Confidentiality of Alcohol and Drug Patient Information

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Goal: The purpose of this course is to summarize certain, not all, regulations published in section 543 of the Public Health Service Act, and its implementing regulation, Title 42 CFR, Part 2, regarding the confidentiality of alcohol and drug patient records and to review additional considerations required by related HIPAA Privacy Rule regulations and/or state mandates for health care providers to report on certain high risk behaviors, such as elder abuse and/or threats to harm self or others.

It is important to note that the information contained in this article is not definitive in the sense that any organization should take action based on it without a careful review of its own of all the applicable regulations. Rather this article is simply intended to identify certain key considerations in looking at confidentiality of patient information as it is regulated primarily by Title 42 CFR Part 2 and secondarily by the HIPAA Privacy Rule.

Specific Objectives: At the completion of this course, participants will be able to:

1) State the requirements of Title 42 CFR Part 2 regarding the confidentiality of alcohol and drug patient records and information presented herein

2) State strategies for addressing any differences in HIPAA regulations presented herein

Whatsoever things I see or hear concerning the life of men, in my attendance on the sick or even apart therefrom, which ought not be noised abroad, I will keep silence thereon, counting such things to be as sacred secrets.

- Oath of Hippocrates, 4th Century, B.C.E.

Introduction: Few relationships depend as much on an individual’s willingness to sacrifice privacy as the relationship between health care provider and patient, client or customer. Because the forced intimacy of the treatment relationship often requires the disclosure of information that many people would prefer to keep private, keeping the relationship and details of it confidential has been a matter of long-standing concern – even more so in the mental health and substance abuse fields. As a result, most of the ethics codes of healthcare professionals

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1 The information used in this article comes from the published regulations themselves, explanations and comparisons among Part 2 and HIPAA regulations published by The Legal Action Center, sometimes under SAMHSA auspices, interpretations and explanations provided by the Electronic Privacy Information Center (epic.org) and answers to frequently asked questions about privacy regulations provided by state departments of mental health or addictions. The author is not a lawyer and is only trying to understand this incredibly complex area of regulation like you, the reader.

2 epic.org. (n.d.) at http://epic.org/privacy/medical/

include standards requiring the protection of patient information.

As epic.org, the Electronic Privacy Information Center, a public interest research center in Washington, D.C., notes: "Over time, health information has come into use by many organizations and individuals who are not subject to medical [or healthcare] ethics codes, including employers, insurers, government program administrators, attorneys, law enforcement personnel and others. As uses of medical [or healthcare] information multiplied, so have regulatory protections for this highly sensitive and deeply personal information."  

The regulatory regime for protecting privacy of health information is complex and fragmented.  

- **Protections apply differentially.**
  - Some protections apply only to information held by government agencies [or federally-assisted agencies, whether receiving that support directly or indirectly].
  - Some protections apply to specific groups, such as federal employees or school children.
  - Some protections apply to specific conditions or types of information, such as information related to HIV/AIDS or substance abuse treatment.

- **State laws regarding confidentiality of patient information vary considerably.** Each health care organization must familiarize itself with the variety of applicable state laws regarding confidentiality of patient information and any exceptions to whatever protections are defined.

- **At the federal level, there exist a variety of laws that may apply to alcohol and drug treatment programs,** depending on the services they provide and/or the type of agency through which those services are provided. The Privacy Act of 1974, which applies to federal agencies, and the Family Educational Rights and Privacy Act (FERPA), which applies to student education records, are two such laws. Both require that any information released be done so with written permission from the individual or their guardian, as appropriate, with some exceptions. Such exceptions include in the event of medical emergencies and when ordered by a court. Interestingly, both also provide the right to individuals receiving services in relevant agencies or organizations to request amendments or corrections to records and, if said correction is denied by the organization, require that organizations include the individual’s statement about the contested information in the record and release it if information in the record is released.

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4 epic.org (n.d.) at http://epic.org/privacy/medical/#overview
42 CFR Part 2: The most stringent protections afforded those in alcohol and substance abuse treatment are the regulations governing the Confidentiality of Alcohol and Drug Abuse Patient Records, known as Title 42 C.F.R. Part 2\(^8\) (and referred to as Part 2 in this article). These regulations were signed into law by President Nixon in the 1970s, following a series of incidents in which law enforcement officials and others sought to obtain substance use records of many individuals to use in prosecuting these individuals for crimes. Congress enacted regulations that provided stringent confidentiality protections to alcohol and drug patient records. The then U.S. Department of Health Education and Welfare issued implementing regulations in 1975.\(^9\) According to The Legal Action Center, law enforcement is still seeking alcohol and drug treatment records to pursue criminal investigations of patients.\(^11\)

It was felt that, without a strong guarantee of privacy, people needing alcohol and/or drug treatment might not engage in treatment for fear that they would be arrested, lose custody of children, lose jobs, be denied health care or receive “lower quality” health care, be excluded or evicted from public housing or be unable to attain health, disability or life insurance.\(^12\)

While these regulations restricted the information that could be disclosed and restricted how it could be used, e.g., not for criminal prosecution, they did not afford alcohol and drug patients the right to request amendments or corrections to their records – a right given under other federal confidentiality regulations – and under the HIPAA Privacy Rule.

**HIPAA:** The first comprehensive set of federal regulations of health information, the Privacy Rule under the Health Insurance Portability and Accountability Act of 1996 (also known as HIPAA), came into effect in April 2003. The Security Rule, also required under HIPAA, was issued in final form on February 20, 2003.\(^13\)\(^14\)

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8 Electronic Code of Federal Regulations (Current as of November 23, 2011) at http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&rgn=div5&view=text&node=42:1.0.1.1.2&idno=42#42:1.0.1.1.2.1.1.1


10 Electronic Code of Federal Regulations (Current as of November 23, 2011) at http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&rgn=div5&view=text&node=42:1.0.1.1.2&idno=42#42:1.0.1.1.2.1.1.1


The establishment of HIPAA provided a “federal floor” of privacy protection for health information in the U.S. and defined PHI (or protected health information) very broadly. However, it did not necessarily reduce the complexity of applicable regulations. Other federal and state laws governing the specific situations mentioned above still apply if they are more protective (or “stringent”).

For example, the federal regulations on the Confidentiality of Alcohol and Drug Abuse Patient Records supersede both HIPAA and more permissive state laws. These regulations do not permit any disclosure related to treatment, payment or health care operations without patient consent, except in certain defined exceptions, while HIPAA does. Thus, in applying the regulations to one possible scenario, an organization that holds itself out as providing any kind of treatment for substance abusers, whether primary or secondary, and is classified as federally assisted needs to be certain that those patients receiving said substance abuse treatment consent to the disclosure of health care information to insurers. If that organization complies with HIPAA regulations only, it will not be compliant with Part 2 regulations regarding alcohol and drug abuse patient records and information.

Given the complexity of the various state and federal regulations that may apply to organizations, interesting dilemmas may arise when trying to apply Part 2 and HIPAA Privacy Rule regulations to any particular organization. If an organization provides alcohol and drug abuse services, can be classified as federally-assisted and qualifies as a HIPAA covered entity, then both sets of rules apply with the more stringent (usually Part 2) superseding the other. If state rules are even more stringent, then they apply.

So, let’s ask a question. What regulations apply if an organization provides alcohol and drug abuse services, e.g., in a mental health center, to individuals for whom their substance abuse is considered secondary to a primary mental health diagnosis? The New York Office of Mental Health in responding to a Frequently Asked Question about the applicability of Part 2 regulations in such a situation stated that the key was in determining if that mental health center was a federally-assisted program for providing alcohol and drug abuse services. They stated that, if the organization was not licensed for alcohol and drug abuse services, then they were probably not federally assisted and, thus, did not.

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14 One can find numerous resources online to in fully preparing for HIPAA. The following url is only one. It gives information about HIPAA and certain important changes associated with The HITECH Act that will need to be addressed. Consider it as one example of the kind of guidance you can find online. You will need to alter suggestions for purely HIPAA or HITECH compliance to include requirements in Part 2 - http://www.wsma.org/getfile.cfm?mo_fileid=3643. Other important information to read is that which addresses the "urban legends" surrounding HIPAA, the myths. One such article can be found at http://www.cdt.org/files/pdfs/20090109mythsfacts2.pdf. It is important to review several.
15 epic.org (n.d.) at http://epic.org/privacy/medical/#overview
16 See definitions further into this article.
not have to comply with Part 2 regulations. This would mean that, under HIPAA, they could release patient information that included information on alcohol and drug abuse without patient consent if the release was for the purposes of treatment, for example.

These interpretations can obviously be quite confusing and potentially a little scary! The actual wording of Part 2 specifies that a provider needs to hold themselves out as providing alcohol or drug treatment and be federally assisted. It does not specifically state that the federal assistance needs to be tied directly to the alcohol and/or drug treatment. So, when it comes to interpretations such as the one made above, each organization needs to get clear legal guidance for itself. The New York state Office of Mental Health even states over and over that their responses cannot be considered legal opinions, meaning they won’t stand by them in a court of law. With reports of increased enforcement coming for HIPAA via HITECH (see the next section), one needs opinions that someone will stand behind in a court of law.

The simplest solution, where such dilemmas may exist, is what many organizations do – and that is developing a single set of procedures to use in all cases – a single set that meets all requirements.

**The HITECH Act:** The Health Information Technology for Economic and Clinical Health Act is part of the American Recovery and Reinvestment Act of 2009 (ARRA). Because this legislation anticipates a massive expansion in the exchange of electronic protected health information (ePHI) as a result of its incentives to move toward EHRs (electronic health records), the HITECH Act widens the scope of privacy and security protections available under HIPAA; it increases the potential legal liability for non-compliance; and it provides for more enforcement.\(^\text{18}\)

To mention just a few of the additional requirements:

- It requires that organizations notify patients and others, depending on the size of the breach, of data breaches (that is, unauthorized uses and disclosures of unsecured PHI). Unsecured PHI is essentially unencrypted electronic PHI.
- It requires organizations who have implemented an EHR (electronic health record) to permit individuals to obtain their PHI in electronic format.
- It applies certain HIPAA provisions directly to business associates/qualified service organizations (in Part 2) rather than simply through contract agreements between provider and QSO or business associate.

*Note that beyond mentioning The HITECH ACT as the most recent federal act governing confidentiality of health care information and something to be taken into account for all organizations using EHRs, we will not be commenting much on its rules.*

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**Do These Protections Really Matter to Individuals Served in Mental Health or Substance Abuse Treatment Settings?**

Much of this effort to protect patient information is based on the assumptions that

• Confidentiality is important, perhaps necessary, for the creation of trust in the clinical psychotherapeutic relationship and that

• Trust is necessary for mental health (and presumably substance abuse) treatment to work.

Research suggests that these assumptions have at least some empirical support. For example, a number of studies suggest that the relative strength of confidentiality protections can play an important role in individual decisions to seek or forgo mental health and substance abuse treatment. *In particular, the willingness of a person to make the self-disclosures necessary to such mental health and substance abuse treatment may decrease as the perceived negative consequences of a breach of confidentiality increase.*

For example, let’s look at the results in one older study.

- **More informed = Less disclosure:** Those individuals seeking admission to treatment who received *more extensive information about confidentiality laws* than usual *admitted to fewer socially unacceptable* sexual behaviors and fewer child punishment and neglect behaviors on an intake questionnaire.

- **Less informed + More psychopathology = More disclosure:** Those who were *less informed and had higher psychopathology ratings* (based on MMPI scores) *admitted to more thoughts about harm to self or others* than those with lower psychopathology or who were better informed about confidentiality.

- **For substance users, More informed + More psychopathology = More disclosure:** Interestingly, in this study, those who had higher psychopathology and who were better informed disclosed more about their substance use than did those with lower psychopathology and/or those who were less well informed about confidentiality. This finding was predicted by the researchers since the confidentiality regulations about disclosure of substance abuse were much more stringent.

  - While the differences between groups were fairly small, these findings appear to support the validity of the various ethical standards and laws that require individuals to be informed of their privacy rights before initiating treatment – suggesting that, if well informed about confidentiality regulations and risks, they will make self-protective choices about disclosure. They also support the arguments made by some that such informed consent may discourage individuals from being candid in treatment – and, thus, may interfere with the “trust” considered necessary to be effective.

A more recent (2010) report on a series of studies looking at the impact of disclosure risk and possible harm to survey respondents and its impact on participant willingness to participate in surveys found that *the sensitivity of the survey topic as well as explicit*

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20 Taube and Elwork (February 1990) at [http://psycnet.apa.org/journals/pro/21/1/72.pdf](http://psycnet.apa.org/journals/pro/21/1/72.pdf)
information about the possible harms that might result from disclosure reduces the willingness of people to participate in online and mail surveys. The probability of disclosure (i.e., that someone other than the researcher would be able to link the participant’s name with their answers) alone had no effect on willingness to participate.21

What does Title 42 C.F.R. Part 2 on the Confidentiality of Alcohol and Drug Patient Records Restrict and Permit?

Title 42 C.F.R. Part 2 restricts the disclosure and use of alcohol and drug abuse patient records which are maintained in connection with the performance of any federally assisted alcohol and/or drug abuse program.

**Disclose or disclosure** refers to

- A communication of patient identifying information,
- The affirmative verification of another person’s communication of patient identifying information (as in verifying that a person is in treatment if asked by another person who provides the individual’s name), or
- The communication of any information from the record of a patient who has been identified.

In general, the law restricts the disclosure of alcohol and drug abuse patient records and information, including identity, diagnosis, prognosis or treatment except for certain specified purposes (or uses) and/or under certain specified circumstances.

*Stated specifically in the regulation, “The restrictions on disclosure in these regulations apply to any information, whether recorded or not, which would identify a patient as an alcohol or drug abuser either directly, by reference to other publicly available information or through verification of such an identification by another person.”*22

*Or, stated another way, the information protected by Part 2 is any information disclosed by a Part 2 program that identifies an individual directly or indirectly as having a current or past drug or alcohol problem, or as a participant in a Part 2 program.*

The law very specifically restricts the use of alcohol and drug patient records, whether recorded or not, in initiating criminal charges against a person served or in criminal investigations of the person served – with one exception as stated below.

The law continues to apply to patient information even if the individual is no longer receiving services from the given organization or provider.

21 Singer and Couper (September 2010) at [http://www.jstor.org/pss/10.1525/jer.2010.5.3.1](http://www.jstor.org/pss/10.1525/jer.2010.5.3.1)


**Conditions under which disclosure is acceptable include the following.** It may be worth noting that this federal statute does not compel disclosure – only allows it. States may compel disclosure as in the case of suspected child abuse. Or disclosure may be given to help the patient as in the case of a medical emergency but it is not compelled by this law.

- **When the patient or individual served gives prior written consent for such disclosure.** There are set guidelines for the format of this consent presented later on.

- If the patient or individual served does not or is unable to give prior written consent for disclosure, the provider may disclose certain information in the following situations.

  - **To medical personnel to the extent needed to meet a bona fide medical or health care emergency.** This can include a mental health emergency. According to SAMHSA, Part 2 does not distinguish between physical and mental health emergencies. A medical emergency is simply defined as a health emergency affecting any individual that requires immediate medical intervention.

  The regulation suggests that the information that should be disclosed under these circumstances should only be that information necessary to treat or manage the medical emergency. Thus, it would seem that information about an individual’s physical or mental health history and status, relevant treatment while in the Part 2 program and relevant substance use information might reasonably be disclosed in the event of a healthcare emergency. Details of the individual’s criminal history are probably not relevant to the needs of medical personnel to respond to the medical emergency.

  However, according to SAMHSA, if there is a medical emergency, Part 2 would allow the entire record to be released to a treating provider who indicates that he or she needs access to that information to treat a condition that poses an immediate threat to the health of the individual and requires immediate medical intervention.

  It is important to remember here that a Part 2 organization is not compelled by Part 2 to release Part 2 restricted information. It is also important to know that if a medical emergency exists, again according to SAMHSA, Part 2 provisions do not prohibit the redisclosure of Part 2 information once it is released. Consequently, medical personnel treating a patient for a medical emergency may include in their own records the information they obtained in treating the emergency, and may then redisclose that information to others without obtaining patient consent. This fact appears to make it very important that Part 2 organizations be clear to release only that information necessary for treatment of the healthcare emergency. If applicable to them, the HIPAA Privacy Rule may be helpful here because it generally requires

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that uses and disclosures of PHI be the *minimum necessary for the intended purpose of the use or disclosure.*

Further, Part 2 requires that when a disclosure is made in connection with a medical emergency, the Part 2 program must document in the patient’s record:

- The name and affiliation of the medical personnel receiving the information,
- The name of the individual making the disclosure,
- The date and time of the disclosure, and
- The nature of the emergency; thus, enabling a privacy officer or reviewer to determine that such access was proper.

**If authorized by an appropriate order of a court having jurisdiction.** The court is charged with determining the extent of information to be released to them and with imposing appropriate safeguards against unauthorized disclosure of the individual’s protected information.

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. The regulation 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 HIPAA Privacy Rule permits [but does not require] 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. 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.

**If an incident of child abuse or neglect is suspected,** reporting is allowed in accordance with applicable state law to appropriate state authorities. However, if said report results in civil or criminal proceedings, the restrictions in the law do apply to the original alcohol or drug abuse patient records, meaning that information can only be disclosed with the written consent of the patient or if authorized by an appropriate court order. Even when disclosed in accordance with the law, the

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information cannot be introduced as evidence in a criminal proceeding or to investigate or prosecute a patient with respect to a suspected crime.

**State Mandated Reporting of other forms of abuse and/or danger to self or others:** Part 2 only allows reporting child abuse or neglect and, thereby, allows the disclosure of relevant alcohol and drug abuse information. It does not, however, appear to allow disclosure of that information if reporting other kinds of abuse.

HIPAA, on the other hand, allows a covered entity to use or disclose protected health information to the extent that such use or disclosure is required by law. HIPAA also states that providers are permitted to disclose PHI if a covered entity in good faith believes the disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public. The disclosure must be made to a person who is reasonably able to prevent or lessen the threat, or for identification and apprehension of an individual.\(^\text{30}\)

Part 2 is the more stringent requirement regarding disclosure while state laws mandating reporting of elder or vulnerable adult abuse or domestic violence are more stringent. How does one put the two together?

The state of Oregon’s Department of Human Services\(^\text{31}\) has promulgated the following disclosure rule in making mandated reports of abuse:

- A provider may disclose relevant substance abuse information in making an initial report of suspected child abuse.

- However, in reporting elder\(^\text{32}\) or vulnerable adult abuse, substance abuse information should not be disclosed without authorization. If it is necessary to make a report without authorization, the report must be done without revealing a person is in substance abuse treatment or has a substance abuse problem.

Presumably the same disclosure restrictions would apply in the case of mandated reporting of domestic violence and/or mandated reporting of a person’s believed threat to harm self or others.

- **To law enforcement if a patient commits a crime on the program premises or against program personnel or makes a threat to commit such a crime.** Information to be released is limited to

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\(^{31}\) Oregon Department of Human Services (April 1, 2011) at [http://apps.state.or.us/caf/fsm/12gp-b.htm](http://apps.state.or.us/caf/fsm/12gp-b.htm)

\(^{32}\) See the National Center on Elder Abuse at [http://www.ncea.aao.gov/ncearoot/Main_Site/Find_Help/APS/APS_Laws.aspx](http://www.ncea.aao.gov/ncearoot/Main_Site/Find_Help/APS/APS_Laws.aspx) for some information on state laws and resources regarding elder abuse.
• The circumstances of the incident, including
• The patient status of the individual committing or threatening to commit the crime,
• That individual’s name and address and
• The individual’s last known whereabouts.

To qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner.

To personnel within a program or between a program and an entity that has direct administrative control over the program for the purpose of performing duties that are part of the provision of diagnosis, treatment or referral for treatment of alcohol or drug abuse patients.

To Qualified Service Organizations information needed to provide services to the program. Examples of qualified service organizations include those who provide data processing, bill collecting, dosage preparation, laboratory analyses, or legal, medical, accounting, or other professional services, or services to prevent or treat child abuse or neglect, including training on nutrition and child care and individual and group therapy.

Note that the provider organization must have entered into a written agreement with the Qualified Service Organization (QSO) such that the QSO acknowledges that it is fully bound by these regulations when dealing with patient information and that it will resist in judicial proceedings any efforts to gain access to patient records except as permitted by the regulations.

As electronic records and various infrastructures are being put into place to facilitate the communication of patient information between various health care providers, questions arise about how Part 2 organizations can participate and remain compliant with the Part 2 regulations. SAMHSA notes the following, in addressing the issue of participation in Health Information Exchanges (HIEs), entities that provide an infrastructure to exchange patients’ health records among participating providers:

In non-medical emergencies,

• Either a patient consent or a Qualified Service Organization Agreement (as noted above) will need to be in place in order for the Part 2 program to disclose the information to the HIE, and
• Patient consent will be needed to allow the HIE to redisclose the Part 2 information to other HIE affiliated members.

Under the HIPAA 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
need by the organization to provide services. The Privacy Rule has different requirements regarding the content of the business associate contract. Substance abuse programs must comply with both Part 2 and the HIPAA Privacy Rule requirements for qualified service organizations/business associates.

According to SAMHSA, 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. 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.

If an individual served is or was a member of the Armed Forces and is receiving services from the Armed Forces and/or the Veterans’ Administration (VA), information is not restricted within the Armed Forces or within those components of the VA providing health care to veterans or between such components and the Armed Forces. For any non-military or non-VA provider, whether an organization or an individual, this regulation may not be applicable.

Additional definitions to keep in mind include the following:

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

However, the HIPAA Privacy Rule does treat medical record numbers as protected health information (PHI), thus, limiting their disclosure. Substance abuse programs must comply with the more stringent of the regulations, which in this case in the HIPAA rule.

Records refers to any information, whether recorded or not, relating to a patient received or acquired by a federally assisted alcohol or drug program.

33 The Health and Human Services Office for Civil Rights has published sample contract language
Federally assisted programs, the programs to whom Part 2 applies, are any alcohol or drug abuse treatment programs providing service

- In whole or in part, directly or by contract or otherwise by any department or agency of the United States, except for the Armed Forces and the VA and/or
- Under the license, certification, registration or other authorization granted by any department or agency of the U.S., including Medicare certification, authorization to conduct methadone maintenance treatment, registration to dispense a controlled substance for the purpose of treating alcohol or drug abuse and/or
- Supported by funds provided by any department or agency of the U.S., either via direct federal assistance or indirectly through state funding which may be directly or indirectly provided through federal funds given to the state and/or
- Under IRS tax exempt status.

It is important to note that these Part 2 regulations apply only to federally assisted programs, presumably federally assisted for the provision of alcohol or drug abuse treatment. While most alcohol and drug treatment programs are federally assisted, there are for-profit programs and private practitioners who do not receive federal assistance of any kind and who possess none of the certifications, licenses or registrations that would qualify them as federally assisted – who, for example, only treat people who self-pay or have private insurance and do not accept Medicare or Medicaid. Unless the state through its licensing regulations requires these entities to comply with Title 42, C.F.R. Part 2, they are not subject to the requirements of that federal regulation.37

Covered entities, the organizations to whom HIPAA applies, are a health care provider that conducts certain transactions, such as billing or requests for service approvals, in electronic form, a health care clearinghouse or a health plan.

Penalties: For Part 2, any person who violates any provision of those statutes or these regulations shall be fined not more than $500 in the case of a first offense, and not more than $5,000 in the case of each subsequent offense.38

For HIPAA, the Privacy Rule includes both civil and criminal penalties for violations of privacy. Generally, penalties are expected to be assessed in cases where organizations or individuals act with willful neglect or intent to cause harm. Civil penalties are specified at $100 per violation, not to exceed $25,000 per person per year for identical violations. Criminal penalties for wrongful disclosure of PHI can go up to $250,000 and/or 10 years imprisonment if the offense is committed with intent to sell, transfer, or use PHI for commercial advantage, personal gain, or malicious harm.39

37 SAMHSA: Legal Action Center (n.d) at http://www.samhsa.gov/healthprivacy/docs/EHR-FAQs.pdf
38 http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&rgn=div5&view=text&node=42:1.0.1.1.2&dftnode=42#42:1.0.1.1.2.1.1.1
39 Epic.org (n.d.) at http://epic.org/privacy/medical/#overview
Reportedly, enforcement of HIPAA regulations, especially in smaller organizations, has been lax. The writers of the HIPAA Survival Guide expect enforcement to be greater in the future, especially under The HITECH ACT provisions.\textsuperscript{40}

**Notifications required:** Part 2 defines specific notifications and formats for those notifications to patients and/or to recipients of information.

- **To patients:** At the time of admission or as soon thereafter as the patient is capable of rational communication, **Part 2 programs must provide a written summary to the patient of the federal law and regulations that protect the confidentiality** of their records and information.

Part 2 requires the following elements be included in the written summary

1. A general description of the limited circumstances under which a program may acknowledge that an individual is present at a facility or disclose outside the program information identifying a patient as an alcohol or drug abuser.

2. A statement that violation of the Federal law and regulations by a program is a crime and that suspected violations may be reported to appropriate authorities in accordance with these regulations.

3. A statement that information related to a patient’s commission of a crime on the premises of the program or against personnel of the program is not protected.

4. A statement that reports of suspected child abuse and neglect made under State law to appropriate State or local authorities are not protected.

5. A citation to the Federal law and regulations.

The program may devise its own notice or may use the notice example provided in the law to comply with these requirements for a written summary.

In addition, the program may include in the written summary information concerning State law and any program policy not inconsistent with State and Federal law on the subject of confidentiality of alcohol and drug abuse patient records. An expanded version of this written notice including additional state and program protections and exceptions may be a good way to comply with accreditation requirements to inform patients of the limitations of confidentiality.

**The HIPAA Privacy Rule requires that patients be given a notice of the program’s privacy practices as well as their rights under the Privacy Rule** at the time of admission or as soon thereafter as the patient is capable of rational communication.\textsuperscript{41}

\textsuperscript{40} Leyva and Leyva (2009-2011) at http://www.hipaasurvivalguide.com/hitech-act-summary.php

\textsuperscript{41} Microsoft Office provides a HIPAA Privacy Policy Template at http://office.microsoft.com/en-us/templates/hipaa-privacy-policy-TC010074381.aspx. Modify this as described in this article to come up with a privacy policy that meets all relevant requirements – federal and state. Then develop your Privacy Notice. After reviewing several online privacy notices for this article, it is clear that many organizations who provide alcohol and drug abuse services are not developing privacy notices that combine HIPAA, Part 2 and state requirements in their privacy policies.
Programs subject to both rules can combine their requirements into a single notice. A combined notice must contain all the elements required by Part 2, as noted above, and in addition, contain the following elements required by HIPAA:

- 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.

For substance abuse treatment programs, these would include uses and disclosures:

- To qualified service organizations or business associates who provide services to the program in its efforts to provide treatment, receive payment and otherwise operate
- 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.

notices. They have simply put up a minimum HIPAA template notice. The following is one Privacy notice that addresses HIPAA, Part 2 and state confidentiality regulations - [http://www.pacounseling.com/privacy/](http://www.pacounseling.com/privacy/). Again, before promulgating your HIPAA Privacy Notice, make sure you get appropriate legal guidance that it complies with all requirements — and make sure you write it so your patient population can understand it.

The following elements were obtained from a SAMHSA document comparing HIPAA Privacy Rule requirements with Part 2 requirements. It can be found at SAMHSA (June 2004) at [http://www.samhsa.gov/HealthPrivacy/docs/SAMHSAPart2-HIPAAComparison2004.pdf](http://www.samhsa.gov/HealthPrivacy/docs/SAMHSAPart2-HIPAAComparison2004.pdf)

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. This should include disclosures about mandated reporting of elder or vulnerable adult abuse, domestic violence and duty to warn in cases of potential harm to self or others. Those organizations that only inform patients about restrictions in general statements such as “Information is confidential except where permitted by law” do not meet the intent of the HIPAA Privacy Rule. Similarly simply telling patients the limits is not enough.

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 section 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.
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;45

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 and a statement describing how it will provide patients with a revised notice of its practices.

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 rights46 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.

45 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.

46 Details regarding these rights will not be reviewed here at this time. However, these are rights that greatly empower patients regarding the use of, access to and correctness of their personal health care information. It is recommended that organizations become familiar with them and develop procedures for meeting them.
Confidentiality of Alcohol and Drug Abuse Patient Records

The confidentiality of alcohol and drug abuse patient records maintained by this program is protected by Federal law and regulations. Generally, the program may not say to a person outside the program that a patient attends the program, or disclose any information identifying a patient as an alcohol or drug abuser Unless:

1. The patient consents in writing:
2. The disclosure is allowed by a court order; or
3. The disclosure is made to medical personnel in a medical emergency or to qualified personnel for research, audit, or program evaluation.

Violation of the Federal law and regulations by a program is a crime. Suspected violations may be reported to appropriate authorities in accordance with Federal regulations.

Federal law and regulations do not protect any information about a crime committed by a patient either at the program or against any person who works for the program or about any threat to commit such a crime.

Federal laws and regulations do not protect any information about suspected child abuse or neglect from being reported under State law to appropriate State or local authorities.


To recipients of disclosed information: As required in Part 2, each disclosure made with the patient’s written consent 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.
Required Elements of a Patient Consent to Release Information Form: A written consent to a disclosure under the Part 2 regulations must be in writing and include all of the following items:

1. The specific name or general designation of the program or person permitted to make the disclosure.
2. The name or title of the individual or the name of the organization to which disclosure is to be made.
3. The name of the patient.
4. The purpose of the disclosure.
5. How much and what kind of information is to be disclosed.
6. The signature of the patient and, when required for a patient who is a minor, the signature of a person authorized to give consent; or, when required for a patient who is incompetent or deceased, the signature of a person authorized to sign in lieu of the patient.
7. The date on which the consent is signed.
8. A statement that the consent is subject to revocation at any time except to the extent that the program or person which is to make the disclosure has already acted in reliance on it. Acting in reliance includes the provision of treatment services in reliance on a valid consent to disclose information to a third party payer.
9. The date, event, or condition upon which the consent will expire if not revoked before. This date, event, or condition must insure that the consent will last no longer than reasonably necessary to serve the purpose for which it is given.

Part 2 and the HIPAA Privacy Rule have different requirements regarding the conditions under which the release of health information requires patient authorization to release it. HIPAA does not require authorization to release information for “treatment, payment, or healthcare operations”. Part 2 does.

Authorizations to release information, when required by the Privacy Rule, must contain additional information. In addition to what is already required under Part 2, HIPAA requires that the authorization form 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 the HIPAA regulations.
- 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.
Finally, the consent must be written in plain language.\(^{47}\)

In addition, the HIPAA Privacy Rule requires that the organization provide the patient with a copy of the signed form and must keep a copy of each signed form for six (6) years from its expiration date.\(^{48}\)

**Should you have two or more different consent to release information forms?** 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 HIPAA Privacy Rule statements would not have to be added to the consent forms – because the Privacy Rule does not require patient authorization to release information that is used for treatment. 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.\(^{49},^{50}\)

Part 2 permits a patient to revoke consent orally; the Privacy Rule requires written revocation of an authorization. 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.\(^{51}\)

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\(^{50}\) For examples of consent to release information forms that purportedly meet Part 2 and/or HIPAA Privacy Rule requirements, go to the following links - [http://www.callen-lorde.org/pdf/HIPAA%20Form.pdf](http://www.callen-lorde.org/pdf/HIPAA%20Form.pdf) for a form designed to meet both Part 2 and HIPAA; [http://www.health.ny.gov/forms/doh-2557.pdf](http://www.health.ny.gov/forms/doh-2557.pdf) for a form designed to meet HIPAA requirements and address state requirements for release of HIV-related information; [http://www.sadler.com/HIPAA_Release_of_Information_Form.pdf](http://www.sadler.com/HIPAA_Release_of_Information_Form.pdf) for a form that meets HIPAA requirements, not Part 2 requirements; [http://www.guilfordpediatrics.com/pdf/HIPAA_Records_Release_Form.pdf](http://www.guilfordpediatrics.com/pdf/HIPAA_Records_Release_Form.pdf) for a form designed to meet multiple requirements. You can search for sample forms yourself to use in designing your own forms. Please note that by providing links to these forms, the author is in no way stating that they are good. They are only provided as examples of how different organizations have approached the task of complying with these regulations.

Multi-party Consent to Release Information Forms: According to SAMHSA, a Part 2 consent form can authorize an exchange of information between multiple parties named in the consent form. The key is to make sure the consent form authorizes each party to disclose to the other ones the information specified and for the purpose specified, in the consent.

Expired, deficient, or false consent. A disclosure may not be made on the basis of a consent which:

- Has expired,
- On its face substantially fails to conform to any of the requirements set forth in the section on required elements of a consent to release information form,
- Is known to have been revoked, or
- Is known, or through a reasonable effort could be known, by the person holding the records to be materially false.

A warning: If your patients tend to give consent to release information freely, you may need to find a way of flagging the clinical records of those who restrict the release of information or do not consent to releasing certain information. It is too easy to forget without such ‘internal warning’ procedures.

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Sample Format for Part 2 required consent
Additional information is required if the authorization is to meet HIPAA Privacy Rule regulations

Consent to Release Confidential Patient Information (Part 2)

1. I ____________________________________________________ □ Request □ Authorize:
   (Name of patient)

2. ____________________________________________________
   (Name or general designation of program or person which is to make the disclosure)

3. To disclose: __________________________________________
   (Kind and amount of information to be disclosed; Organizations often provide lists of different kinds of information that might be disclosed most frequently. It is important to leave space for entering more limited disclosures as appropriate.)

4. To: __________________________________________________
   (Name or title of the person or organization to which disclosure is to be made)

5. For the purpose of: _____________________________________
   (Purpose of the disclosure; Again organizations often use lists of purposes for disclosure such as coordination of care, referral, treatment, evaluation and so on)

6. Date ________________________________________________ (on which this consent is signed)

7. Signature of patient ______________________________________

8. Signature of parent or guardian (where required) ______________

9. Signature of person authorized to sign in lieu of the patient (where required)

   (If the HIPAA Privacy Rule applies, and this person can be considered a personal representative, a description of the representative’s authority to act for the individual must be described.)

10. This consent is subject to revocation at any time except to the extent that the program which is to make the disclosure has already taken action in reliance on it. If not previously revoked, this consent will terminate upon: ______________________
   (Specific date, event, or condition)
**In summary,** we have briefly reviewed the major federal regulations that apply to protecting the confidentiality of alcohol and drug abuse patient information, touching a few of the key items, but not all of them. Little information can be released without the written consent of the patient. Exceptions are in situations of medical emergency, under court order, when there is a suspicion of child abuse, to qualified service organizations and to researchers, auditors, and other such reviewers. Information that is released in these circumstances should be no more than is required to meet the specific need for the release.

When state laws require or mandate other kinds of reporting, such as elder abuse, danger to self or others, the existence of certain infections and so on, because the federal regulation on confidentiality of alcohol and drug abuse patient records does not provide for these situations in the law, organizations must release said information without also releasing any information about an individual’s substance abuse problems or substance abuse treatment.

HIPAA Privacy Rule regulations are not as strict as the 42 CFR Part 2 regulations in that they allow organizations to disclose patient information for purposes of treatment, payment and healthcare operations. However, a federally-assisted alcohol or drug program cannot release such information without patient consent. Thus, organizations to whom both regulations apply must devise procedures that meet both sets of regulations.

HIPAA requires more extensive information than does Part 2 in its consent to release information forms and in its notifications about privacy and protections of confidentiality.

While there is some national standardization in the development and implementation of these regulations, state laws also apply – and these differ from state to state. The complexities of the laws, sometimes alone but especially in combination make the task of complying a difficult one.