CONFIDENTIALITY OF ALCOHOL AND DRUG ABUSE PATIENT RECORDS REGULATION AND THE HIPAA PRIVACY RULE

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Course Author: John H. Tinsley, PhD

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ABOUT THE INSTRUCTOR

Dr. John H. Tinsley is a former assistant professor of Medical Physiology at the Texas A&M University System College of Medicine. He received his Ph.D. from Texas A&M University, College Station, Texas; M.S. from the University of North Carolina; and his B.S. from the University of Oklahoma.

He has been teaching, training, consulting and conducting research in the fields of Medical Physiology and Behavioral Biology for over twenty-nine years. Dr. Tinsley has authored over twenty-five professional and refereed articles, including invited reviews. He has been a member of the American Society for Physiology, and work done in 2001 led to an international award from The European Society on Microcirculation. Dr. Tinsley has received research funding from the Veteran's Administration, American Heart Association, and Scott and White Hospital. In addition, he has served on numerous review committees for national grant-funding agencies and scientific journals.

Critical Regulatory Update: What Has Changed Since 2004

This course was originally developed based on the 2004 SAMHSA guidance on 42 CFR Part 2 and the HIPAA Privacy Rule. Since then, two major legislative and regulatory changes have fundamentally altered the relationship between these two frameworks. Practitioners must understand what changed, why it changed, and what it means for daily clinical operations.

The Regulatory Landscape: 2004 vs. Today

When this course was written, 42 CFR Part 2 and HIPAA operated as essentially parallel but separate systems. Part 2 imposed stricter requirements on SUD treatment records than HIPAA imposed on other medical records. The practical result was that SUD programs operated under a dual regulatory framework — complying with HIPAA for general health information and with Part 2's more restrictive requirements for anything related to substance use treatment.

The key differences under the original framework:

Consent requirements. Under the 2004 Part 2 framework, each disclosure of SUD treatment information required a separate, specific written consent form identifying the recipient, the purpose of the disclosure, the specific information to be disclosed, and an expiration date. A single patient might need to sign dozens of consent forms to allow their treatment team, primary care physician, insurance company, and referring court to communicate. Under HIPAA, a general consent for treatment, payment, and health care operations covered most routine disclosures without individual authorization for each one.

Redisclosure. Part 2 prohibited any recipient of SUD information from redisclosing it to a third party without additional patient consent — even within the same health system. A hospital emergency department that received SUD records from a treatment program could not share that information with the patient's primary care provider without obtaining a new consent. HIPAA had no equivalent redisclosure restriction for treatment purposes.

Information segmentation. Because Part 2 records could not flow freely through electronic health record systems, many health systems maintained separate, siloed databases for SUD treatment information. A clinician viewing a patient's medical record might see their cardiac history, diabetes management, and surgical records — but not their substance use treatment history, which existed in a separate system requiring separate login credentials and separate consent to access.

The CARES Act (2020): The First Major Shift

Section 3221 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act, signed into law in March 2020, began the process of aligning Part 2 with HIPAA. The key change: once a patient provides initial written consent, Part 2 records may be disclosed for treatment, payment, and health care operations — the same broad categories HIPAA uses — without requiring a new consent form for each individual disclosure (CARES Act, Pub. L. No. 116-136, § 3221, 2020).

This was not a minor administrative adjustment. It fundamentally changed how SUD treatment programs handle information sharing. Under the old framework, a treatment counselor who wanted to coordinate care with a patient's psychiatrist, primary care physician, and probation officer needed three separate consent forms. Under the CARES Act framework, a single consent covering treatment, payment, and health care operations can authorize routine information sharing across the patient's care team.

The field's response was mixed. A 2022 study surveyed 40 representatives from 30 SUD treatment organizations about their perceptions of the changes. Only 63% reported being "somewhat knowledgeable" about Section 3221, though 77% of organizations had held discussions about implementing the changes. Sixty-five percent anticipated barriers including "complexity and tensions in the law, staff education, cost, technological adjustments." Two-thirds of respondents wanted practical resources such as webinars and implementation templates to guide their transition (Ivanova et al., 2022).

The 2024 Final Rule: Completing the Alignment

In February 2024, the U.S. Department of Health and Human Services published a final rule completing the alignment of 42 CFR Part 2 with HIPAA (89 Fed. Reg. 12472, 2024). The final rule implemented the CARES Act changes and added further provisions:

Single consent model. The final rule codified the CARES Act's single-consent approach. Programs may now use a single consent form that authorizes disclosure for treatment, payment, and health care operations, replacing the prior requirement for transaction-specific consent.

Redisclosure permitted. Recipients of Part 2 information may now redisclose that information for treatment, payment, and health care operations purposes — eliminating the prior prohibition that prevented care coordination within health systems.

Anti-discrimination protections retained. The final rule maintained and strengthened the prohibition against using SUD treatment records in criminal, civil, or administrative proceedings against the patient without a court order or explicit patient consent. This protection — the original rationale for Part 2's existence — survived the alignment process intact.

Breach notification. Part 2 programs are now subject to HIPAA's breach notification requirements, meaning patients must be notified if their SUD records are improperly disclosed.

Patient right of access. Patients now have the same right to access their SUD treatment records that HIPAA provides for other medical records, including the right to receive copies and to request amendments.

What This Means for Practitioners

The regulatory shift does not eliminate confidentiality protections for SUD patients. It modernizes how those protections operate. The core principle that drove the original 1975 legislation — that stigma deters treatment-seeking and that confidentiality encourages it — remains the foundation. What has changed is the recognition that completely siloed records also harm patients by preventing the care coordination that improves outcomes.

For practitioners completing this course, the key operational changes are:

1. **Consent forms need updating.** Programs still using pre-2020 consent forms with transaction-specific language should revise them to reflect the single-consent model permitted under the CARES Act and codified in the 2024 final rule.

2. **Electronic health record integration is now permissible.** Programs that maintained separate databases for Part 2 records can now integrate SUD treatment information into unified electronic health records — with patient consent.

3. **Redisclosure is permitted for TPO.** Information shared with other providers for treatment, payment, or health care operations may be redisclosed for those same purposes without additional consent.

4. **Criminal use protections remain absolute.** SUD records still cannot be used against patients in criminal proceedings without a court order meeting specific criteria. This protection is stronger than HIPAA's general provisions.

5. **Staff training is essential.** The transition from the old framework to the new one requires deliberate education. The 2022 study found that most organizations recognized the need for training but lacked resources to deliver it effectively (Ivanova et al., 2022).

From Siloed Records to Integrated Care: What the Research Shows

The original rationale for 42 CFR Part 2's strict confidentiality protections was straightforward: stigma associated with substance use deters people from seeking treatment, and the threat of information disclosure — particularly to law enforcement or employers — compounds that deterrence. This rationale has not changed. What has changed is the recognition that completely siloed SUD treatment records also harm patients by preventing care coordination.

A 2024 study at Denver Health documented what happened when a large safety-net health system integrated previously separated SUD treatment data into their unified electronic health record. The results were substantial: the number of tracked patients initiating treatment tripled from 562 to 1,411. Treatment retention at 90 days improved from 45% to 74%. Staff found the consolidated system more efficient for coordinating care across multiple clinical settings (Tillman et al., 2024).

These gains were made possible by the regulatory revisions described above. Prior to the CARES Act, maintaining separate electronic health record systems for SUD treatment was the standard practice

in many health systems — not because clinicians preferred it, but because the regulatory framework required it. Integration does not mean abandoning confidentiality. It means implementing consent-based sharing within a unified system where clinicians can see the full clinical picture.

Patient Perspectives: Do Patients Want Their Records Shared?

The regulatory framework assumes that stronger privacy protections encourage treatment-seeking. But what do patients themselves say?

A 2025 qualitative study interviewed 27 individuals in SUD treatment about their perspectives on record sharing. The findings challenged some assumptions: most participants did not view confidentiality concerns as a major barrier to seeking treatment. They "identified many benefits to record sharing," including better-coordinated care and reduced need to repeat their history at every new provider. Stigma — not privacy — emerged as the primary concern. Notably, most participants "were unaware of how their substance use treatment records were protected or who had access to their records" (Aluri et al., 2025).

The study also documented gender-specific concerns. Female participants reported experiences where "health care professionals, particularly in emergency or perinatal care contexts, treated them differently or negatively" upon learning of their substance use history. This finding underscores that confidentiality regulations alone do not eliminate stigma — they must be accompanied by clinical workforce education and cultural change within healthcare systems.

A separate 2025 cross-sectional survey of 357 patients across four Arizona clinics quantified the relationship between stigma, trust, and willingness to share SUD data. The researchers found that "stigma was significantly correlated with increased sensitivity and reduced willingness to share data" beyond the primary treatment facility. Conversely, "trust in providers and higher satisfaction with care were linked to greater willingness to share data with all providers." Patients were most comfortable sharing information for emergencies and direct treatment, and least comfortable sharing for administrative or research purposes (Wei et al., 2025a).

The Provider Perspective: Barriers to Data Sharing

Clinicians face their own challenges navigating SUD confidentiality in practice. A 2025 study examined perspectives from 31 healthcare providers across four treatment facilities through focus group discussions. The most frequently cited obstacles were patient reluctance to share (48%), data access challenges (42%), and poor provider coordination (29%). Providers emphasized that incomplete health information — the direct consequence of siloed records — compromises clinical decision-making and patient safety (Wei et al., 2025b).

For practitioners working under the updated regulatory framework, these findings point to a dual obligation: protecting patient privacy while actively engaging patients in informed conversations about how their records are handled, who has access, and what the benefits and risks of sharing are. The 2025 qualitative study's finding that most patients were unaware of their privacy protections suggests that this conversation is not happening consistently in practice.

Ethical Challenges in the Pandemic Era and Beyond

The COVID-19 pandemic introduced ethical dilemmas that tested the boundaries of SUD confidentiality in practice. A 2023 study conducted in-depth interviews with 18 front-line substance use counselors from residential and outpatient treatment programs. Researchers found that rapid shifts to telehealth, changes in group therapy formats, and new intake procedures created novel ethical tensions around confidentiality, informed consent, and the therapeutic relationship. While some adaptations created challenges for maintaining privacy standards, others enabled more flexible, client-centered approaches that some programs have continued post-pandemic (McCuistian et al., 2023).

For practitioners, these findings serve as a reminder that confidentiality is not a static set of rules applied identically across all contexts. Modality changes — telehealth, virtual groups, electronic communication — each introduce specific confidentiality considerations that require deliberate policy development and clinical staff training.

THE CONFIDENTIALITY OF ALCOHOL AND DRUG ABUSE PATIENT RECORDS REGULATION AND THE HIPAA PRIVACY RULE: IMPLICATIONS FOR ALCOHOL AND SUBSTANCE ABUSE PROGRAMS

June 2004

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The Confidentiality of Alcohol and Drug Abuse Patient Records Regulation and the HIPAA Privacy Rule: Implications for Alcohol and Substance Abuse Programs

Introduction

In the early 1970's, Congress recognized that the stigma associated with substance abuse and fear of prosecution deterred people from entering treatment and enacted legislation that gave patients a right to confidentiality. For the almost three decades since the Federal confidentiality regulations (42 CFR Part 2 or Part 2) were issued, confidentiality has been a cornerstone practice for substance abuse treatment programs across the country.

In December, 2000, the Department of Health and Human Services (HHS) issued the "Standards for Privacy of Individually Identifiable Health Information" final rule (Privacy Rule), pursuant to the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), 45 CFR Parts 160 and 164, Subparts A and E.[1] Substance abuse treatment programs that are subject to HIPAA must comply with the Privacy Rule.[2] [3] Substance abuse treatment programs that already are complying with Part 2 should not have a difficult time complying with the Privacy Rule, as it parallels the requirements of Part 2 in many areas. Programs subject to both sets of rules must comply with both, unless there is a conflict between them. Generally, this will mean that substance abuse treatment programs should continue to follow the Part 2 regulations. In some instances, programs will have to establish new policies and procedures or alter existing policies and practices. In the event a program identifies a conflict between the rules, it should notify the Substance Abuse and Mental Health Services Administration of HHS immediately for assistance in resolving the conflict.

This guidance is for substance abuse treatment programs that are subject to and already complying with the confidentiality requirements of Part 2.[4] It explains which programs must also comply with the Privacy Rule and outlines what compliance will require. The guidance is not a legal opinion. To comply with the Privacy Rule, programs should apply this guidance to their individual situations; programs may also want to call upon State agencies, provider organizations and legal counsel for assistance in establishing and implementing the practices and policy changes required by the Privacy Rule.

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[1] In August 2002, HHS adopted modifications to the Privacy Rule.

[2] The compliance date for the Privacy Rule was April 14, 2003. However, small health plans, as defined by the Privacy Rule, are not required to be in compliance until April 14, 2004.

[3] This guidance applies to substance abuse treatment programs that are also covered entities as defined by the Privacy Rule. Programs should seek legal counsel for assistance in determining whether they are covered entities.

[4] The Part 2 regulations apply to substance abuse treatment "programs" as defined by 42 CFR §2.11 that are "federally assisted" as defined by 42 CFR §2.12(b).

I. Applicability

A. Programs to which the Privacy Rule applies

The Privacy Rule applies to "covered entities" which are health plans, health care clearinghouses and health care providers[5] who transmit health information in electronic form (*i.e.*, via computer-based technology) in connection with transactions for which HHS has adopted a HIPAA standard in 45 CFR Part 162. See 45 CFR §160.103. HIPAA transactions that a substance abuse treatment program[6] might engage in include:

- Submission of claims to health plans
- Coordination of benefits with health plans
- Inquiries to health plans regarding eligibility, coverage or benefits or status of health care claims
- Transmission of enrollment and other information related to payment to health plans
- Referral certification and authorization (*i.e.,* requests for review of health care to obtain an authorization for providing health care or requests to obtain authorization for referring an individual to another health care provider)

If a substance abuse treatment program transmits health information electronically in connection with one or more of these Part 162 transactions, then it must comply with the Privacy Rule. Part 162 may be amended in the future to cover additional transactions.[7]

B. Information that is protected under Part 2 and the Privacy Rule

Part 2 protects any and all information that could reasonably be used to identify an individual and requires that disclosures be limited to the information necessary to carry out the purpose of the disclosure. See 42 CFR §§2.11 and 2.13(a). Under the Privacy Rule, a program may not use or disclose "protected health information" (PHI) except as permitted or required by the Rule.[8] See 45 CFR §164.502(a). Neither rule applies to information that has been de-identified.[9] See 45 CFR §164.514(a) (de-identification of

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[5] The Privacy Rule generally defines a health care provider to include a person or organization who furnishes, bills or is paid for health care in the normal course of business, which would include substance abuse treatment programs.

[6] A substance abuse treatment program is defined as an individual or entity that provides alcohol or drug abuse diagnosis, treatment or referral. For the purposes of this document, the term "program" includes both individual substance abuse providers and substance abuse provider organizations.

[7] Neither Part 2 nor the Privacy Rule protects employment records held by a program in its role as employer. Note that while 42 CFR Part 2 arguably applies to substance abuse patient records covered by the Family Educational Rights and Privacy Act (FERPA) (20 USC §1232g; 34 CFR Part 99), the Privacy Rule does not.

[8] PHI is defined as individually identifiable health information held or transmitted by a covered entity or its "business associate," with limited exceptions. See 45 CFR §160.103.

[9] The Privacy Rule includes numerous elements that make information identifiable, such as, but not limited to, information regarding employers, relatives and household members that are not necessarily

PHI) and 42 CFR §2.11 (definition of "patient identifying information"). The Privacy Rule permits programs to assign a code or other means of record identification to allow information that has been de-identified to be re-identified, as provided in 45 CFR §164.514(c).

The two regulations have some differences in the definition of what information is protected. For instance, the Privacy Rule treats medical record numbers as PHI, subject to all the same requirements as other PHI. Part 2 would permit a program to disclose a medical record number because the regulation does not apply to "a number assigned to a patient by a program, if that number does not consist of, or contain numbers . . . which could be used to identify a patient with reasonable accuracy and speed from sources external to the program." See 42 CFR §2.11. Programs subject to both rules must follow the Privacy Rule's protection of a medical record number.

C. When protections begin for someone seeking substance abuse treatment

Part 2 protects all information about any person who has applied for or been given diagnosis or treatment for alcohol or drug abuse at a federally assisted program. See 42 CFR §2.11 (definition of a "patient"). Information is subject to the Privacy Rule if it is individually identifiable information created, received, or maintained by the covered entity. Former patients and deceased patients are protected under both Part 2 and the Privacy Rule. See 42 CFR §§2.11 and 2.15 and 45 CFR §§164.501 and 164.502(f). Programs should generally continue to follow Part 2, but note that if PHI is received prior to a patient applying to a program, under the Privacy Rule, such information is protected.

II. How the Privacy Rule affects disclosures of information

A. The General Rule

The "general rules" established by Part 2 and the Privacy Rule regarding uses and disclosures of patient health information are very different.[10]

Substance abuse treatment programs must comply with both rules. Generally, this will mean that they will continue to follow Part 2's general rule and not disclose information unless they can obtain consent or point to an exception to that rule that specifically permits the disclosure. Programs must then make sure that the disclosure is also permissible under the Privacy Rule.

B. When disclosures are permitted

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identifiable information under Part 2. Such information should be protected consistent with the Privacy Rule requirements.

[10] Part 2 uses the term "disclosure" to cover what the Privacy Rule refers to as "uses" and "disclosures." See the definition of these terms in 45 CFR §160.103. Some Privacy Rule provisions differ for "uses" and "disclosures." For convenience, we generally use the Part 2 term "disclosure" throughout to encompass both uses and disclosures under the Privacy Rule. In some instances, however, specific uses or disclosures are discussed.

1. Part 2 Consent[11] and Privacy Rule Authorization

42 CFR Part 2	The Privacy Rule
Programs may not use or disclose any information about any patient unless the patient has consented in writing (on a form that meets the requirements established by the regulations) or unless another very limited exception specified in the regulations applies. Any disclosure must be limited to the information necessary to carry out the purpose of the disclosure.	The Privacy Rule permits uses and disclosures for "treatment, payment and health care operations" as well as certain other disclosures without the individual's prior written authorization. Disclosures not otherwise specifically permitted or required by the Privacy Rule must have an authorization that meets certain requirements. With certain exceptions, the Privacy Rule generally requires that uses and disclosures of PHI be the minimum necessary for the intended purpose of the use or disclosure.

Substance abuse treatment programs most often make disclosures after a patient has signed a consent form that meets the requirements of 42 CFR §2.31. Note that a disclosure under Part 2 includes the acknowledgment that someone has applied to or is enrolled in the program, and thus is only permitted if the patient has signed a consent form (or another of the regulations' narrow exceptions applies). See 42 CFR §§2.11 and 2.13. A Part 2 consent form 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 (and, in some States, a parent or guardian);
- 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.

[11] This document uses the term "consent" when referring to any written permission provided by a patient for the use or disclosure of identifiable health information. The Privacy Rule uses the term "authorization" for certain permissions, and also permits, but does not require, programs to obtain "consent" for the use and disclosure of PHI for purposes of treatment, payment, or health care operations.

When programs operating under Part 2 disclose information pursuant to a consent form, they must include a written statement that the information cannot be redisclosed. See 42 CFR §2.32.

The core required elements for the Privacy Rule written authorization are similar to those of Part 2. However, to comply with the Privacy Rule authorization requirements, the Part 2 consent must also contain a statement reflecting the ability or inability of the substance abuse treatment program to condition treatment on whether the patient signs the form as described in 45 CFR §164.508(c)(2)(ii). In addition, the consent may be signed by a personal representative, and if so, must include a description of such representative's authority to act for the patient. See 45 CFR §164.508(c)(1)(vi). Finally, the consent must be written in plain language. See 45 CFR §164.508(c)(3).

The requirements above must be met with respect to the Part 2 consent form when the purpose of the disclosure is *not* for "treatment, payment or health care operations" or for any other permitted or required disclosure under the Privacy Rule. See 45 CFR §164.502(a).[12] The statements would have to be added when the consent form authorizes a program to make a disclosure for which an authorization is required under the Privacy Rule, e.g., those disclosures addressed by 45 CFR §164.508.

The Privacy Rule imposes three additional steps programs must take when disclosing information pursuant to a patient's written consent:

- Programs must ensure that the consent complies with the applicable requirements of 45 CFR §164.508.
- Programs must give patients a copy of the signed form (45 CFR §164.508(c)(4)).
- Programs must keep a copy of each signed form for six (6) years from its expiration date (45 CFR §164.508(b)(6)).

Therefore, substance abuse treatment programs should generally continue to use the consent form for disclosures subject to Part 2. If the Privacy Rule requires authorization for the disclosures, the substance abuse treatment program may use the Part 2 consent form with additional elements required by the Privacy Rule as listed above.

<u>Minors</u>

[12] See the Privacy Rule's definitions of "treatment," "payment," and "health care operations" at 45 CFR §164.501. When a substance abuse treatment program obtains information about a patient from a school, relatives, health care providers and health plans for treatment or payment activities, when it refers a patient to other providers and services and when it coordinates care with other health care providers, it almost always makes an implicit disclosure that the patient has applied for or has received alcohol or drug abuse treatment services and thus the program is required to treat these contacts as disclosures and obtain patient consent prior to such contact. In most of these instances, the disclosure from the program is for treatment purposes and the additional Privacy Rule statements would not have to be added to the consent forms. Note that programs may add the Privacy Rule statements in all circumstances, and programs may find it more convenient to use only one kind of consent form.

The Privacy Rule defers to requirements in other applicable laws regarding the use or disclosure of health information regarding minors and, thus, does not change the rules in Part 2 regarding minors and consent. See 45 CFR §164.502(g). A minor must always sign the consent form for a program to release information even to his or her parent or guardian (42 CFR §2.14).[13] Some States require programs to obtain parental permission before providing treatment to a minor. In these States only, programs must get the signatures of both the minor and a parent, guardian, or other person legally responsible for the minor (42 CFR §2.14(c)(2)).

Revocation of Consent

Part 2 permits a patient to revoke consent orally (see 42 CFR §2.31(a)(8)); the Privacy Rule requires written revocation of an authorization (45 CFR §164.508(b)(5)). Substance abuse treatment programs must continue to honor verbal revocations but may want to obtain written revocation when possible or at a minimum document the revocation in the patient's record. Both Part 2 and the Privacy Rule allow the program to make a disclosure for services already rendered in reliance on a signed consent or authorization form. See 42 CFR §2.31(a)(8) and 45 CFR §164.508(b)(5)(i).

2. Other permissible disclosures under Part 2

Substance abuse treatment programs are accustomed to complying with Part 2's general rule prohibiting disclosure, unless the patient has consented in writing or the disclosure falls within one of the regulations' limited exceptions (*e.g.*, child abuse reporting, medical emergencies). In some instances, the Privacy Rule does not require a change in these practices. In others, the Privacy Rule will require some modification of programs' practices.

a. When little or no changes may be needed

Programs should generally continue to follow the rules in Part 2 regarding:

i. Internal program communications

Both Part 2 and the Privacy Rule allow for communications within programs on a "need to know" basis. Part 2 requires that the communication of information within the program (or to an entity with direct administrative control over the program)[14] be

[13] The only exception to this rule is when the program director determines that a minor applying for services lacks capacity for rational choice and that the minor applicant's situation poses a substantial threat to life or physical well being of the minor or any other person that may be reduced by communicating relevant facts to the minor's parent or guardian. See 42 CFR §2.14(d).

[14] In applying the Privacy Rule, programs should consider whether the program and the entity with "direct administrative control" over the program are two separate legal entities. If they are two separate legal entities, PHI flowing between the program and the other entity will generally be governed by the Privacy Rule's requirements regarding "disclosure" rather than "use" of PHI. However, the Privacy Rule recognizes that health care providers may have different organizational arrangements and has established different rules to reflect such arrangements. See the Privacy Rule's provisions regarding hybrid entities

limited to those persons who 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. See 42 CFR §2.12(c)(3). Similarly, the Privacy Rule requires programs to identify the staff persons or classes of persons in its workforce who need access to PHI, the categories of PHI they need access to, and any conditions appropriate to such access. See 45 CFR §164.514(d)(2)(i). The program must then make reasonable efforts to limit access of such persons or classes of persons to PHI based on these determinations. See 45 CFR §164.514(d)(2)(ii). Substance abuse treatment programs subject to the Privacy Rule will have to establish written policies to comply with the minimum necessary requirement of the Privacy Rule, although in practice, the programs should be able to operate as they have under Part 2 in this regard.

ii. Crimes on program premises or against program personnel

Part 2 permits programs to disclose limited information to law enforcement officers. Such disclosures must be directly related to crimes and threats to commit crimes on program premises or against program personnel and must be limited to the circumstances of the incident and the patient's status, name, address and last known whereabouts. See 42 CFR §2.12(c)(5). The Privacy Rule permits programs to disclose to law enforcement officials PHI that the program believes in good faith constitutes evidence of a crime that occurred on the program's premises. See 45 CFR §164.512(f)(5). It also permits any member of the program's staff who is the victim of a crime to report certain information about the suspected perpetrator to law enforcement officials. See 45 CFR §164.502(j)(2). Programs should continue to follow the rules established by Part 2.

iii. Child abuse reporting

Part 2 permits programs to comply with State laws that require the reporting of child abuse and neglect. See 42 CFR §2.12(c)(6). The Privacy Rule also permits such reporting. See 45 CFR §164.512(b)(1)(ii). However, Part 2 limits programs to making only an initial report; it does not allow programs to respond to follow-up requests for information or to subpoenas, unless the patient has signed a consent form or a court has issued an order that complies with the rule (see "Subpoenas and court-ordered disclosures," below). Programs should continue to follow the rules established by Part 2.

iv. Medical emergencies

Part 2 allows patient-identifying information to be disclosed to medical personnel who have a need for the information about a patient for the purpose of treating a condition which poses an immediate threat to the health of any individual and which requires

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(45 CFR §164.105(a) and (c)), affiliated covered entities (45 CFR §164.105(b) and (c)), and organized health care arrangements (OHCAs) (45 CFR §160.103 (definition of "business associate" and "OHCA"), 45 CFR §164.506(c)(5), and 45 CFR §164.520(d)).

immediate medical intervention. See 42 CFR §2.51. A program can disclose information only to medical personnel and must limit the amount of information to that which is necessary to treat the emergency medical condition. Immediately following the disclosure, the program must document the following in the patient's records:

- 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.

These practices are not affected by the Privacy Rule.

v. Subpoenas and court-ordered disclosures

Part 2 permits programs to release information in response to a subpoena if the patient signs a consent permitting release of the information requested in the subpoena. When the patient does not consent, Part 2 prohibits programs from releasing information in response to a subpoena, unless a court has issued an order that complies with the rule. See 42 CFR Part 2, Subpart E. Subpart E sets out the procedure the court must follow, the findings it must make, and the limits it must place on any disclosure it authorizes.

The Privacy Rule permits a program to disclose PHI pursuant to a subpoena without a prior written authorization, if it receives satisfactory assurance from the party seeking the information that reasonable efforts have been made to ensure that the individual has been given notice of the request for PHI and the opportunity to object, or reasonable efforts have been made to secure a qualified protective order. See 45 CFR §164.512(e)(1)(ii). The Privacy Rule has different requirements regarding court orders, but programs can comply with both Part 2 and the Privacy Rule by continuing to follow the Part 2's court order requirements. Unless the disclosure requires authorization under the Privacy Rule, the Part 2 consent form can be used.

b. When some change is required

i. Disclosures that do not reveal patient-identifying information

Part 2 permits a substance abuse treatment program to disclose information about a patient if the disclosure does not identify the patient as an alcohol or drug abuser or as someone who has applied for or received substance abuse assessment or treatment services. See 42 CFR §§2.11 and 2.12(a). This allows a program that is part of a larger entity, such as a hospital, to disclose information about a patient so long as it does not explicitly or implicitly disclose the fact that the patient is an alcohol or drug abuser. For example, a program that is part of a hospital could disclose to a public health department that a named patient has TB by identifying itself only as part of the hospital and not as a substance abuse treatment program and by taking care not to mention that the patient is in substance abuse treatment.

Many programs that are part of larger entities are accustomed to using this exception in Part 2 to gather information about patients from, for example, other health care providers, schools, and employers, or to refer patients to other providers.[15] Some of these practices by programs that are part of larger entities will continue to be permissible under the Privacy Rule, which does not require patients to authorize disclosures for purposes of treatment, payment or health care operations. The Privacy Rule also permits programs to share information about an individual's treatment or payment related to the individual's health care with persons involved in the individual's care. See 45 CFR §164.510(b).

The Privacy Rule also allows for certain disclosures to be made without authorization that are not for treatment, payment or health care operations. See 45 CFR §164.512. For example, the Privacy Rule permits a program to disclose, without the patient's prior authorization, to a public health department that the patient has TB when the health department is authorized to collect such information. However, any program that is accustomed to making "non-patient identifying" disclosures of information that do not identify the subject as a substance abuser and that are not for treatment purposes should consult the Privacy Rule directly to determine whether those disclosures continue to be permissible.

Part 2 does not permit freestanding programs to make inquiries about patients or refer patients to other providers without written consent. The Privacy Rule does not change this prohibition.

ii. Disclosures to agencies that provide services to programs

Disclosures to Qualified Service Organizations

Both Part 2 and the Privacy Rule recognize that substance abuse treatment programs sometimes need to disclose information about patients to persons or agencies that provide services to the program, such as legal or accounting services. The Part 2 regulations call such service providers "qualified service organizations" and permit programs to sign "qualified service organization agreements" (QSOAs) allowing them to disclose patient-identifying information needed by the organization to provide services to the program. See 42 CFR §2.12(c)(4). In the agreements, the outside service providers acknowledge that in receiving, storing, processing or otherwise dealing with patients' records they are fully bound by Part 2 and 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.

Under the Privacy Rule, such outside service providers are "business associates" of the substance abuse treatment program and the program must have a business associate agreement with the business associate in order to share PHI needed by the organization

[15] As noted above, when a program makes an inquiry about, or refers, a patient, it is often making an implicit disclosure that the patient is in substance abuse treatment.

to provide services (see 45 CFR §§160.103 and 164.502(e)).[16] The Privacy Rule has different requirements regarding the content of the business associate contract (the HHS Office for Civil Rights has published sample contract language). See 67 Federal Register 53264 (August 14, 2002).

Substance abuse treatment programs must meet the requirements of both Part 2 and the Privacy Rule if they are going to continue to share information with lawyers, accountants and others that provide services to the program.

Transition Provisions: The Privacy Rule permits programs to continue to use current contracts with service providers until April 14, 2004, if the contract existed prior to October 15, 2002, and the contract is not subsequently renewed or modified. Any contract that is renewed or modified after October 15, 2002, must comply with the business associate contract requirements. See 45 CFR §164.532(d).

Disclosures to accreditation bodies

Part 2 permits disclosures to accreditation bodies such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) under either the QSO provision or the "audit and evaluation" exception, discussed below. The Privacy Rule, however, considers accreditation bodies business associates conducting health care operations on behalf of the covered entity. See 45 CFR §§160.103; 164.501. Substance abuse treatment programs subject to the Privacy Rule who undergo accreditation will have to sign business associate contracts with accreditation organizations. Additionally, substance abuse treatment programs must comply with Part 2, either by ensuring that the business associate contract contains all the requirements of a QSOA or by fulfilling the mandates of the audit and evaluation provisions.

iii. Audit and evaluation

Both Part 2 and the Privacy Rule 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. The Privacy Rule requires that uses and disclosures be limited to the minimum necessary to accomplish the audit or evaluation. Each rule has its own additional requirements. Substance abuse treatment programs subject to both Part 2 and the Privacy Rule must combine those requirements. Three options result:

- If the audit or evaluation is conducted by a program or its employees, it is permissible under both sets of regulations; no patient consent or authorization is required. See 42 CFR §2.12(c)(3) and 45 CFR §164.502(a)(1)(ii).

[16] A memorandum of understanding would generally be used between government entities rather than a business associate contract.

- If the audit or evaluation is conducted by a "health oversight agency,"[17] the program may disclose patient-identifying information so long as the health oversight agency makes the written commitments required by 42 CFR §2.53(d) and the disclosure meets the requirements in 45 CFR §164.512(d). If the health oversight agency copies or removes patient records from the program, it must agree in writing to abide by the requirements of 42 CFR §2.53(b).
- If an audit or evaluation is conducted by an outside entity on behalf of the program as opposed to a "health oversight agency," the program must have a signed a business associate contract with the auditor or evaluator that satisfies the requirements of both the Privacy Rule and Part 2 by incorporating either the necessary QSO agreement requirements (as discussed above in II.B.2.b.ii) or the appropriate provisions of 42 CFR §2.53.

iv. Research

The Part 2 regulations and the Privacy Rule have different requirements for disclosures of health information to researchers. See 42 CFR §2.52 and 45 CFR §164.512(i). This will be the subject of additional guidance.

III. Other Changes Required by the Privacy Rule[18]

A. Patient Notice/Notice of Privacy Practices

Part 2 requires that programs notify patients that Federal law and regulations protect the confidentiality of alcohol and drug abuse patient records and give them a written summary of the regulations' requirements. See 42 CFR §2.22. The Privacy Rule requires that patients be given a notice of the program's privacy practices as well as their rights under the Privacy Rule. See 45 CFR §164.520. Programs subject to both rules can combine their requirements into a single notice.

1. Notice content

Accordingly, the combined notice must contain all the elements required by 42 CFR §2.22, and in addition, contain the following:

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[17] Under the Privacy Rule, a "health oversight agency" is an agency or authority or the United States, a State, a territory, a political subdivision of a State or a territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such a public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is authorized by law to oversee the health care system (whether public or private) or government programs in which health information is necessary to determine eligibility or compliance or to enforce civil rights laws for which health information is relevant (45 CFR §164.501). Disclosures to health oversight agencies when an individual is the subject of the investigation are prohibited under certain circumstances by the Privacy Rule (45 CFR §164.512(d)(2)).

[18] This last section addresses issues on which Part 2 is largely silent. Thus, these can be seen as new requirements imposed by the Privacy Rule to which programs now must adhere.

- A statement, prominently displayed stating: "THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY;"
- A description in sufficient detail of the types of uses and disclosures that the program may make without the patient's consent or authorization.[19] For substance abuse treatment programs, these would include uses and disclosures:
    - In connection with treatment, payment or health care operations (include at least one example of each);
    - To qualified service organizations or business associates who provide services to the program's treatment, payment or health care operations;
    - In medical emergencies;
    - Authorized by court order;
    - To auditors and evaluators;
    - To researchers if the information will be protected as required by Federal regulations;
    - To report suspected child abuse or neglect; and
    - To report a crime or a threat to commit a crime on program premises or against program personnel.
- A statement that other disclosures will be made only with the patient's written consent or authorization which can be revoked, unless the program has taken action in reliance on the consent or authorization. ;[20]
- A statement that the program may contact the patient to provide appointment reminders or information about treatment alternatives or other health-related benefits and services that may be of interest to the patient;[21]
- A statement that it is required by law to maintain the privacy of PHI and to notify patients of its legal duties and privacy practices, including any changes to its policies;
- A statement that the program must abide by the terms of the notice currently in effect; a statement that the program reserves the right to change the terms of its notice and to make the new notice provisions effective for all information it maintains;[22] and a statement describing how it will provide patients with a revised notice of its practices;

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[19] The Privacy Rule also requires that the notice contain information about any more restrictive law. For example, if State law further limits disclosure of HIV-related information, that restriction should also appear in the notice.

[20] Programs often need to provide PHI to criminal justice agencies that mandate patients into treatment. Under Part 2, such disclosures may be made pursuant to a non-revocable consent that complies with 42 CFR §2.35. Under the Privacy Rule, such disclosures may be made pursuant to an authorization or pursuant to a court order. In order to comply with both rules, programs may find it helpful to ask the court in such a situation to issue an order that the program disclose necessary information to the court and other law enforcement personnel.

[21] A substance abuse treatment program engaging in these kinds of activities must be careful in contacting the patient that it does not make any patient-identifying disclosures to others. If the program does not intend to contact the patient, they do not need to include this statement.

[22] This is also voluntary. However, if this statement is not included, any changes in privacy practices described in the notice will apply only to PHI the program created or received after issuing a revised notice reflecting such changes. 45 CFR §164.520(b)(1)(v)(C).

- The name or title and telephone number of a person or office the patient can contact for further information;
- A statement of the patient's rights with respect to PHI and a brief description of how the patient may exercise those rights, including:
    - The right to request restrictions on certain uses and disclosures of PHI, including the statement that the program is not required to agree with requested restrictions;
    - The right to receive confidential communications of PHI (such as having mail and telephone calls be limited to home or office location);
    - The right to access and amend PHI;
    - The right to receive an accounting of the program's disclosures of PHI;
    - The right to complain—free from retaliation—to the program and to the Secretary of Health and Human Services (HHS) about violations of privacy rights, and information on how to file a complaint with the program; and
    - The right to obtain a paper copy of the notice upon request.
- The effective date of the notice.

See 45 CFR §164.520(b).

2. Distribution of the Notice

Part 2 requires that programs provide the notice at the time of admission or as soon thereafter as the patient is capable of rational communication. See 42 CFR §2.22(a). The Privacy Rule requires that the substance abuse treatment program must provide the notice to a patient on the date of the first service delivery, including service delivered electronically, after April 14, 2003.[23] The program must also have the notice available on site for patients to request to take with them and posted in a clear and prominent location where it is reasonable to expect patients to be able to read it. Whenever there is a material change to the notice, the notice must be promptly revised, made available upon request, and re-posted as previously referenced. See 45 CFR §§164.520(c)(2); 164.530(i)(4)(i)(C).

The program must make a good faith effort to obtain patients' written acknowledgment of receipt of the notice, except in an emergency treatment situation, on the date of the first service delivery. If written acknowledgment is not obtained, the program must document its efforts and the reason it was not able to obtain the acknowledgement. See 45 CFR §164.520(c)(2)(ii).

Any program that maintains a web site that provides information about its services or benefits must prominently post its notice on the site and make it available electronically through the site. When patients agree, the program can provide the notice by e-mail. See 45 CFR §164.520(c)(3).

[23] There is an exception in emergency situations. If treatment is provided on an emergency basis, the program must provide the notice as soon as practicable after the emergency is resolved. See 45 CFR §164.520(c)(2)(i)(B).

B. Patient rights

The Privacy Rule provides patients with new Federal privacy rights, including the right to request restrictions of uses and disclosures of PHI, and the right to access, amend, and receive an accounting of disclosures of PHI. See 45 CFR §§164.522, 164.524, 164.526,164.528.

1. Right to request a restriction of uses and disclosures

The Privacy Rule requires that programs allow patients to request that the program restrict uses or disclosures of PHI for the purpose of treatment, payment or health care operations and for involvement in the patient's care and notification under 45 CFR §164.510(b). The program is not required to agree to a requested restriction. If, however, a program agrees to a restriction, the program may not then violate the agreed-upon restriction, except for emergency treatment purposes, so long as the program requests that the emergency treatment provider not further use or disclose the PHI. A covered entity may terminate the agreement to a restriction, effective after the patient has been informed of the termination. See 45 CFR §164.522(a).

The Privacy Rule gives the individual the right to request that communication of PHI be done by alternative means or to alternative locations (confidential communications). See 45 CFR §164.522(b)(1)(i). This might include the right to request that mail and telephone calls be limited to home or office location. The Privacy Rule requires programs to accommodate reasonable requests.

2. Right to access PHI

Neither Part 2 nor the Privacy Rule requires programs to obtain written consent from individuals before permitting them to see their own records. Likewise, neither rule prohibits a program from giving a patient access to his or her own records, including the opportunity to inspect and copy any records that the program maintains about the patient. 42 CFR §2.23. However, the Privacy Rule permits programs to require that such requests be in writing. See 45 CFR §164.524(b)(1). The Privacy Rule provides patients with a right of access to inspect and obtain a copy of their PHI. See 45 CFR §164.524(a)(1).[24] Certain information, however, is exempt from this right of access:

[24] The Privacy Rule requires access to information in a designated record set for as long as the PHI is maintained in the designated record set. "Designated record set" is defined as "[a] group of records maintained by or for a covered entity that is: (i) The medical records and billing records about individuals maintained by or for a covered health care provider; (ii) The enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or (iii) Used, in whole or in part, by or for the covered entity to make decisions about individuals." 45 CFR §164.501. The program must document the designated record sets that are subject to access and the titles of the persons or offices responsible for receiving and processing requests for access (45 CFR §164.524(e)). It must retain the documentation for six (6) years from the date it was last effective, whichever is later (45 CFR §164.530(j)). Under Part 2, the information need not be contained in a designated record set. Thus, programs could permit access to all disclosable patient records.

- Psychotherapy notes;[25]
- Information compiled in reasonable anticipation of or for use in a civil, criminal, or administrative action or proceeding; and
- Information that may be subject to or exempt from certain Clinical Laboratory Improvement Amendment (CLIA) provisions.

See 45 CFR §164.524(a)(1).

The Privacy Rule requires that programs respond to a patient's request for access within 30 days after receipt of the request (within 60 days if the information is not maintained or accessible on-site). The program may extend the deadline once by not more than 30 days, if within 30 days of the receipt of the request (or 60 days of receipt if the information is not on-site), the patient is provided with a written statement containing the reasons for the delay and the date by which it will permit access. See 45 CFR §164.524(b). If the program does not maintain the requested information, but knows where the requested information is maintained, it must inform the patient where to direct his or her request. See 45 CFR §164.524(d)(3).

If a program grants the patient's request for access to his or her records, it can charge the patient a reasonable, cost-based fee, consistent with the restrictions on fees as provided in the Privacy Rule. See 45 CFR §164.524(c)(4).[26]

Denial of Access

The Privacy Rule allows a program to deny a patient access without providing an opportunity for review of the denial, on the following grounds:

- The information is specifically exempted from the right of access by the Privacy Rule. See 45 CFR §164.524(a)(1);
- The program is a correctional institution or a provider acting under the direction of the correctional institution and denies in whole or in part an inmate's request to obtain a copy of his or her records if doing so would jeopardize the health, safety, security, custody, or rehabilitation of the individual or of other inmates, or the safety of an officer, employee or other person at the correctional institution or responsible for transporting the inmate. See §164.524(a)(2)(ii));
- The requested information was created or obtained by a program in the course of research that includes treatment. The individual's access to such information

[25] The Privacy Rule defines "psychotherapy notes" as "notes recorded (in any medium) by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session and that are separated from the rest of the individual's medical record. *Psychotherapy notes* excludes medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date." 45 CFR §164.501.

[26] Information obtained by patient access to his or her own record is subject to Part 2's restriction on use of the information to initiate or substantiate any criminal charges against the patient or to conduct any criminal investigation of the patient. See 42 CFR §2.23(b).

may be temporarily suspended for as long as the research is in progress, provided that the individual has agreed to the denial of access when consenting to participate in the research and the program has informed him or her that the right of access will be reinstated upon completion of the research. See 45 CFR §164.524(a)(2)(iii);
- The requested information is subject to the Privacy Act and would be denied under the access provisions of the Privacy Act, 5 USC §522a. See 45 CFR §164.524(a)(2)(iv); or
- The requested information was obtained under a promise of confidentiality from someone other than a health care provider and such access would be likely to reveal the source of the information. See 45 CFR §164.524(a)(2)(v).

The Privacy Rule permits a program to deny patient access, provided that the patient is given the right to have such a denial reviewed, on the following grounds:

- A licensed health care professional has determined, in the exercise of professional judgment, that the access requested is reasonably likely to endanger the life or physical safety of the patient or another person;
- The information makes reference to another person (other than a health care provider) and a licensed health care professional has determined, in the exercise of professional judgment, that the access is reasonably likely to cause substantial harm to such other person; or
- The request for access is made by the patient's personal representative and a licensed health care professional has determined, in the exercise of professional judgment, that the provision of access to such personal representative is reasonably likely to cause substantial harm to the patient or another person.

See 45 CFR §164.524(a)(3).

If the program's denial is based on one of the last three reasons, the patient has the right to have that denial reviewed by a licensed health care professional who is designated by the program to act as a reviewing official and who did not participate in the original decision to deny access. See 45 CFR §164.524(a)(4).

If the program denies a patient access to all or parts of his or her PHI, it must give the patient a timely denial written in plain language containing:

- The basis for the denial;
- If applicable, a statement of the patient's review rights, including a description of how the patient may exercise those rights; and
- A description of how the patient may complain to the program or to the Secretary of HHS. The description must include information regarding how the patient may complain to the program pursuant to the program's complaint procedures or to the Secretary, and must include the name or title, and telephone number of the contact person or office designated by the program to receive complaints.

See 45 CFR §164.524(d)(2).

A program that denies a patient access in part must give the patient access to any other PHI requested after excluding the information to which the program had reason to deny access. See 45 CFR §164.524(d)(1).

3. The right to amend PHI

The Privacy Rule gives patients the right to have the program amend their PHI or a record about the patient in a designated record set. See 45 CFR §164.526. The program must act on a patient's request for amendment within 60 days after it receives the request. The program may extend the deadline once by not more than 30 days if, within the 60 days, the patient is provided with a written statement of the reasons for the delay and the date by which it will respond. See 45 CFR §164.526(b)(2).

A program that accepts a patient's request to amend PHI must:

- Timely inform the patient of its decision to accept the amendment;
- Make the appropriate amendment by identifying the records in the designated record set that are affected by the amendment and appending or otherwise providing a link to the location of the amendment; and
- If the patient agrees, make reasonable efforts to notify and provide the amendment within a reasonable period of time to:
    - Persons identified by the patient as having received the patient's PHI and needing the amendment; and
    - Persons, including business associates, that the program knows to have received the PHI that is the subject of the amendment and that may have relied, or could foreseeably rely on such information to the detriment of the patient.

See 45 CFR §164.526(c).

A program must obtain patient consent on forms that comply with 42 CFR §2.31 before it provides any copies of the amendment to other persons or organizations.

Denial of Amendment

A program may deny a patient's request for amendment if it determines that:

- It did not create the information, unless the patient provides a reasonable basis to believe that the originator of the PHI is no longer available to act on the requested amendment;
- The information or record is accurate and complete; or

- The information that is the subject of the request is not part of a designated record set or would not otherwise be available for inspection under the Privacy Rule's request for access provisions.

See 45 CFR §164.526(a)(2).

If a program denies a patient's request to amend records, it must give him or her a timely denial, written in plain language, and contain:

- The basis for the denial;
- Notice of the patient's right to file a written statement of disagreement with the denial and how the patient may file such a statement;
- Notice that, if the patient does not submit a statement of disagreement, the patient may request that the program include his or her request for amendment and its denial with any future disclosures of the PHI that is subject to the amendment; and
- A description of how the patient may complain about the program's actions to the program or to the Secretary of HHS. The description must include information regarding how the individual may complain to the program pursuant to its complaint procedures or to the Secretary, and must include the name or title, and telephone number of the contact person or office designated by the program to receive complaints.

See 45 CFR §164.526(d)(1).

The program may prepare a written rebuttal to the patient's statement of disagreement. If it prepares such a rebuttal, it must provide a copy to the patient who submitted the statement of disagreement. This information (e.g. the statement of disagreement and rebuttal), or in some cases, a summary, must all be included in any subsequent disclosures of the information to which the disagreement relates as provided in 45 CFR §164.526(d)(3), (4), and (5).

The program must document the titles of the persons or offices responsible for receiving and processing requests for amendment. It must retain the documentation for six (6) years from the date it was created or last effective, whichever is later. See 45 CFR §164.526(f).

4. Right to an accounting of disclosures of PHI

The Privacy Rule provides individuals with the right to obtain an accounting of certain disclosures of PHI made by a program during the six (6) years prior to the request. See 45 CFR §164.528(a).

A program does not have to provide an accounting for any disclosures that were made:

- For treatment, payment, and health care operations as provided in 45 CFR §164.506;
- To the patient as provided in 45 CFR §164.502;
- Incident to a use or disclosure that is otherwise permitted as provided in 45 CFR §164.502;
- Pursuant to the patient's written consent (an "authorization" meeting the Privacy Rule's requirements at 45 CFR §164.508);
- For the facility's directory or to persons involved in the patient's care or other notification purposes as set forth by the rule at 45 CFR §164.510;
- For national security or intelligence purposes as provided by the rule at 45 CFR §164.512(k)(2);
- To correctional institutions or law enforcement officials having custody of an inmate or individual and as specified under 45 CFR §164.512(k)(5);
- As part of a limited data set in accordance with the rule at 45 CFR §164.514(e); and
- Before April 14, 2003.

See 45 CFR §164.528(a)(1). In addition, a program must temporarily suspend a patient's right to receive an accounting of disclosures to a health oversight agency or law enforcement official if the program receives notification that it would be reasonably likely to impede the activities of the agency or official. See 45 CFR §164.528(a)(2).

The accounting must be in writing[27] and include:

- The date of each disclosure;
- The name and address (if known) of the entity or person who received the PHI;
- A brief description of the PHI disclosed; and
- A brief statement of the purpose of the disclosure that reasonably informs the individual of the basis for the disclosure, or a copy of a written request for disclosure, if any.

See 45 CFR §164.528(b)(2).

For substance abuse treatment programs, the following disclosures are typically made without patient consent and must therefore be included in an accounting of disclosures:

- Disclosures to health oversight agencies;
- Disclosures to researchers that include patient-identifying information;[28]
- Disclosures to public health authorities;[29]

[27] There are special provisions under the Privacy Rule that are applicable to accounting for recurrent disclosures and certain research disclosures. See 45 CFR §§164.528(b)(3) and (b)(4).
[28] There are special provisions under the Privacy Rule that are applicable to accounting for research. See 45 CFR §164.528(b)(4)).
[29] When a program authorizes access to an entire universe of records, e.g., for public health surveillance activities, the Privacy Rule's accounting requirement can be met without the program having to make a

- Court-ordered disclosures;
- Reports of patient crimes on program premises or against program personnel; and
- Child abuse and neglect reports.

Programs should establish mechanisms to document all disclosures for which they must account.

The accounting must be made within 60 days of the program's receipt of the request. The program may extend the deadline once by not more than 30 days if, within the 60 days, the patient is provided with a written statement of the reasons for the delay and the date by which it will provide the accounting. A program must respond to a patient's request for one accounting within any 12-month period without charge. For any subsequent request within a 12-month period, it may charge a patient a reasonable, cost-based fee. If the program imposes a fee, it must inform the patient of the fee in advance and give the patient an opportunity to withdraw or modify the request. See 45 CFR §164.528(c).

The program must also document the following:

- The information it was required to provide the patient;
- The written accounting it provided the patient; and
- The titles of the persons or offices responsible for receiving and processing requests for an accounting.

This documentation must be retained for six (6) years from the date created or last effective, which ever is later. See 45 CFR §164.528(d).

C. Administrative Requirements

1. Complaints about the program's privacy practices

Part 2 allows violations of those regulations to be reported to the United States Attorney for the judicial district in which the violation occurs. See 42 CFR §2.5.

The Privacy Rule establishes a process for individuals to file a complaint with the Secretary of HHS if they believe a program violated the Privacy Rule. The complaint must be written, either on paper or electronically, and filed with HHS' Office for Civil Rights within 180 days of when the complainant knew, or should have known, that the act or omission complained of occurred, unless a waiver is granted. The complaint must name the program and describe the violation of the Privacy Rule. See 45 CFR §160.306. Programs must also establish a process for individuals to make complaints about the program's privacy policies and procedures or the program's compliance with

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notation in each medical record that has been accessed by public health authorities. See Office for Civil Rights, Frequently Asked Questions, http://www.hhs.gov/ocr/hipaa.

such policies and procedures or with the requirements of the Privacy Rule. See 45 CFR §164.530(d).

2. Other administrative requirements

Programs subject to the Privacy Rule are required to meet administrative requirements including:

- Designate a privacy official who is responsible for the development and implementation of its policies and procedures and a contact person or office responsible for receiving complaints and able to provide further information. See 45 CFR §164.530(a).
- Train all members of the workforce on the program's policies and procedures. Each new member of the workforce must receive training within a reasonable period of time after s/he joins the workforce. Whenever a workforce member's functions are affected by a material change in privacy policies or procedures, that person must receive additional training within a reasonable period of time after the material change becomes effective. The program must document all training and retain the records for a period of six (6) years after the training. See 45 CFR §164.530(b).
- Have in place appropriate administrative, technical, and physical safeguards to protect the privacy of PHI. See 45 CFR §164.530(c).
- Establish written policies and procedures that identify the staff persons or classes of persons who need access to patients' PHI, the categories of PHI they need access to, and any conditions appropriate to such access. The program must make reasonable efforts to limit access based on these determinations. See 45 CFR §164.514(d)(2).
- Establish policies and procedures to ensure that, for disclosures of information that occur on a routine and recurring basis, reasonable efforts are made to limit disclosures to the minimum necessary to accomplish the intended purpose of the disclosure. See 45 CFR §§164.502(b) and 164.514(d)(3)(i). For "all other disclosures," the program must develop criteria designed to limit the information it discloses to the information reasonably necessary to accomplish the purpose for which disclosure is sought and review requests for disclosure on an individual basis in accordance with those criteria. See 45 CFR §164.514(d)(3)(ii). Programs must also develop policies, procedures and criteria to ensure that requests to other entities subject to the Privacy Rule for PHI are limited to information "which is reasonably necessary to accomplish the purpose for which the request is made." See 45 CFR §164.514(d)(4). The written polices and procedures must be retained for six (6) years after the last time they were effective. See 45 CFR §164.530(j).
- Establish and apply appropriate sanctions against members of its workforce who fail to comply with its privacy policies and procedures. See 45 CFR §164.530(e).

- Mitigate, to the extent practicable, any harmful effect that is known to the program that results from a use or disclosure in violation of its policies and procedures. See 45 CFR §164.530(f).
- Refrain from taking intimidating, threatening, coercing, discriminating, or other retaliatory action against any individual who exercises rights under the Privacy Rule, including filing a complaint, assisting in an investigation, compliance review, proceeding or hearing pursuant to the Privacy Rule, as well as any individual who opposes any act or practice made unlawful by the Privacy Rule, provided that he or she has a good faith belief that the practice is unlawful and the manner of opposition is reasonable and does not invoke an impermissible disclosure of PHI. See 45 CFR §164.530(g).
- Not require patients to waive their rights to complain to the Secretary of HHS or their other rights under the Privacy Rule as a condition of treatment, payment, enrollment in a health plan, or eligibility for benefits. See 45 CFR §164.530(h).
- Implement policies and procedures regarding PHI that are designed to comply with the standards, implementation specifications, and other requirements of the Privacy Rule, and maintain the policies and procedures in written or electronic form for six years from the date the document was created, or last effective, whichever is later. See 45 CFR §164.530(i) and (j).

D. Security of information

Part 2 requires programs to maintain patient written records in a secure room, locked file cabinet, safe or other similar container. The regulations also require programs to adopt written procedures to regulate access to patients' records. See 42 CFR §2.16.

Section 164.530(c) of the Privacy Rule requires programs to maintain reasonable and appropriate administrative, technical and physical safeguards to protect the privacy of PHI. The issue of security has been addressed in more detail through a separate Security Rule issued by HHS on February 20, 2003 that established the physical and technical security standards required to guard the integrity, confidentiality and availability of confidential information that is electronically stored, maintained or transmitted. See 68 Federal Register 8334. Covered entities must be in compliance with the Security Rule by April 20, 2005, except small health plans which have until April 20, 2006.

Conclusion

Compliance with Part 2 has given the substance abuse treatment programs extensive experience with protecting patient confidentiality. Although substance abuse programs will need to make some changes to their business practices, they have a good starting point to work from in achieving compliance with the HIPAA Privacy Rule. Substance abuse treatment programs should contact their respective State substance abuse agencies and/or provider organizations, as well as legal counsel for assistance in implementing practices that will comply with both Part 2 and the Privacy Rule.

For more information about the HIPAA Standards

http://www.hipaa.samhsa.gov is the SAMHSA website which provides information and links for all HIPAA standards.

Standards for Privacy of Individually Identifiable Health Information (45 CFR Parts 160 and 164)
More information can be obtained from the Office for Civil Rights HIPAA website
http://hhs.gov/ocr/hipaa

Standards for Electronic Transactions (45 CFR Parts 160 and 162)
The Standards for Electronic Transactions can be obtained from the Center for Medicare and Medicaid Services (CMS) website at
http://cms.gov/hipaa/hipaa2/default.asp

Standard Unique Employer Identifier (45 CFR Parts 160 and 162)
http://cms.gov/hipaa/hipaa2/default.asp

Security Standards (45 CFR Parts 160, 162 and 164)
http://cms.gov/hipaa/hipaa2/default.asp

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Substance Abuse and Mental Health Services Administration
Center for Substance Abuse Treatment
www.samhsa.gov

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Appendix A: Confidentiality of Alcohol and Drug Abuse Patient Record Regulation and the HIPAA Privacy Rule

Directions: To receive credits for this course, you are required to take a post test and receive a passing score. We have set a minimum standard of 80% as the passing score to assure the highest standard of knowledge retention and understanding. The test is comprised of multiple choice and/or true/false questions that will investigate your knowledge and understanding of the materials found in this CEU Matrix – The Institute for Addiction and Criminal Justice distance learning course.

After you complete your reading and review of this material, you will need to answer each of the test questions. Then, submit your test to us for processing. This can be done in the following manner:

Submit your test via the Internet. All of our tests are posted electronically, allowing immediate test results and quicker processing. First, you may want to answer your post test questions found at the end of this appendix. Then, return to your browser and go to the Student Center located at:

http://www.ceumatrix.com/studentcenter

Once there, log in as a Returning Customer using your Email Address and Password. Then click on 'View Lesson Quiz' and you will be presented with the electronic exam.

To take the exam, simply select from the choices of "a" through "e" for each multiple choice question. For true/false questions, select either "a" for true, or "b" for false. Once you are done, simply click on the submit button at the bottom of the page. Your exam will be graded and you will receive your results immediately. If your score is 80% or greater, you will receive a link to the course evaluation. You will also receive a link to the Certificate of Completion. This is the final step in the process, and you may save and / or print your Certificate of Completion.

If, however, you do not achieve a passing score of at least 80%, you will need to review the course material and return to the Student Center to resubmit your answers.

NOTE: THE EXAM QUESTIONS AND /OR ANSWERS MAY BE IN A DIFFERENT ORDER IN THE ONLINE EXAM

Answer the following questions by selecting the most appropriate response.

1. HIPAA transactions that a substance abuse treatment program might engage in include:
   a. coordination of benefits with health plans
   b. transmission of enrollment and other information related to payment to health plans
   c. submission of claims to health plans
   d. referral certification and authorization
   e. all of the above

2. Information is subject to the Privacy Rule if it is individually identifiable information created, received, or maintained by the covered entity.
   a. true
   b. false

3. Deceased patients are not necessarily protected under the Privacy Rule.
   a. true
   b. false

4. When disclosing information pursuant to a patient's written request, programs must do all of the following except:
   a. give patients a copy of the signed form
   b. provide a copy to the patient's next of kin when requested
   c. ensure that the consent complies with the applicable requirements
   d. keep a copy of each signed form for 6 years

5. Communication within programs regarding a patient is allowed:
   a. at all times
   b. when the receptionist needs to schedule future appointments
   c. to all members of a group therapy session
   d. on a "need to know" basis
   e. if in writing

6. An example of a permitted disclosure would be to law enforcement officials when a patient commits robbery at a store next to the treatment center.
   a. true
   b. false

7. Following disclosure to medical personnel in emergency situations the program must document the following in the patient's records:
   a. date and time of disclosure
   b. name and affiliation of the medical personnel
   c. nature of the emergency
   d. name of individual making the disclosure
   e. all of the above

8. If subpoenaed, a program must release information even if the patient does not sign a consent form.
   a. true
   b. false

9. Disclosure to accreditation bodies such as the JCAHO required programs to _____ with accreditation bodies.
   a. merge
   b. incorporate
   c. sign business associate contracts
   d. sign privacy agreements
   e. break relationships

10. All but ____ are types of uses and disclosures that a program may make without the patient's consent.
    a. authorized by court order
    b. to report child abuse
    c. to auditors and evaluators
    d. to patient creditors
    e. to researchers if the information will be protected

11. The Privacy Rule does not require that the programs allow patients to request that the program restrict uses or disclosures of information.
    a. true
    b. false

12. The Privacy Rule does not provides patients right of access to obtain their information for all of the following except _____
    a. court orders
    b. information subject to Clinical Laboratory Improvement Amendment provisions.
    c. psychotherapy notes
    d. information complied for use in a civil or criminal proceeding

13. If a program grants the patient's request for access to his/her records, the program must provide the records at no charge to the patient.
    a. true
    b. false

14. If a patient is denied access to his/her information, a program must give a written denial containing:
    a. the statement of the patient's review rights
    b. the basis for the denial
    c. description of how the patient may complain to the Secretary of HHS
    d. the name of the contact person designated to receive complaints
    e. all of the above

15. A program may deny a patient's request for amendment of his/her information if:
    a. the program is federally funded
    b. the program did not create the information
    c. the information is accurate and complete
    d. the information is part of a designated record set
    e. both b and c

16. The Privacy Rule provides individuals with the right to obtain an accounting of certain disclosures of information made by a program during the ____ years prior to the request.
    a. 4
    b. 5
    c. 6
    d. 7
    e. 8

17. A program must have in place appropriate administrative, technical, and physical safeguards to protect the privacy of information.
    a. true
    b. false

18. Programs must maintain written records _____
    a. in triplicate
    b. for 25 years
    c. available in the "clouds"
    d. in a secure, locked manner
    e. at the director's home