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42 CFR PART 2
CONFIDENTIALITY OF SUBSTANCE USE DISORDER PATIENT RECORDS: WHAT PSYCHIATRISTS NEED TO KNOW

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42 CFR PART 2 - CONFIDENTIALITY OF SUBSTANCE USE DISORDER PATIENT RECORDS: WHAT PSYCHIATRISTS NEED TO KNOW

I. PURPOSE OF THE REGULATIONS

To encourage those addicted to drugs and alcohol to get treatment, the federal government wanted to promise that addiction treatment records would be confidential. The 42 CFR Part 2 (Part 2) regulations were promulgated in 1975 to control the disclosure and use of patient records generated by treatment at federally assisted drug and/or alcohol treatment programs. The privacy provisions in Part 2 were motivated by eliminating the stigma and fear of prosecution faced by people with substance use disorders (SUD) which dissuaded many from seeking treatment. Part 2 is intended to ensure that a patient receiving SUD treatment does not face adverse consequences in relation to criminal and civil proceedings, such as child custody, divorce, housing, and employment. The Part 2 regulations prohibit, absent a patient's valid written consent, the disclosure and use of patient identifying information that would identify a patient as an alcohol or drug abuser.

II. BRIEF HISTORY OF THE REGULATIONS

1970, 1972: Congress enacted the "Alcohol and Drug Abuse Acts"

1975: HHS promulgated regulations to implement the statutes

1987: Regulations were updated

1995: The "Program" definition was modified to clarify that the regulations cover only specialized individuals or units that hold themselves out as providing alcohol or drug abuse diagnosis, treatment or referral to treatment

2017: Regulations were significantly updated to modernize them to include EHRs, etc.

2018: More changes went into effect, including a shortened notice on disclosed records prohibiting re-disclosure

The Substance Abuse and Mental Health Services Administration (SAMHSA), within the Department of Health and Human Services (HHS), is the agency responsible for the Part 2 regulations.

III. WHAT IS A "PROGRAM" THAT MUST COMPLY WITH PART 2?

A "Program" covered by Part 2 is one that offers substance abuse education, treatment or prevention and is regulated or assisted by the federal government. Defining a Part 2 Program is a fact-specific determination.

First, a "Program" means:

1. An **individual** or **entity** (other than a general medical facility) who **holds itself out** as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment; or

   Note: *according to SAMHSA's FAQs, the phrase "**holds itself out**" is not defined in the regulations, but can be understood to mean several things, such as advertising or posting notices in the office, certifications in addiction medicine, internet statements, or any activity that would lead one to reasonably conclude that the provider is providing or provides alcohol or drug abuse diagnosis, treatment, or referral treatment.*

2. An identified **unit** within a general **medical facility** that holds itself out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment; or

3. **Medical personnel** or other staff in a general medical facility whose **primary function** is the provision of substance use disorder diagnosis, treatment, or referral for treatment and who are identified as such providers.

Second, the Program must also be "federally assisted," which is broadly defined as meaning the Program is:

1. Being operated by a department or agency of the United States;

2. Operating based on the authorization of a department or agency of the United States (e.g., the Program has received a license, certification, registration, or other authorization from the government);

3. Receiving federal financial assistance or is part of an organization receiving federal financial assistance; or

4. Receives tax deductions or is operating under tax-exempt status.

For more information on the definition of a Program that must comply with Part 2, see:

- FAQ #10 in SAMHSA's FAQs
- SAMHSA's factsheet
- Legal Action Center's resources (from SAMHSA's website)

IV. QUALIFIED SERVICE ORGANIZATION AGREEMENTS (QSOA)

A Qualified Service Organization (QSO) is defined as an individual or entity who:

1. Provides services to a Part 2 Program, such as data processing, bill collecting, dosage preparation, laboratory analyses, or legal, accounting, population health management, medical staffing, or other professional services, or services to prevent or treat child abuse or neglect, including training on nutrition and child care and individual and group therapy, and

2. Has entered into a written agreement with a Part 2 Program under which that individual or entity:

    i. Acknowledges that in receiving, storing, processing, or otherwise dealing with any patient records from the Part 2 Program, it is fully bound by the regulations in this part; and

    ii. If necessary, will resist in judicial proceedings any efforts to obtain access to patient identifying information related to substance use disorder diagnosis, treatment, or referral for treatment except as permitted by the regulations in this part.

Prior to releasing Part 2 records to a QSO, there must be a **written agreement** in which the QSO acknowledges that it is bound by the Part 2 confidentiality regulations, promises not to redisclose patient identifying information to which it becomes privy, and promises to resist unauthorized efforts to gain access to any patient identifying information that may come into its possession. The Program should only disclose information to the QSO that is necessary for it to perform its duties under the QSOA.

A Business Associate Agreement (BAA), required under HIPAA, **is not sufficient** to protect the privacy of patients under Part 2. Part 2 requirements for disclosure are separate and more restrictive than HIPAA's requirements. However, the QSOA provisions required under Part 2 can be incorporated into a BAA.

Keep in mind that these Part 2 rules **only apply** to the medical records of a psychiatrist who meets the definition of a Program AND has treatment records related to substance abuse issues. A psychiatrist who treats addiction patients, as well as patients with non-addiction issues, only needs to follow the Part 2 rules for the patient(s) treated for addiction.

V. WHAT DO THE REGULATIONS SAY?

There are many specific requirements under Part 2; see Appendix I for a listing of the regulation's sections. Among the most important requirements are:

1. Patients must be provided with a notice of their rights at the outset of treatment. For more information, see Appendix II
2. Only limited disclosures of patient information are allowed; see section VI
3. All disclosed records must **prohibiting** further re-disclosure

   The regulations provide the following two options for the wording of this 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 information in this record that identifies a patient as having or having had a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person unless further disclosure is expressly permitted by the written consent of the individual whose information is being disclosed 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 (see § 2.31). The federal rules restrict any use of the information to investigate or prosecute with regard to a crime any patient with a substance use disorder, except as provided at §§ 2.12(c)(5) and 2.65;

   OR

   42 CFR Part 2 prohibits unauthorized disclosure of these records.

4. Patients may request a list of entities to whom their information has been disclosed.
5. There are criminal penalties for violation.
6. Enforcement is by the local US Attorney's office; if the Program that allegedly

violated Part 2 is an opioid treatment Program, violations can also be reported to the SAMHSA office responsible for opioid treatment Program oversight. Contact information may be found in Appendix II.

VI. ONLY LIMITED DISCLOSURES ARE ALLOWED UNDER PART 2

Part 2 treatment information can only be disclosed as follows:

1. With patient's written consent that complies with Part 2's requirements (see Appendix IV) – disclosing only that information necessary to carry out the stated purpose of the disclosure.

2. To a QSO pursuant to a written QSOA – disclosing only that information necessary for the QSO to perform its duties under the QSOA.

3. In medical emergencies.

4. For research.

5. For audit and evaluation purposes.

6. With a court order that complies with Part 2's requirements. Regular court orders will not suffice; the court is required to make certain findings, and the court order must contain the following elements:

    i. Civil court order:

        A. Court finds that good cause exists.

        B. Court finds that other ways of obtaining the information are not available or would not be effective.

        C. Court finds that the public interest and need for the disclosure outweigh the potential injury to the patient, the physician-patient relationship, and the treatment services.

        D. Court order limits disclosure to those parts of the patient's record which are essential to fulfill the objective of the order.

        E. Court order limits the disclosure to those persons who need the information.

F. Court order includes such other measures as are necessary to limit disclosure for the protection of the patient, the physician-patient relationship and the treatment service.

ii. Criminal court order:

A. The crime involved is extremely serious, such as one which causes or directly threatens loss of life or serious bodily injury including homicide, rape, kidnapping, armed robbery, assault with a deadly weapon, and child abuse and neglect.

B. There is a reasonable likelihood that the records will disclose information of substantial value in the investigation or prosecution.

C. Other ways of obtaining the information are not available or would not be effective.

D. The potential injury to the patient, to the physician-patient relationship and to the ability of the Program to provide services to other patients is outweighed by the public interest and the need for the disclosure.

E. If the applicant is a law enforcement agency or official, that:

a. The person holding the records has been afforded the opportunity to be represented by independent counsel; and

b. Any person holding the records which is an entity within federal, state, or local government has in fact been represented by counsel independent of the applicant.

VII. DISCLOSURES NOT ALLOWED UNDER PART 2

Note that there is no Part 2 provision allowing the release of Program records pursuant to a bare subpoena. Under Part 2, to compel disclosure, a subpoena must be accompanied by a valid consent or court order. This is true, regardless of state law. (For more information on state law and Part 2, see SAMHSA's FAQs in Appendix III.)

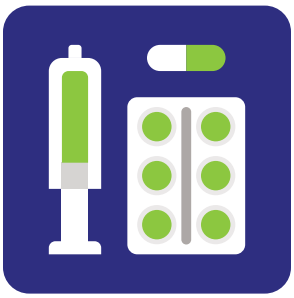
Also, under Part 2, there is no provision allowing a psychiatrist to warn a third party at risk of being harmed by a patient. However, in most cases, the duty to warn or protect the third party is satisfied by hospitalizing the patient, thereby protecting the intended victim. This issue, and others, are addressed in Appendix III.

VIII. HIPAA AND PART 2

While both federal regulations cover medical record confidentiality, Part 2 regulations are much more stringent. For example, under HIPAA, there is a process for subpoenaing medical records without an authorization. Under Part 2, as discussed above, Program records can never be released pursuant to just a subpoena – an authorization or valid court order is required.

Both sets of regulations require various documentation, including agreements with third parties to whom information is disclosed, patient notices, and patient permissions to release information.

	HIPAA REGULATIONS	PART 2 REGULATIONS
Agreements with third parties to whom information is disclosed for the third party to provide a service	Business Associate Agreement (BAA)	Qualified Service Organization Agreement (QSOA) *Note: The limited provisions required by Part 2 can be incorporated into a BAA*
Notice to patient	Notice of Privacy Policies (NPP)	Notice to Patients of Federal Confidentiality Requirements (see Appendix II) *Note: The limited provisions required by Part 2 can be incorporated into the NPP*
Patient permission to release information (See Appendix IV for the required elements under both regulations)	Authorization	Consent *Note: The requirements are very similar; provisions required by Part 2, if not already in the authorization, can be added to the authorization. Example: New York Courts authorization form (http://www.nycourts.gov/forms/Hipaa_fillable.pdf) covers HIPAA and Part 2, as well as state law.*



APPENDIX I

OUTLINE OF SECTIONS IN 42 CRF PART 2 REGULATIONS

(https://www.ecfr.gov/cgi-bin/text-idx?SID=0f9b2a146b539944f00b5ec90117d296&mc=true&node=pt42.1.2&rgn=div5)

SUBPART A – INTRODUCTION

§ 2.1 Statutory Authority for Confidentiality of Substance Use Disorder Patient Records

§ 2.2 Purpose and Effect

§ 2.3 Criminal Penalty for Violation

§ 2.4 Reports of Violation

SUBPART B – GENERAL PROVISIONS

§ 2.11 Definitions

§ 2.12 Applicability

§ 2.13 Confidentiality

§ 2.14 Minor Patients

§ 2.15 Incompetent and Deceased Patients

§ 2.16 Security for Reports

§ 2.17 Undercover Agents and Informants

§ 2.18 Restrictions on the Use of Identification Cards

§ 2.19 Disposition of Records by Discontinued Programs

§ 2.20 Relationship to State Laws

§ 2.21 Relationship to Federal Statutes Protecting Research Subjects...

§ 2.22 Notice to Patients of Federal Confidentiality Requirements

§ 2.23 Patient Access and Restrictions on Use

SUBPART C – DISCLOSURES WITH PATIENT CONSENT

§ 2.31 Consent Requirements

§ 2.32 Prohibition on Re-Disclosure

§ 2.33 Disclosures Permitted with Written Consent

§ 2.34 Disclosures to Prevent Multiple Enrollments

§ 2.35 Disclosures to Elements of the Criminal Justice System Which Have Referred Patients

SUBPART D – DISCLOSURES WITHOUT PATIENT CONSENT

§ 2.51 Medical Emergencies

§ 2.52 Research

§ 2.53 Audit and Evaluation

SUBPART E – COURT ORDERS AUTHORIZING DISCLOSURE AND USE

§ 2.61 Legal Effect of Order

§ 2.62 Order Not Applicable to Records Disclosed Without Consent to Researchers, Auditors and Evaluators

§ 2.63 Confidential Communications

§ 2.64 Procedures and Criteria for Orders Authorizing Disclosures for Noncriminal Purposes

§ 2.65 Procedures and Criteria for Orders Authorizing Disclosure and Use of Records to Criminally Investigate or Prosecute Patients

§ 2.66 Procedures and Criteria for Orders Authorizing Disclosure and Use of Records to Investigate or Prosecute a Part 2 Program or the Person Holding the Records

§ 2.67 Orders Authorizing the Use of Undercover Agents and Informants to Investigate Employees or Agents of a Part 2 Program in Connection with a Criminal Matter

APPENDIX II

NOTICE TO PATIENTS OF PART 2 CONFIDENTIALITY REQUIREMENTS

In an earlier version of the Part 2 regulations, the government included a sample notice to patients. This is set forth below in its original version along with drafting notes for edits to the notice from the new regulations.

CONFIDENTIALITY OF SUBSTANCE USE DISORDER TREATMENT RECORDS

The confidentiality of alcohol and drug abuse *[drafting note: consider replacing "alcohol and drug abuse" with "substance use disorder"]* patient records maintained by this Program is protected by federal law and regulations *[drafting note: insert parenthetical with required legal citations - "42 USC § 290-dd-2, 42 CFR Part 2"]*. 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 unless:

1. The patient consents in writing;
2. The disclosure is allowed by 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.

[Drafting note: add as number 4 – "The disclosure to a Qualified Service Organization is made pursuant to a written Qualified Service Organization Agreement"]

Violation of the federal law and regulations by a Program is a crime. Suspected violations may be reported to *[drafting notes: add "the United States Attorney" and provide contact information for the local US Attorney's Office, which can be found at https://www.justice.gov/usao/find-your-united-states-attorney; also, add "The report of any violation by an opioid treatment program may also be directed to SAMHSA" and provide contact information, which can be found at https://www.samhsa.gov/medication-assisted-treatment/opioid-treatment-programs/compliance-officers]*

Federal law and regulations do not protect any information about a crime committed by a patient whether 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.

APPENDIX III

FAQS FROM SAMHSA

(www.samhsa.gov/about-us/who-we-are/laws-regulations/confidentiality-regulations-faqs)

APPLYING THE SUBSTANCE ABUSE CONFIDENTIALITY REGULATIONS

Substance Abuse and Mental Health Services Administration
U.S. Department of Health and Human Services
42 CFR Part 2 (REVISED)

These Frequently Asked Questions (FAQs) are for information purposes only and are not intended as legal advice. Specific questions regarding compliance with federal law should be referred to your legal counsel. State laws may also apply.

In 2010, the HHS Substance Abuse and Mental Health Services Administration (SAMHSA) and the HHS Office of the National Coordinator (ONC) published FAQs "Applying the Substance Abuse Confidentiality Regulations to Health Information Exchange (HIE)." The 2010 FAQs are available at Applying the Substance Abuse Confidentiality Regulations to Health Information Exchange (HIE) (PDF | 381 KB).

QUESTION 1

When a patient has signed a consent form allowing disclosure to multiple parties, can the patient revoke consent for disclosure to one or more of those parties while leaving the rest of the consent in force?

Yes. Under 42 CFR Part 2 (hereafter referred to as "Part 2"), a patient can revoke consent to one or more parties named in a multi-party consent form while leaving the rest of the consent in effect. In a non-Health Information Exchange (HIE) environment, this can be accomplished simply by the Part 2 program indicating on the consent form or in the patient's record that consent has been revoked with respect to one or more named parties. In an HIE environment, the revocation with respect to one or more parties should be clearly communicated to the Health Information Organization (HIO) as well as noted in the patient's record by the Part 2 program.

NOTES: Health Information Exchange ("HIE") is a generic term that refers to a number of methods and mechanisms through which information can be exchanged electronically. As used in these FAQs, the term Health Information Organization "HIO" means an organization that oversees and governs the exchange of health-related information among organizations according to nationally recognized standards.

To ensure compliance with consent requirements, an HIO should have policies and procedures in place for implementing patient decisions to give and revoke consent. Once a patient has revoked a Part 2 consent with respect to one or more parties, that revocation should be immediately communicated to the HIO by the entity obtaining the patient's revocation so that it implements the revocation decision and no longer transmits the Part 2 program's protected patient information to those one or more parties. Part 2 permits a patient to revoke consent orally [42 CFR § 2.31(a)(8),(c)(8)]. While oral revocations must be honored under Part 2, SAMHSA recommends the entity obtaining the revocation get it in writing and/or document the revocation in the patient's record. Part 2 prohibits a program from making a disclosure on the basis of a consent which it knows has been revoked. A program however is entitled to act in reliance on a signed consent prior to a revocation, and such disclosure would not be improper [42 CFR § 2.31(c)(3) and § 2.31(a)(8)]. SAMHSA recommends that a revocation be communicated as soon as practicable to entities relying on such consent.

We note that the requirements of the HIPAA Privacy Rule must also be considered. For information on HIPAA, see the HHS Health Information Privacy website at www.hhs.gov/ocr/privacy/index.html or http://archive.samhsa.gov/HealthPrivacy/docs/SAMHSAPart2-HIPAAComparison2004.pdf (PDF | 379 KB).

QUESTION 2

Does a consent form allowing for a program to disclose Part 2 information remain in effect when the disclosing program merges with another or undergoes corporate restructuring?

Whether a consent form remains in effect when a program merges with another program or undergoes corporate restructuring depends on how the entity making the disclosure is identified on the consent form.

Under Section 2.31(a)(1), the disclosing entity can be listed by "specific name or general designation." If a particular program is designated by specific name as the entity permitted to make the disclosure, then the consent form would no longer be valid if the program's name is changed (following a merger or restructuring or for another reason) since the new entity is not identified as the same one that was listed on the consent form. If the disclosing entity is listed by a general designation, such as "any drug or alcohol treatment program that is affiliated with the XYZ HIO," then that consent would continue to be valid if the program making the disclosure merges or undergoes corporate restructuring, assuming the new merged program is also an HIO-affiliated member.

Note that section 2.19 sets forth the requirements when a Part 2 program is discontinued or taken over or acquired by another program, as opposed to just undergoing a name change or restructuring. This section provides that a discontinued program or one acquired by another program must purge patient identifying information from its records or destroy the records unless the patient consents to the transfer of his or her records, except to the extent that there is a legal requirement that records be retained.

In cases where a recipient organization has undergone a name change, whether or not a new consent form is needed depends upon the specific designation made on the original consent. Section 2.31(a)(2) allows for specification of either the name or title of the individual or the name or the organization to which the disclosure is to be made. Therefore, an organizational name change alone may not necessitate a new consent.

QUESTION 3

May a Part 2 program disclose patient information to providers of "on-call coverage" pursuant to a Qualified Service Organization Agreement (QSOA)?

Yes. 42 CFR § 2.11 defines "Qualified Service Organization (QSO)" and lists the types of services that a QSO provides, and further references Qualified Service Organization Agreements (QSOA). Medical services are included on that list and thus a Part 2 program can enter into a QSOA with providers of "on-call coverage."

A QSOA is a two-way agreement between a Part 2 program and the entity providing the service, in this case the provider of on-call coverage. The QSOA authorizes communication between those two parties, however the Part 2 program should only disclose information

to the QSO that is necessary for the QSO to perform its duties under the QSOA. Also, the QSOA does not permit a QSO to redisclose information to a third party unless that third party is a contract agent of the QSO, helping them provide services described in the QSOA, and only as long as the agent only further discloses the information back to the QSO or to the Part 2 program from which the information originated. For additional information, see FAQ Number 10 of the 2010 FAQs published by SAMHSA and the ONC at: Applying the Substance Abuse Confidentiality Regulations to Health Information Exchange (HIE) (PDF | 381 KB)

Thus, if a QSOA exists between a Part 2 program and an HIO for services rendered to the program by the HIO, the QSOA would not allow the HIO to redisclose that information to a third party like providers of "on-call coverage." For an HIO to redisclose Part 2 information to providers of "on-call coverage" that are not part of the Part 2 program, a consent form that allows the HIO to make the redisclosures to the providers of "on-call coverage" would be needed.

Since "on-call coverage" arrangements are fluid and the identity of the health care provider who is providing the on-call coverage might not be known, the designation of the recipient could be "the health care provider who is providing on-call coverage for the ABC treatment program." By designating the recipient as the "on-call coverage provider," the requirement that the recipient's name or title be listed would be met. Consent for disclosures to providers of on-call coverage can be included in the same consent form used for other disclosures of patient information if the program so chooses.

An HIO can also redisclose Part 2 information without patient consent to providers of "on-call coverage" who are part of the Part 2 program or of an entity having direct administrative control over the program, as long as the on-call providers need the information in connection with their duties that arise out the provision of diagnosis, treatment or referral for treatment services [42 CFR § 2.12(c)(3)].

QUESTION 4

Can a single Part 2 consent form be used to authorize patient information to be exchanged through an HIO's system for different purposes, such as treatment, payment, disease management and/or quality improvement?

Yes. Part 2 allows the use of a single consent form authorizing the disclosure of Part 2 patient information to different recipients for different purposes. However, Part 2 also requires a consent form to specify the kind and amount of information that can be disclosed to each of the recipients named in the consent. The amount of information to be disclosed "must be limited to that information which is necessary to carry out the purpose of the disclosure" [42 C.F.R. § 2.13(a)]. This will vary depending on the different purposes for which different recipients are being allowed access to the information made available through an HIE. Thus the consent form would have to be structured to make it clear what information may be given to which recipients, and for which purposes. The HIE system

must also be designed to limit the different recipients' access through the HIE to only the kind and amount of patient information each needs to fulfill the specific purpose for which they are being allowed access.

QUESTION 5

Does Part 2 permit a healthcare provider to disclose information without consent when there is an immediate threat to the health or safety of an individual or the public?

Part 2 permits the disclosure of information under certain circumstances without consent during a medical emergency or in other limited situations. If a Part 2 program (or a healthcare provider that has received Part 2 patient information) believes that there is an immediate threat to the health or safety of any individual, there are steps described below that the Part 2 program or healthcare provider can take in such a situation:

Notifications to medical personnel in a medical emergency: *A Part 2 program can make disclosures to medical personnel if there is a determination that a medical emergency exists, i.e., there is a situation that poses an immediate threat to the health of any individual and requires immediate medical intervention [42 CFR § 2.51(a)]. Information disclosed to the medical personnel who are treating such a medical emergency may be redisclosed by such personnel for treatment purposes as needed. For additional information regarding disclosures during a medical emergency, see FAQs Numbered 7, 8, and 9 below.*

Notifications to law enforcement: *Law enforcement agencies can be notified if an immediate threat to the health or safety of an individual exists due to a crime on program premises or against program personnel. A Part 2 program is permitted to report the crime or attempted crime to a law enforcement agency or to seek its assistance [42 CFR § 2.12(c)(5)]. Part 2 permits a program to disclose information regarding the circumstances of such incident, including the suspect's name, address, last known whereabouts, and status as a patient in the program.*

Immediate threats to health or safety that do not involve medical emergencies or crimes on programs premises or against program personnel: *Part 2 programs and health care providers and HIOs who have received Part 2 patient information, can make reports to law enforcement about an immediate threat to the health or safety of an individual or the public if patient-identifying information is not disclosed. Immediate threats to health or safety that do not involve a medical emergency or crimes (e.g., a fire) are not addressed in the regulations. Programs should evaluate those circumstances individually.*

Reports of child abuse and neglect: *The restrictions on disclosure do not apply to the reporting under State law of incidents of suspected child abuse and neglect to the appropriate State or local authorities. However, Part 2 restrictions continue to apply to the original alcohol or drug abuse patient records maintained by the program including their disclosure and use for civil or criminal proceedings which may arise out of the report of suspected child abuse and neglect [42 CFR § 2.12(c)(6)]. Also, a court order under Part 2 may authorize disclosure of confidential communications made by a patient to a program*

in the course of diagnosis, treatment, or referral for treatment if, among other reasons, the disclosure is necessary to protect against an existing threat of life or of serious bodily injury, including circumstances which constitute suspected child abuse and neglect [42 CFR § 2.63(a)(1)].

Court ordered disclosures: *Under the regulations, Part 2 programs or "any person having a legally recognized interest in the disclosure which is sought" may apply to a court for an order authorizing disclosure of protected patient information [42 CFR § 2.64]. Thus, if there is an existing threat to life or serious bodily injury, a Part 2 program or "any person having a legally recognized interest in the disclosure which is sought" can apply for a court order to disclose information.*

QUESTION 6

Under what circumstances can information disclosed pursuant to Part 2 be redisclosed?

Once Part 2 information has been initially disclosed (with or without patient consent), no redisclosure is permitted without the patient's express consent to redisclose or unless otherwise permitted under Part 2.

Disclosures made with patient consent must be accompanied by a statement notifying the recipient that Part 2 redisclosure is prohibited, unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by Part 2 (42 CFR § 2.32).

When disclosures are made without patient consent under the following circumstances, limited redisclosures without obtaining the patient's consent: are permitted, such as medical emergencies [42 CFR § 2.51], child abuse reporting [42 CFR § 2.12(c)(6)], crimes on program premises or against program personnel [42 CFR § 2.12(c)(5)], and court ordered disclosures when procedures and criteria are met [42 CFR §§ 2.61-2.67].

When disclosures are made under the following circumstances the recipient is prohibited from redisclosing the information without consent, except under the following restricted circumstances:

Research: *Researchers who receive patient identifying information are prohibited from redisclosing the patient-identifying information to anyone except back to the program [42 CFR § 2.52(b)].*

Audits and Evaluations: *Part 2 permits disclosures to persons and organizations authorized to conduct audits and evaluation activities, but imposes limitations by requiring any person or organization conducting the audit or evaluation to agree in writing that it will redisclose patient identifying information only (1) back to the program, or (2) pursuant to a court order to investigate or prosecute the program (not a patient), or (3) to a government agency that is overseeing a Medicare or Medicaid audit or evaluation [42 CFR § 2.53(c)(d)].*

Qualified Service Organization Agreements (QSOAs): *Part 2 requires the QSO to agree in writing that in receiving, storing, processing, or otherwise dealing with any information from the program about patients, it is fully bound by Part 2, it will resist, in judicial proceedings if necessary, any efforts to obtain access to information pertaining to patients except as permitted by Part 2, and will use appropriate safeguards to prevent the unauthorized use or disclosure of the protected information [42 CFR § 2.11]. In addition, QSOAs may allow disclosure in certain circumstances.*

Authorizing Court Orders: *When information is disclosed pursuant to an authorizing court order, Part 2 requires that steps be taken to protect patient confidentiality. In a civil case, Part 2 requires that the court order authorizing a disclosure include measures necessary to limit disclosure for the patient's protection, which could include sealing from public scrutiny the record of any proceeding for which disclosure of a patient's record has been ordered [42 CFR § 2.64(e)(3)]. In a criminal case, such order must limit disclosure to those law enforcement and prosecutorial officials who are responsible for or are conducting the investigation or prosecution, and must limit their use of the record to cases involving extremely serious crimes or suspected crimes. For additional information regarding the contents of court orders authorizing disclosure, see 42 CFR § 2.65(e).*

QUESTION 7

How can a Part 2 program ensure that it will be notified that a health care provider invoked the medical emergency exception and gained access to protected Part 2 information?

The Part 2 regulations at 42 CFR § 2.51 specify 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 recipient of the information, the name of the individual making the disclosure, the date and time of the disclosure, and the nature of the emergency [42 CFR § 2.51(c)]. See previous FAQs, and specifically, Number 30 of the 2010 FAQs. SAMHSA recommends that HIE data systems be designed to ensure that the Part 2 program is notified when a disclosure occurs and Part 2 records are released pursuant to a medical emergency. To promote compliance, SAMHSA recommends that the notification include all the information that the Part 2 program is required to document in the patient's records (e.g., date and time of disclosure, the nature of the emergency, etc.). Similarly, SAMHSA recommends that the information about emergency disclosures be kept in the HIO's electronic system and protected using appropriate safeguards.

Before a Part 2 program enters into an affiliation with an HIO, it should consider whether the HIO system has the capability to comply with all Part 2 requirements, including the capacity to notify the Part 2 program when its records have been disclosed pursuant to a medical emergency. For additional information regarding disclosures during a medical emergency, see the FAQs Numbered 5, 8, and 9.

QUESTION 8

What categories of health care professionals are considered "medical personnel" for the purpose of obtaining information during a medical emergency?

Part 2 allows patient identifying information to be disclosed to medical personnel in a medical emergency [42 CFR § 2.51]. Part 2 does not define the term "medical personnel" but merely provides that information can be given to medical personnel who have a need for 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 immediate medical intervention. It is up to the health care provider or facility treating the emergency to determine the existence of a medical emergency and which personnel are needed to address the medical emergency. The name of the medical personnel to whom the disclosure was made, their affiliation with any health care facility, the name of the individual making the disclosure, the date and time of the disclosure, and the nature of the medical emergency must be documented in the patient's records by the Part 2 program disclosing them [42 CFR § 2.51(c)]. Additional information about disclosures in medical emergencies is found in FAQs Numbered 5, 7, and 9.

QUESTION 9

Can the Part 2 medical emergency exception be invoked to head off a potential medical emergency such as a potential drug interaction?

If a health care provider treating an individual determines that a medical emergency exists as defined in Part 2, i.e., "a condition which poses an immediate threat to the health of any individual [not just the patient], and which requires immediate medical intervention," and in treating the medical emergency the health care provider needs information about potential drug interactions, then that information and any other information contained in the Part 2 record that the treating health care provider determines he or she needs to treat the medical emergency can be disclosed. If no such determination exists, SAMHSA recommends trying to obtain consent from the patient.

If a health care provider is treating a patient in a non-emergency situation and the health care provider is concerned about a potential drug interaction, in an HIE environment, an HIO may only disclose a Part 2 program patient's records to a health care provider if the patient signs a consent form releasing the Part 2 record to the health care provider. Such a consent form may already exist if the patient previously signed a Part 2 consent form allowing the HIO to disclose Part 2 information to HIO affiliated health care providers and the provider seeking access is listed as a recipient on that form.

A health care provider who is concerned about a potential drug interaction and treating a patient in a non-emergency situation can also gain access to a Part 2 program patient's record if the health care provider has signed a QSOA with the patient's Part 2 program (and the information is limited to what is needed for the provider to provide services to the Part

2 program) or obtains patient consent.

In a non-emergency situation, if the health care provider concerned about a potential drug interaction is part of the Part 2 program (or of an entity that has direct administrative control over the program), he or she can gain access to the Part 2 patient's record without consent if the health care provider needs the information to treat the patient. 42 CFR § 2.12(c)(3) does not restrict communications between and among such personnel who have a need for the information in connection with their duties arising out of the provision of diagnosis, treatment or referral for treatment services.

It should be noted that concern alone about potential drug interaction may not be sufficient to meet the standard of a medical emergency. Thus, based on the circumstances of the presenting situation, SAMHSA recommends that health care providers should obtain consent from the patient where feasible.

QUESTION 10

Do all primary care providers who prescribe controlled substances to treat substance use disorders meet the definition of a "program" under Part 2?

No. Not every primary care provider who prescribes controlled substances meets the definition of a "program" or part of a "program" under Part 2. For providers to be considered "programs" covered by the Part 2 regulations, they must be both "federally-assisted" and meet the definition of a program under 42 CFR § 2.11. Physicians who prescribe controlled substances to treat substance use disorders are DEA-licensed and thus meet the test for federal assistance [42 CFR § 2.12(b)(2)]. Nevertheless, the regulations establish additional criteria to meet the definition of a "program":

1. If a provider is *not* a general medical care facility, then the provider meets Part 2's definition of a "program" if it is an individual or entity that holds itself out as providing, and provides alcohol or drug abuse diagnosis, treatment or referral for treatment.
2. If the provider is an identified unit within a general medical care facility, it is a "program" if it holds itself out as providing, *and* provides, alcohol or drug abuse diagnosis, treatment or referral for treatment.
3. If the provider consists of medical personnel or other staff in a general medical care facility, it is a program if its primary function is the provision of alcohol or drug abuse diagnosis, treatment or referral for treatment *and* is identified as such specialized medical personnel or other staff within the general medical care facility.

In addition, in explaining Part 2's applicability and coverage, § 2.12(e)(1) states that "coverage includes, but is not limited to, employee assistance programs, programs within general hospitals, school-based programs and private practitioners who hold themselves out as providing, and provide alcohol or drug abuse diagnosis, treatment or referral for treatment" [42 CFR § 2.12(e)(1)].

Accordingly, primary care providers who do not work in general medical care facilities meet Part 2's definition of a program if their principal practice consists of providing alcohol or drug abuse diagnosis, treatment or referral for treatment, and they hold themselves out as providing the same. If their principal practice consists of providing alcohol or drug abuse diagnosis, treatment or referral for treatment, but they do not hold themselves out as providing those services, then it is likely that they would not meet the definition of a program. The phrase "holds itself out" is not defined in the regulations, but could mean a number of things, including but not limited to state licensing procedures, advertising or the posting of notices in the offices, certifications in addiction medicine, listings in registries, internet statements, consultation activities for non-"program" practitioners, information presented to patients or their families, or any activity that would lead one to reasonably conclude that the provider is providing or provides alcohol or drug abuse diagnosis, treatment or referral for treatment.

Further, while the term "general medical care facility" is not defined in the definitions section of 42 CFR 2.11, hospitals, trauma centers, or federally qualified health centers would generally be considered "general medical care" facilities. Therefore, primary care providers who work in such facilities would only meet Part 2's definition of a program if 1) they work in an identified unit within such general medical care facility that holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment, or 2) the primary function of the provider is alcohol or drug abuse diagnosis, treatment or referral for treatment and they are identified as providers of such services. In order for a program in a general medical care facility to share information with other parts or units within the general medical care facility, administrative controls must be in place to protect Part 2 information if it is shared.

In addition, a practice comprised of primary care providers could be considered a "general medical facility." As such, only an identified unit within that general medical care facility which holds itself out as providing and provides alcohol or drug abuse diagnosis, treatment or referral for treatment would be considered a "program" under the definition in the Part 2 regulations. Medical personnel or staff within that facility whose primary function is the provision of those services and who are identified as such providers would also qualify as a "program" under the definition in the Part 2 regulations. Other units or practitioners within that general medical care facility would not meet the definition of a Part 2 program unless such units or practitioners also hold themselves out as providing and provide alcohol or drug abuse diagnosis, treatment or referral for treatment.

QUESTION 11

Is information generated by the provision of SBIRT (Screening, Brief Intervention and Referral to Treatment) services covered by Part 2?

Screening, Brief Intervention and Referral to Treatment (SBIRT) is a cluster of activities designed to identify people who engage in risky substance use or who might meet the

criteria for a formal substance use disorder. Clinical findings indicate that the overwhelming majority of individuals screened in a general medical setting do not have a substance use disorder and do not need substance use disorder treatment.

The determination whether patient information acquired when conducting SBIRT services is subject to Part 2 depends on whether the entity conducting the SBIRT activities is a federally-assisted "program" as defined in the regulations. If the entity conducting SBIRT services is not a federally-assisted program, then the SBIRT services and patient records generated by such services would not be covered under 42 CFR Part 2, although HIPAA and state laws may apply. However, if the entity or unit within a general medical care facility conducting the SBIRT services is a federally-assisted program under Part 2, then the SBIRT patient records would be subject to Part 2 regulations.

See FAQ Number 10 of these FAQs for a discussion of the definition of a program under 42 CFR Part 2.

QUESTION 12

What is Part 2's relationship to state laws?

42 CFR § 2.20, states that "no State law may authorize or compel any disclosure prohibited by these [Part 2] regulations." However, States may impose additional confidentiality protections. Thus, § 2.20 provides that, "If a disclosure permitted under these regulations is prohibited under State law, neither these regulations nor the authorizing statutes may be construed to authorize any violation of that State law."

QUESTION 13

Would a logon or splash page notification on an HIO's portal that contains the Part 2 notice prohibiting redisclosure be sufficient to meet Part 2's requirement that disclosures made with patient consent be accompanied by such a statement?

No. Part 2 requires each disclosure made with written patient consent to be accompanied by a written statement that the information disclosed is protected by federal law and that the recipient cannot make any further disclosure of it unless permitted by the regulations (42 CFR § 2.32). A logon page is the page where a user logs onto a computer system; a splash page is an introductory page to a web site. A logon or splash page notification on a HIO's portal including the statement as required by § 2.32 would not be sufficient notification regarding prohibitions on redisclosure since it would not accompany a specific disclosure. The notification must be tied to the Part 2 information being disclosed in order to ensure that the recipient of that information knows that specific information is protected by Part 2 and cannot be redisclosed except as authorized by the express written consent of the person to whom it pertains or as otherwise permitted by Part 2.

QUESTION 14

If a Part 2 program has signed QSOAs with two service providers, can those services providers redisclose Part 2 information to each other?

No. A QSOA is a two-way agreement between a Part 2 program and the entity providing the service, for example a lab. The QSOA authorizes communication only between the Part 2 program and QSO. The QSO, in this case the lab, would not be allowed to redisclose lab results about the Part 2 program's patient to another QSO such as an HIO, even if the HIO has also signed a QSOA with the Part 2 program. In order for the lab to redisclose Part 2 patient information to the HIO, it would need the patient's signed Part 2 consent or be otherwise permitted by Part 2. One consent form could both authorize the Part 2 program to disclose information to the lab, and authorize the lab to redisclose Part 2 information to the HIO. Once the HIO obtains the lab results it could, through the QSOA it signed with the Part 2 program, send those results to the Part 2 program, assuming that was a service described in the QSOA.

QUESTION 15

If an HIO has a QSOA with a Part 2 program and a patient signs a consent allowing a HIO affiliated provider to gain access to the patient's records through the HIO, does that patient consent allow the HIO to disclose the Part 2 information?

Yes, as long the consent form signed conforms to the requirements of Part 2. (See previously issued FAQ Number 11 published by SAMHSA and ONC in 2010 for a list of the required elements of a patient consent under Part 2: Applying the Substance Abuse Confidentiality Regulations to Health Information Exchange (HIE) (PDF | 381 KB). A QSOA does not allow a QSO such as an HIO to redisclose Part 2 information to a third party, except to a contract agent of the HIO if it needs to do so in order to provide the service(s) described in the QSO. However, if a patient signs a consent form authorizing the HIO, which has received the disclosed information from the Part 2 program, to redisclose the Part 2 information to a HIO affiliated member, then the Part 2 information can be redisclosed by the HIO.

Part 2's consent provision requires that a consent form include the "specific name or general designation of the program or person permitted to make the disclosure" [42 CFR Part 2, § 2.31(a)(1)]. In the case where Part 2 information is made available to an HIO, whether through a QSOA or written patient consent, the consent form allowing the HIO to redisclose the Part 2 information must identify by name or general designation the Part 2 program(s) as the entity permitted to make the disclosure of the Part 2 information. This is because, while the HIO is redisclosing the Part 2 information, the disclosing entity remains the Part 2 program. The consent can also name the HIO as a redisclosing party.

As noted above, the disclosing Part 2 program may be identified either by its specific name or by "general designation." Language such as "all programs in which the patient has been

enrolled as an alcohol or drug abuse patient" would be an acceptable general designation.

QUESTION 16

Under Part 2, can an HIO or HIO affiliated member use a consent form that generally designates the entities permitted to make disclosures of Part 2 information, and refers to the HIO's website for a list of those disclosing entities?

Yes, the consent form can refer to the HIO's website for the list of entities permitted to make disclosures if the disclosing entity is identified by a "general designation" in the consent form as permitted under Part 2. Part 2's consent provisions allow either the "name or general designation of the program or person permitted to make the disclosure" to be specified on the consent form. Because a general designation is permitted, if such general designation is used, then the specific names of those disclosing entities do not need to be included on the consent form and patients can be referred to the HIO's website for a list of those entities.

This is in contrast to Part 2's consent provision regarding recipients of Part 2 data. 42 CFR § 2.31(a)(2) requires that a consent form include "the name or title of the individual or the name of the organization to which disclosure is to be made." Thus, as was previously noted in previously issued FAQ Number 18 published by SAMHSA and ONC in 2010 (Applying the Substance Abuse Confidentiality Regulations to Health Information Exchange (HIE) (PDF | 381 KB)), Part 2 consents cannot refer patients to the HIO's website for a list of potential recipients of their data but rather must identify within the consent all the HIO affiliated members by name or title that are potential recipients of the Part 2 data. Therefore, a new consent form (e.g. by the additional Part 2 program or the HIO) would be required when a new recipient of the information is added.

QUESTION 17

How does the Supreme Court's decision in United States v. Windsor which overturned section 3 of the Defense of Marriage Act (DOMA), affect 42 CFR Part 2?

On June 26, 2013, in United States v. Windsor, the Supreme Court held that section 3 of the Defense of Marriage Act (DOMA), which prohibited federal recognition of same-sex spouses/marriages, was unconstitutional. Consistent with HHS policy, same-sex spouses/marriages are to be recognized in SAMHSA regulatory provisions. This means that, as a person or entity subject to SAMHSA's confidentiality regulation governing alcohol and drug abuse patient records, this policy applies to you. The regulation contains a provision, that is affected by the Windsor decision, which addresses consent on behalf of incompetent or deceased patients and provides that in the absence of a personal representative, consent to disclosure of information identifying a deceased patient as an alcohol or drug abuse patient may be given by the patient's spouse or, if none, by any responsible member of the patient's family. See 42 C.F.R. § 2.15(b)(2). SAMHSA now interprets this provision to

include same-sex spouses in the meaning of the terms "spouse" and "family." This means that, for purposes of this provision under 42 C.F.R. Part 2, you are required to treat as valid the marriages of same-sex couples whose marriage was legal when entered into. This applies regardless of whether the couple now lives in a jurisdiction that recognizes same-sex marriage or a jurisdiction that does not recognize same-sex marriage. Any same-sex marriage legally entered into in one of the 50 states, the District of Columbia, a U.S. territory or a foreign country will be recognized. However, this does not apply to registered domestic partnerships, civil unions or similar formal relationships recognized under state law as something other than a marriage.

Last Updated: 05/01/2018

APPENDIX IV

REQUIRED ELEMENTS HIPAA "AUTHORIZATION" AND PART 2 "CONSENT"

REQUIRED AUTHORIZATION ELEMENTS UNDER HIPAA (45 CFR § 164.508(c))

(1.) **Core elements:**

- (i.) A description of the information to be used or disclosed;
- (ii.) The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure;
- (iii.) The name or other specific identification of the person(s), or class of persons, to whom the covered entity may make the requested use or disclosure;
- (iv.) A description of each purpose of the requested use or disclosure;
- (v.) An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure;
- (vi.) Signature of the individual and date. If the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual must also be provided.

(2.) **Required Statements:** In addition to the core elements, the authorization must contain statements adequate to place the individual on notice of all the following:

- (i.) The individual's right to revoke the authorization in writing, and either:
  - (A.) The exceptions to the right to revoke and a description of how the individual may revoke the authorization; or
  - (B.) To the extent that the information in paragraph (c)(2)(i)(A) of this section is included in the notice required by § 164.520 , a reference to the covered entity's notice.

(ii.) The ability or inability to condition treatment, payment, enrollment or eligibility for benefits on the authorization, by stating either:

(A.) The covered entity may not condition treatment, payment, enrollment or eligibility for benefits on whether the individual signs the authorization when the prohibition on conditioning of authorizations in paragraph (b)(4) of the section applies; or

(B.) The consequences to the individual of a refusal to sign the authorization when, in accordance with paragraph (b)(4) of this section, the covered entity can condition treatment, enrollment in the health plan, or eligibility for benefits on failure to obtain such authorization.

(iii.) The potential for information disclosed pursuant to the authorization to be subject to re-disclosure by the recipient and no longer be protected by this subpart.

REQUIRED CONSENT ELEMENTS UNDER 42 CFR PART 2 (§ 2.31)

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, including an explicit description of the substance use disorder information that may be disclosed.
6. A statement that the consent is subject to revocation at any time except to the extent that the Program or person which is to disclose information has already acted in reliance on it.
7. Expiration date (or expiring event of condition).
8. The signature of the patient:
    i. If the patient is a minor, the signature of a person authorized to give consent (Note, under § 2.14 the person authorized to give consent may be the minor); or
    ii. If the patient is incompetent or deceased, the signature of a person authorized to sign in lieu of the patient.
9. The date on which the consent is signed.

APPENDIX V

CHECKLIST FOR PART 2 PROGRAMS UNDER 42 CFR PART 2

- ☐ Train staff and employees to understand and comply with regulations.

  NOTE: *Part 2 training can be incorporated into your HIPAA training – initial training upon hiring and annual training.*

- ☐ Consider having staff sign confidentiality agreements.

- ☐ Inform patients about confidentiality by 1) informing patients that federal law and regulations protect their patient records and 2) giving patients a written summary of federal law and regulations. § 2.22

  NOTE: *This Part 2 patient notice can be incorporated into a HIPAA Notice of Privacy Practices.*

- ☐ Part 2 programs must have in place formal policies and procedures to protect unauthorized uses and disclosures of patient identifying information and protect against security threats to patient identifying information. § 2.16

- ☐ Must not re-disclose patient records without patient consent, unless a limited exception applies. § 2.32

- ☐ Ensure consent form for release of Part 2 records complies with Part 2 requirements. § 2.31

- ☐ When a disclosure is made in connection with a medical emergency, the Part 2 Program must document the name of the recipient of information, the date and time of disclosure, and nature of the emergency. § 2.51

- ☐ Must not release patient records per subpoena. § 2.61

- ☐ Must not release patient records per regular court order. § 2.61

- ☐ Have a Qualified Service Organizations Agreement prior to disclosing Part 2 information to a Qualified Service Organization. § 2.11

  NOTE: *This Part 2 agreement can be incorporated into your HIPAA Business Associate Agreement.*

- ☐ The amount of information disclosed to a qualified service organization must be limited to that information which is necessary to carry out the purpose of the disclosure. § 2.13

- ☐ Upon request, must provide patients who have consented to disclose their patient identifying information a list of entities to which their information has been disclosed to § 2.13

- ☐ If a Part 2 Program is discontinued or is acquired by another program it must remove patient identifying information from its records or destroy its records unless patient gives consent to transfer the records or there is a legal requirement to keep the records for a certain period. § 2.19

APPENDIX VI

MODEL EMPLOYEE CONFIDENTIALITY AGREEMENT

Regardless of whether you are a HIPAA covered entity, if you employ others in your practice, they should be asked to sign a confidentiality agreement acknowledging their obligation to maintain the privacy of patient information. It is recommended that this be reviewed with your employees on a yearly basis.

EMPLOYEE CONFIDENTIALITY AGREEMENT

Confidential patient information includes **any** information about a patient or a patient's care regardless of whether it is written, observed, or overheard. Confidential information may not be disclosed without the express permission of _____ [name of person who approves requests for release of information] or under his/her direction.

Examples of unauthorized use/disclosure of confidential information include but are not limited to:

- Revealing the fact that an individual is a patient of the practice.
- Discussing a patient with anyone within the office who does not need that information to perform his or her job.
- Discussing a patient with anyone outside of the office including spouses, family members, and friends.
- Reading a patient's chart without a legitimate treatment and or business purpose.
- Posting information about a patient (even without the patient's name) on any form of social media.
- Leaving a patient's chart or other information where it may be viewed by others.
- Discussing a patient within earshot of those not authorized to receive patient information including coworkers and other patients.
- Providing another person with your user ID, passcodes, or similar system access information.

I understand that the unauthorized use/disclosure of confidential patient information may be grounds for discipline and/or immediate termination. I further understand that this obligation will continue even after my employment here has ended.

_____	_____
Employee Signature	Supervisor Signature
_____	_____
Date	Date

PRMS

CONTACT US

(800) 245-3333
TheProgram@prms.com
PRMS.com

@PRMS
LinkedIn.com/company/PRMSprograms
Facebook.com/PRMSprograms

MORE THAN AN **INSURANCE POLICY**