 requirements are more stringent, so compliance with Part 2 also will ensure compliance with HIPAA for purposes of court orders. Subpart E of Part 2 sets out the procedures the court must follow, the findings it must make, and the limits it must place on any disclosure it authorizes.

A subpoena is not a substitute for a court order. Although HIPAA permits a program to disclose PHI pursuant to a subpoena without a prior written authorization, if certain conditions are met, Part 2 only permits programs to release information in response to a

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<sup>59</sup> 42 C.F.R. § 2.51; 45 C.F.R. § 164.512(b)(1).

<sup>60</sup> 42 C.F.R. § 2.51(c).

<sup>61</sup> See 42 C.F.R. § 2.61; 45 C.F.R. § 164.512(e).

subpoena if the patient signs a consent permitting release of the information requested in the subpoena.<sup>62</sup> Therefore, it is the written consent that authorizes the release, *not* the subpoena. When the patient does not consent, Part 2 prohibits programs from releasing information in response to a subpoena.<sup>63</sup> In this case, a valid court order would have to be obtained.

#### 6. *Audit and Evaluation Activities*

Both Part 2 and HIPAA permit programs to disclose patient-identifying information to qualified persons who are conducting an audit or evaluation of the program, without patient consent, provided that certain safeguards are met.<sup>64</sup> As with other disclosure requirements discussed, HIPAA requires that disclosures be limited to the minimum necessary to accomplish the audit or evaluation. Each rule has its own additional requirements.

#### 7. *Research Activities*

Part 2 regulations and HIPAA have different requirements for disclosures of health information to researchers.<sup>65</sup> As with other exceptions, the program must apply the more stringent requirements.

#### 8. *Disclosures to Qualified Service Organizations/Business Associates*

Both Part 2 and HIPAA recognize that SUD treatment programs sometimes need to disclose information about patients to persons or agencies providing services to the program, such as legal, accounting, or accreditation services. Part 2 refers to such service providers as “qualified service organizations” (QSOs), while HIPAA calls such outside providers “business associates.”

Part 2 requires programs and QSOs to execute “qualified service organization agreements.”<sup>66</sup> These agreements must require the outside service organization to

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<sup>62</sup> See 45 C.F.R. § 164.512(e)(1); 42 C.F.R. § 2.64(a).

<sup>63</sup> See 42 C.F.R. § 2.64(a).

<sup>64</sup> See 42 C.F.R. § 2.53; 45 C.F.R. § 164.512(d).

<sup>65</sup> 42 C.F.R. § 2.52; 45 C.F.R. § 164.512(i).

<sup>66</sup> 42 C.F.R. § 2.12(c)(4).

acknowledge that, in receiving, storing, processing, or otherwise dealing with patients' records, it is fully bound by Part 2. Further, the outside entity must promise to safeguard the information, including resisting in judicial proceedings any effort to obtain access to the information, except as permitted by the Part 2 regulations.

HIPAA requires covered entities to have business associate agreements with certain vendors or other service providers, similar, but not identical to, QSO agreements. The Office for Civil Rights provides guidance in the form of sample language for business associate agreements.<sup>67</sup>

### ***F. Breach Requirements***

Unlike HIPAA, Part 2 does not contain any breach reporting or notification obligations. Additionally, while a disclosure that violates Part 2 may rise to the level of a "breach" as defined under HIPAA's Breach Notification Rule, not every violation of Part 2 will be considered a breach. As such, it is important for Part 2 programs to identify and distinguish between those situations that trigger HIPAA's Breach Notification Rule, requiring notification, and those that do not.

Under HIPAA's Breach Notification Rule, a covered entity is obligated to notify the individual in the event of a breach, which is defined as the unauthorized acquisition, access, use or disclosure of PHI, which poses a significant risk of financial, reputational, or other harm to the affected individual.<sup>68</sup> An impermissible use or disclosure of PHI under HIPAA is presumed to be a breach. As a corollary, if HIPAA permits the use or disclosure, then generally the situation would not be considered a breach.

When determining whether a breach has caused PHI to be compromised, the covered entity should engage in a risk assessment that takes into account:

- The nature and extent of PHI involved, such as whether behavioral health or other "sensitive" PHI is included;

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<sup>67</sup> See Dep't of Health and Human Servs., Business Associate Contracts (Jan. 25, 2013), *available at* <http://www.hhs.gov/hipaa/for-professionals/covered-entities/sample-business-associate-agreement-provisions/index.html>.

<sup>68</sup> 45 C.F.R. § 164.402.

- Who received the PHI and whether the recipient is under an obligation to maintain the privacy and security of the PHI;
- Whether the PHI was actually acquired or viewed; and
- Mitigation of the risk to the PHI.<sup>69</sup>

The Breach Notification Rule contains exclusions from what is considered a breach. The unintentional acquisition, access, or use of PHI by a workforce member or person acting under authority of a covered entity or business associate is not a breach if in good faith and within the scope of authority of the individual, and there was no further use or disclosure.<sup>70</sup> Another exception involves the inadvertent disclosure of PHI by an authorized person at a covered entity or business associate to another authorized person at the same covered entity or business associate, with no further use or disclosure.<sup>71</sup> A disclosure where there is a good faith belief that an unauthorized recipient would not reasonably have been able to retain the PHI also is not generally considered a breach.<sup>72</sup> Finally, there is a complete exclusion from a breach in those situations in which the PHI is secured by rendering it unusable, unreadable, or indecipherable through the use of approved technology or methodology.<sup>73</sup> In other words, there is a safe harbor from breach reporting for PHI that has been encrypted.

In the event a breach has occurred, the covered entity must notify the affected individuals within 60 days of discovery.<sup>74</sup> If the breach involves 500 or more residents of a state or jurisdiction, then in addition the covered entity must notify prominent local media outlets of the breach.<sup>75</sup> In these situations, notice of the breach also must be provided to OCR within 60 days of discovery.<sup>76</sup> For breaches of less than 500

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<sup>69</sup> 45 C.F.R. § 164.402(2).

<sup>70</sup> 45 C.F.R. § 164.402(1)(i).

<sup>71</sup> 45 C.F.R. § 164.402(1)(ii).

<sup>72</sup> 45 C.F.R. § 164.402(1)(iii).

<sup>73</sup> 45 C.F.R. § 164.402.

<sup>74</sup> 45 C.F.R. § 164.410(c).

<sup>75</sup> 45 C.F.R. § 164.406.

<sup>76</sup> 45 C.F.R. § 164.408(b).



individuals, notice may be provided to OCR within 60 days following the conclusion of the year in which the breach occurred.<sup>77</sup>

A Part 2 violation may overlap with the definition of breach under HIPAA where a violation of HIPAA's minimum necessary requirement occurs. Under HIPAA, in most cases a covered entity must use or disclose only the minimum PHI necessary to carry out the task or duty, except in certain limited circumstances such as treatment.<sup>78</sup> The minimum PHI necessary for a particular task is to be defined in the covered entity's policies and procedures. Therefore, if the program includes a restriction on the amount of PHI that may be used or disclosed for non-treatment situations that relies upon Part 2 standards, then the violation of Part 2 could be construed as a violation of the minimum necessary requirement.

### **III. The Need for Change: Challenges Faced by Providers in Complying with Part 2**

Over the last three decades, America's health care system has undergone a protracted series of transformations and reforms. The earliest impetus for much of this change can be traced to the establishment of the Medicare and Medicaid programs in 1965, which, in large part, resulted in the first significant increase in health care costs in the United States. Years later, Congress passed the Health Maintenance Organization Act of 1973, aimed at curbing medical inflation through payment of capitated rates to providers.<sup>79</sup> As health care costs continued to grow in the 1980s, corporations began to seize commercial opportunities, privatizing much of health care, which had been previously administered and funded almost exclusively by the government. For the next two decades, numerous states tried their hands at health care reform legislation aimed at decreasing their growing numbers of uninsured residents,<sup>80</sup> but health care costs continued to climb.

The Affordable Care Act (ACA), arguably one of the single most significant pieces of health care legislation in the history of the nation, was signed into law in early 2010.

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<sup>77</sup> 45 C.F.R. § 164.508(c).

<sup>78</sup> 45 C.F.R. § 164.502(b).

<sup>79</sup> 42 U.S.C. § 300e.

<sup>80</sup> Between 2003 and 2006, California, Maryland, Massachusetts, and Vermont passed laws aimed at providing statewide health care coverage for residents.

ACA implemented a number of significant reforms to the health care system in an effort to reduce costs, expand health care coverage, and end suspect practices by insurance companies, including denying coverage to persons with preexisting conditions and imposing annual and lifetime limits on coverage. ACA preserved much of the privatized features of the existing system, while also imposing restrictions on insurers and offering subsidies to individuals with lower incomes to enable them to purchase insurance coverage. Intended to promote care coordination to improve quality of care, ACA established financial incentives for the secure, confidential, electronic exchange of health information, as well as for providers to form coordinated care organizations and to engage in efforts to achieve better patient outcomes.

For SUD treatment providers, these structural and cultural changes have been significant. Increased utilization of electronic health records (EHRs) and electronic exchange of health information have rendered many of the provisions of the Part 2 regulations extremely difficult, or in some cases, impossible, with which to strictly comply. Providers relied exclusively on paper consents, charts, and releases in 1987 when Part 2 was last revised. By contrast, approximately 83% of doctors and providers currently use EHR systems to document clinical care.<sup>81</sup> Simultaneously, efforts in recent years to promote patient-centered, evidence-based care have made the sharing of patient information all the more commonplace and necessary, as providers, hospitals, and insurers have aligned to form larger organizations better equipped to coordinate patient care, control costs, and sustain or grow their market share. Momentum for exchange of patient information and integration of care is difficult to reconcile with Part 2 confidentiality restrictions. Moreover, under the Centers for Medicare & Medicaid Services (CMS) EHR Incentive Program, SUD treatment providers are ineligible for incentive payments for the adoption and meaningful use of certified EHR technology. While SAMHSA has engaged in a number of initiatives and pilot projects to develop standards for segmentation of sensitive data and to advise SUD treatment providers

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<sup>81</sup> Dawn Heisey-Grove & Vaishali Patel, Office of the National Coordinator for Health IT, Any, Certified and Basic: Quantifying Physician EHR Adoption through 2014, ONC Data Brief No. 28 (Sept. 2015) available at <https://www.healthit.gov/policy-researchers-implementers/briefs>.

about using health IT in compliance with Part 2, hurdles persist for providers committed to meaningful compliance with the law.

Although the majority of stakeholders agree that at least some of the Part 2 provisions are archaic and irrelevant in today's health care environment, considerable disagreement persists as to whether the regulations afford real privacy protections to individuals or, alternatively, further stigmatize the disease of addiction. Stakeholders in favor of maintaining Part 2 and many of its restrictions argue that, without the regulations, patients with SUDs would be exposed to even greater discrimination than at present. The unfortunate reality, however, is that while there have been significant advancements in health care, particularly health IT, within recent years, individuals with a SUD diagnosis continue to face discrimination in insurance coverage, employment, criminal justice involvement, and even health care.

Still, there are a number of options for modernizing Part 2 without dismantling the privacy protections afforded patients under the regulations, including SAMHSA's recently finalized revisions.

#### **IV. Revised Part 2 Regulations: The Final Rule**

##### ***A. Introduction***

SAMHSA recently finalized a number of changes to the Part 2 Regulations (Final Rule), which went into effect on March 21, 2017.<sup>82</sup> The Final Rule aims to update and modernize Part 2 and “facilitate information exchange within new health care models while addressing the legitimate privacy concern of patients seeking treatment for a substance use disorders.”<sup>83</sup>

Among its changes, the Final Rule replaces outdated terms such as “alcohol or drug abuse” with the more contemporary, clinically established term “substance abuse disorder.” The Final Rule clarifies that Part 2 programs and other entities or individuals that lawfully maintain Part 2 information must have formal policies and procedures

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<sup>82</sup> See *supra* note 7.

<sup>83</sup> 82 Fed. Reg. 6052, SUMMARY.

related to the security of electronic and paper records, but does not establish that compliance with HIPAA and HITECH requirements is sufficient to meet this requirement or if additional restrictions or requirements will be imposed. As discussed, most Part 2 programs are already subject to HIPAA and HITECH. Additionally, the Final Rule clarifies that “records” include both paper and electronic documentation.

Historically, one of the more contentious provisions in the Part 2 regulations are the written patient consent requirements, discussed previously in Section II(D). These requirements have had the effect of excluding Part 2 programs from participating in integrated provider networks, such as health information exchanges (HIEs) or accountable care organizations (ACOs). Such networks cannot accommodate these onerous consent requirements in their electronic systems, and the Part 2 programs cannot operationalize the requirement to list each individual provider or entity that may be part of such HIE or ACO, due to the constantly changing membership and breadth of such a network. For example, if a new provider were to join the ACO, the Part 2 program would need to secure a written consent from each of its current and former patients for that provider to have access to the network that would contain the patient’s SUD information. It is not feasible or practical for a Part 2 program to undertake such tasks, and therefore the solution has been to exclude Part 2 information. However, this defeats a fundamental purpose of integrated care networks such as HIEs and ACOs. Substance use disorders are chronic diseases that need to be managed along with a patient’s other health care needs. In fact, there is now compelling evidence of significant benefits to patients and significant financial savings to health systems that can be achieved through the integration of the treatment of behavioral health conditions, such as substance use disorders, with the delivery of physical health care.<sup>84</sup> The Final Rule allows the patient to consent to disclosure to an HIE or ACO network generally, so long

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<sup>84</sup> Sujoy Chakravarty, Ph.D, Joel C. Cantor, Sc.D., et al., *Role of Behavioral Health Conditions in Avoidable Hospital Use and Cost*, RUTGERS CTR. FOR HEALTH POLICY (Nov.2014) (researchers found that patients who are high users of hospital care and those with avoidable/preventable inpatient hospital use are disproportionately affected by behavioral health conditions, and behavioral health conditions are associated with a substantial share of hospital costs).

as the “To Whom” section of the consent designates a general description of individuals and entities with a treatment relationship with the patient.<sup>85</sup>

Because of concerns with inadvertent disclosures, the Final Rule eliminates the ability of a Part 2 program to confirm that a patient is not and has never been a patient of the Part 2 program. The Final Rule clarifies that the prohibition on re-disclosure applies only to those records that identify, directly or indirectly, an individual as having been diagnosed, treated, or referred to treatment for a SUD, such as indicated through medical codes and descriptive language. SAMHSA also addressed concerns about limitations on providing Part 2 information for research purposes, and finalized revisions to the current research exception to permit disclosure by Part 2 programs to qualified researchers, provided that such researchers have demonstrated continued compliance with human research requirements.

Part 2 programs must provide a written summary of the Part 2 regulations and corresponding federal law to their patients.<sup>86</sup> SAMHSA finalized a clarification that “written” includes both paper and electronic documentation and that electronic records are included in information for Part 2 purposes. Additionally, Part 2 programs must provide specific contact information for reporting violations to the applicable authorities and agencies, which also may be available in either paper or electronic form. Finally, the Final Rule gives Part 2 programs more discretion to decide when a “bone fide medical emergency” exists and therefore patient consent is not required.

Several of the revisions change the way in which programs comply with Part 2. Any entity or individual operating a Part 2 program should pay particular attention to the changes set forth in the Final Rule.

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<sup>85</sup> See Section IV(D), below, for further discussion of the Final Rule’s revisions to the consent requirements.

<sup>86</sup> 42 C.F.R. § 2.22.

## **B. Definitions**

The Final Rule updates definitions of the following key terms: Patient, Patient Identifying Information, Program, Qualified Service Organization, Records, and Treatment. Other revised definitions include terms such as Part 2 Program, Substance Use Disorder, and Treating Provider Relationship.<sup>87</sup> Overall, these changes appear intended to reconcile Part 2 terminology with that currently used in the behavioral health field and to further clarify application of the Part 2 regulations to SUD treatment providers operating in this increasingly electronic age.

## **C. Applicability**

The Final Rule continues to apply Part 2 only to programs that are federally assisted (e.g. through the Medicare program or under any other license, certification, or registration granted by any federal department or agency) and hold themselves out as providing, and do provide, substance use disorder diagnosis, treatment, or referral for treatment, and can include treatment or rehabilitation centers, employee assistance programs, programs within hospitals, school-based programs, and private practitioners.<sup>88</sup>

## **D. Consent Requirements**

SUD treatment providers participating in the electronic exchange of health information historically faced two primary problems in complying with Part 2. Namely, the prior regulations at 42 C.F.R. § 2.31 required consents to be in writing and to include the specific name or title of the individual or the name of the organization to which disclosure is to be made (i.e., the so-called “To Whom Problem”). The Final Rule provides that a written consent compliant with Part 2 requirements may be paper or electronic.<sup>89</sup> Additionally, electronic signatures on consents are permitted provided they are not prohibited by applicable law (e.g. applicable state law).<sup>90</sup> The Final Rule aims to address the “To Whom Problem” by permitting consents to include a general

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<sup>87</sup> 42 C.F.R. § 2.11

<sup>88</sup> 42.C.F.R. § 2.12

<sup>89</sup> 42 C.F.R. § 2.11.

<sup>90</sup> *Id.*

designation in the “To Whom” section of the consent form (e.g. “my treating providers, past or present”) to allow patients to participate more seamlessly in integrated health care systems, while respecting patient choice to maintain a higher level of privacy as patients are not required to make such a general designation.

The consent form also must include a description of how much, and what kind of, information can be disclosed, including an explicit description of the substance use disorder treatment information that may be disclosed, which can be as broad as “all my substance use disorder treatment information” or as narrow as “medications only.”

The Final Rule also provides that, if the patient makes a general designation of an entity participant, the consent form must include a statement that the patient confirms his or her understanding that, upon request, the provider must provide a list of entities to which the patient’s information has been disclosed pursuant to the general designation (List of Disclosures).<sup>91</sup> As used in this Section, the Final Rule provides that regardless of whether there has been an actual in-person encounter, a “treating provider relationship” exists where (1) a patient is, agrees to, or is legally required to be diagnosed, evaluated, and/or treated, or agrees to accept consultation for any condition by an individual or entity; and (2) the individual or entity agrees to undertake diagnosis, evaluation, and/or treatment of the patient, or consultation with the patient, for any condition.<sup>92</sup>

The Final Rule also augments the “From Whom” requirement, providing that a valid Part 2 consent must include the specific name(s) or general designation(s) of the Part 2 program(s), entity(-ies), or individual(s) permitted to make the disclosure.<sup>93</sup> This is in contradistinction to the prior regulations, where a general designation of the program or person permitted to make the disclosure was sufficient.

The Final Rule balances the flexibility provided through the right to make a general designation of treating providers to whom disclosure may be made with providing protection to the patient through two mechanisms. First, the consent must include a

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<sup>91</sup> 42 C.F.R. § 2.31(a).

<sup>92</sup> 42 C.F.R. § 2.11.

<sup>93</sup> 42 C.F.R. § 2.31(a).

statement that the consent is subject to revocation at any time (except to the extent that the Part 2 program or other lawful holder of patient identifying information that is permitted to make the disclosure has already acted in reliance on it, e.g. the provision of treatment in reliance on a valid consent to disclose information to a third-party payer.) Second, the consent must state the date, event, or condition upon which the consent will expire if not revoked before. This date, event, or condition must ensure that the consent will last no longer than reasonably necessary to serve the purpose for which it is provided.<sup>94</sup>

### ***E. Prohibition on Re-disclosure***

The prior regulations specified that every disclosure of Part 2 information made with the patient's consent must be accompanied by a statement informing the recipient that Part 2 prohibits further disclosure unless expressly permitted by the patient's written consent or by another provision of Part 2.<sup>95</sup> In the notice-and-comment process, stakeholders expressed concerns that such restrictions might limit patient participation in models that encourage information sharing and integration, such as HIEs or ACOs.

The Final Rule only made a slight modification to the existing prohibition against re-disclosure set forth under Section 2.32. The Preamble to the Final Rule makes clear that only data that directly or indirectly identifies a patient as suffering from an SUD is subject to this prohibition. Specifically, the prohibition on re-disclosure provision only applies to information that would identify, directly or indirectly, an individual as having been diagnosed, treated, or referred for treatment for an SUD and allows other health-related information shared by the Part 2 program to be re-disclosed, if permissible under the applicable law.<sup>96</sup> However, this clarification does not seem to be especially meaningful. For example, any information that could potentially identify the patient as suffering from an SUD, such as name, diagnosis, medications, or vital signs, each accompanied by the name of the Part 2 program, would be subject to the prohibition. Thus, the context and not necessarily the data itself is the determining factor of whether

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<sup>94</sup> *Id.*

<sup>95</sup> 42 C.F.R. § 2.32. See *supra* Section II(D), for a discussion on the prohibition on re-disclosures.

<sup>96</sup> 82 Fed. Reg. at 6054.



information could be re-disclosed, which may be difficult for electronic systems to flag or segment because it requires considering all the ways in which the patient could possibly be identified.

SAMHSA specifically addressed, and declined to allow, the ability to re-disclose Part 2 information for care coordination and treatment.<sup>97</sup> In a Supplemental Notice of Proposed Rule Making (SNPRM) that was issued contemporaneously with the Final Rule, SAMHSA is seeking input on whether and to what extent re-disclosure may be permitted for lawful holders' contractors and subcontractors and for those entities assisting with audits and evaluations permitted under existing regulations.<sup>98</sup>

#### ***F. Qualified Service Organizations***

Under Part 2, a QSO is an individual or entity providing a service to Part 2 treatment programs pursuant to a written agreement. QSO services include data processing, bill collecting, dosage preparation, laboratory analyses, or legal, accounting, or other professional services.<sup>99</sup>

The Revised Part 2 Regulations narrow the ability to utilize the QSO arrangement in situations in which it was previously relied upon. For instance, care coordination and medication management are no longer acceptable purposes for using a QSO Agreement.<sup>100</sup> This section of the Part 2 regulations was revised to replace the term "medical services" with "medical staffing services" to make clear that QSO Agreements should not be used to avoid obtaining patient consent. Accordingly, a Part 2 program could use a QSO Agreement to contract with a provider of on-call coverage services or other medical staffing services, but not to disclose a patient's identifying information to his primary care doctor for the purpose of treatment (other than that provided under a QSO Agreement for medical staffing services). For this reason, care coordination and

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<sup>97</sup> 82 Fed. Reg. at 6092.

<sup>98</sup> 82 Fed. Reg. 5485 (Jan. 18, 2017).

<sup>99</sup> 42 C.F.R. § 2.11.

<sup>100</sup> 82 Fed. Reg. 6067.

medication management, both of which have a treatment component, were not added to the list of examples of permissible services offered by a QSO.<sup>101</sup>

The Preamble to the Final Rule provides that a QSO may not be utilized to avoid the use of an appropriate consent in a treatment context. The Revised Part 2 Regulations do expand the accepted uses of a QSO to include population health management. However, this expanded use is not applicable to any exchange of SUD information for treatment purposes on an individual basis. In conjunction with the Final Rule, the SNPRM requests comment on its supporting proposals designed to address the exchange of SUD information while simultaneously protecting it with an abbreviated notice in certain circumstances and defining and limiting the circumstances in which disclosure can be made to contractors and subcontractors such as third-party payers.<sup>102</sup>

### ***G. Disclosures for Research Purposes***

For some time, stakeholders have recognized a need for revisions to Part 2 to support researcher access to information related to SUD treatment. The underlying concern to granting such access, however, has been that there is no way to confirm that a researcher will properly maintain the confidentiality of that information as required under Part 2 once the disclosure is made.

The Final Rule modifies the research exception to permit disclosure of data protected by Part 2 to qualified personnel for the purpose of conducting scientific research by a Part 2 program or any other lawful holder. To carry out the research process correctly, the researcher provides documentation of meeting certain requirements related to other existing protections for human research. SAMHSA also revised Section 2.52 to enable researchers holding Part 2 data to obtain linkages to other datasets, provided that appropriate safeguards are in place as outlined in Section 2.52.<sup>103</sup>

Specifically, under the Final Rule, the Part 2 program or other lawful holder may disclose Part 2 information for the purpose of conducting scientific research if the

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<sup>101</sup> *Id.*

<sup>102</sup> 82 Fed. Reg. 5485.

<sup>103</sup> 82 Fed. Reg. 6054.

individual designated as director, managing director, or chief executive officer or their designee makes a determination that the recipient of the patient identifying information:

- (1) If a HIPAA-covered entity or business associate, has obtained and documented authorization from the patient, or a waiver or alteration of authorization, consistent with the HIPAA Privacy Rule;
- (2) If subject to the Common Rule regarding the protection of human subjects either provides documentation that the researcher is in compliance with the requirements of the Common Rule or that the research qualifies for exemption; or
- (3) If both a HIPAA covered entity or business associate and subject to the Common Rule, has met the requirements of the paragraphs above; and
- (4) If neither a HIPAA covered entity or business associate or subject to the Common Rule, this section does not apply.<sup>104</sup>

The researcher is fully bound by the regulations and, if necessary, will resist in judicial proceedings any efforts to obtain access to patient records.<sup>105</sup> Further, the research may not re-disclose Part 2 information except back to the source of that information.<sup>106</sup>

The researcher may only publish aggregate Part 2 information in any research publications. Finally, the researcher must maintain and destroy patient identifying information in accordance with the Revised Part 2 Regulations' security policies and procedures and other applicable law.<sup>107</sup>

The Final Rule imposes new requirements for data linkages. Researchers conducting research that requests linkages to data sets from a data repository holding Part 2 information must have the request reviewed and approved by an Institutional Review Board (IRB).<sup>108</sup> The researcher also must ensure that Part 2 information is not provided to law enforcement agencies or officials.<sup>109</sup>

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<sup>104</sup> 42 C.F.R. § 2.52(a).

<sup>105</sup> 42 C.F.R. § 2.52(b).

<sup>106</sup> *Id.*.

<sup>107</sup> *Id.*

<sup>108</sup> 42 C.F.R. § 2.52(c).

<sup>109</sup> *Id.*

Data repositories also are subject to restrictions under the Final Rule. The data repository is fully bound by the Final Rule and, after providing access to the researcher, must destroy or delete the linked data from its records, including sanitizing any associated hard copy or electronic media, to render the patient identifying information non-retrievable in a manner consistent with the new security policies and procedures established under the Final Rule.<sup>110</sup> The data repository also must ensure that Part 2 information is not provided to law enforcement agencies or officials.<sup>111</sup>

## **H. Medical Emergencies**

Before the Final Rule went into effect, Part 2 provided that SUD information may be disclosed to medical personnel “for the purpose of treating a condition which poses an immediate threat to the health of any individual and which requires immediate medical intervention.”<sup>112</sup> The Final Rule modifies the medical emergencies provision to reflect the statutory language that Part 2 information may be disclosed to medical personnel without the patient’s consent to the extent necessary to meet a bona fide medical emergency.<sup>113</sup> The intent behind the revision is to give providers more discretion in determining when a “bona fide medical emergency” exists.<sup>114</sup> The Final Rule maintains the requirement that any such disclosures must be documented immediately in writing.

Further, SAMHSA advises that prior to entering into an affiliation with an HIE, a Part 2 program should consider whether the HIE has the capability to comply with Part 2.<sup>115</sup> Many stakeholders have expressed concern that if such information is disclosed in a medical emergency, that information becomes part of the patient’s general medical record and may be subject to additional disclosures without Part 2 protections. Some of these stakeholders will likely see SAMHSA’s advice to Part 2 programs as insufficient and continue to advocate for stricter limitations on further disclosures of information that is disclosed pursuant to a medical emergency.

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<sup>110</sup> 42 C.F.R. § 2.52(c).

<sup>111</sup> *Id.*

<sup>112</sup> 42 C.F.R. § 2.51.

<sup>113</sup> 82 Fed. Reg. 6094.

<sup>114</sup> *Id.*

<sup>115</sup> See <https://www.samhsa.gov/about-us/who-we-are/laws/confidentiality-regulations-fags>; <https://www.samhsa.gov/sites/default/files/fags-applying-confidentiality-regulations-to-hie.pdf>. (accessed May 6, 2017).

Many commenters on the Proposed Rule requested examples of emergency situations to minimize confusion among providers as to the circumstances under which medical emergencies would be considered valid, including examples for which disclosure would be necessary. SAMHSA in the Final Rule announced plans to provide the requested examples in sub-regulatory guidance.<sup>116</sup>

### ***I. Discrimination Protections Indirectly Addressed***

Discrimination against individuals with an SUD diagnosis unfortunately persists. Although the Rehabilitation Act of 1973 and the Americans with Disabilities Act prohibit discrimination against individuals with a SUD in the provision of most benefits, programs, and services, there are a number of limitations to those protections.<sup>117</sup> For example, individuals who currently are engaged in illegal drug use, who are not in treatment, or whose SUD does not limit at least one of their major life activities, are not protected.<sup>118</sup> Despite some state laws prohibiting discrimination against persons with SUDs, many stakeholders argue for enhanced federal protections against discrimination under Part 2.

In the Proposed Rule, SAMHSA mentioned the “legitimate privacy concerns” of SUD patients, noting, specifically, the potential for loss of employment, loss of housing, loss of child custody, discrimination by medical professionals and insurers, arrest, prosecution, and incarceration.<sup>119</sup> Nonetheless, the proposed revisions to the regulations made no mention of discrimination or prohibition of the same. The Final Rule does, however, expand applicability of the Part 2 protections to former, as well as to current, patients and requires Part 2 programs and other lawful holders of patient identifying information to have in place formal policies and procedures addressing security for electronic and paper records.<sup>120</sup>

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<sup>116</sup> 82 Fed. Reg. 6095.

<sup>117</sup> See 29 U.S.C. § 701 *et seq.*; 42 U.S.C. § 12101 *et seq.*

<sup>118</sup> Substance Abuse and Mental Health Services Administration, *Know your Rights* (2007).

<sup>119</sup> 81 Fed. Reg. at 6988.

<sup>120</sup> 42 C.F.R. § 2.11; 42 C.F.R. § 2.16 (2017).

## **V. Concerns Not Addressed in Revised Part 2 Regulations**

In totality, the Final Rule addresses a significant amount, if not a majority, of stakeholders' chief concerns with the prior Part 2 regulations and their current applicability. Some stakeholders argue that Part 2 fails to protect patients' SUD treatment information adequately, while other stakeholders argue that the current patient protections under Part 2, even as revised according to the Final Rule, are still too restrictive. Below is a consideration of some key issues not addressed in the final revisions to the regulations.

### ***A. Alignment of Part 2 and HIPAA***

One popular critique of Part 2 over the last few decades has been its incompatibility with HIPAA. In particular, many argue that the Part 2 consent requirements should be consistent with HIPAA's requirements for if and when authorization is required, thereby enabling coordination of care among behavioral health care and general medical providers.

Many stakeholders also have argued for the addition of a "duty to warn" exception under Part 2 similar to HIPAA's, which would permit disclosures of patient information without patient consent when such disclosures are necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public. Nonetheless, SAMHSA's Final Rule does not reconcile Part 2 with HIPAA in either of these respects. Some of HIPAA's provisions pertaining to disclosures of patient information for research purposes are incorporated in the Final Rule's updated research requirements. In seemingly closing the book on issues raised related to HIPAA, SAMHSA acknowledged its receipt of many comments on the subject, but declined to summarize or address them in detail in the Final Rule, emphasizing the agency's perspective that the population targeted by Part 2 requires more stringent federal protections than other groups protected by health privacy laws.<sup>121</sup>

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<sup>121</sup> 81 Fed. Reg. at 6993; 82 Fed. Reg. 6060-6061.

## ***B. Use of SUD Information in Legal Proceedings***

Part 2 currently contains language in the prohibition on re-disclosures that makes recipients of SUD information aware that Part 2 “restricts any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient.”<sup>122</sup> Part 2 permits disclosure for the purpose of conducting a criminal investigation or prosecution of a patient only if certain criteria are met, including if the crime causes or threatens loss of life or serious bodily injury, the information will be of substantial value to the investigation or prosecution, and there is no other way to obtain the information.<sup>123</sup>

Because a patient’s reticence to seek SUD treatment may be based in part on fear that such treatment information may be accessed by law enforcement or other parties for the purpose of criminal prosecution or establishing civil liability, some stakeholders have suggested limiting the use of Part 2 information in civil and administrative proceedings, as well as criminal investigations and prosecutions. By extending this protection and limiting personal liability, providers hope to encourage individuals to seek treatment. However, there is concern that if access to this information, and the resulting liability, is limited, injured parties may not be properly compensated for damages resulting from such access.

## **VI. Conclusion**

The overlapping and intersecting scopes, definitions, and exceptions under HIPAA and Part 2 can be confusing. Before disclosing any protected information or records without written consent, a provider should ask the following questions:

1. Were attempts made to obtain a written authorization or consent from the patient?
2. Which exception or exceptions apply? (*Disclosure can fall under more than one.*)
3. Is the person or agency to which the information is to be disclosed permitted to receive the information under the disclosure? (*For example,*

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<sup>122</sup> 42 C.F.R. § 2.32.

<sup>123</sup> 42 C.F.R. § 2.65.

*the crimes exception does not permit disclosure to individuals who are not law enforcement personnel.)*

4. Is the information to be disclosed necessary to accomplish the exception's purpose?
5. Does the request comply with the requirements of HIPAA and Part 2?
6. What post-disclosure documentation is required, if any?

The behavioral health field has struggled for many years with balancing protections to SUD client confidentiality alongside advances made in technology and other co-existing federal confidentiality laws such as HIPAA. The result of this long journey is the Final Rule. Practitioners in this area would be wise to familiarize themselves with the outcome of this long process by reviewing the Final Rule. The purpose of this Member Briefing is to provide the context in which the Final Rule was adopted to assist practitioners in their comprehension of this complex area of the law.

*\*The authors would like to acknowledge the contributions of Morgan Fuller, who recently graduated from University of St. Thomas Law School in Minneapolis, MN.*



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