Confidentiality of Substance Use Disorder Patient Records

42 CFR Part 2

Previously called Drug and Alcohol Records

Sue Dill Calloway

RELIAS LEARNING

1

Speaker

- Sue Dill Calloway RN Esq. CPHRM, CCMSCP, AD, BA, BSN, MSN, JD
- President Patient Safety and Healthcare Consulting
- 5447 Fawnbrook Lane
  Dublin, Ohio 43017
- 614 791-1468
  (Call with questions, no emails)
- sdill1@columbus.rr.com
- Email questions to CMS at hospitalscg@cms.hhs.gov

Objectives

- Describe Confidentiality of Substance Use Disorder Patient Records.
- Discuss when a minor can consent to the treatment of a substance abuse disorder.
- Explain that a special consent form is needed to release the medical records of a patient treated for substance abuse disorder under 42 CFR Part 2.

Introduction and History

RELIAS LEARNING 4

Introduction Substance Use Disorder

- Previously referred to as the confidentiality of drug abuse and alcohol abuse records
- First promulgated in 1975 and the last substantive update to the regulation was in 1987 (29 years ago)
- Originally called Confidentiality of Alcohol and Drug Abuse Patient Records
- Renamed **Confidentiality of Substance Use Disorder Patient Records**
- Also known as the **42 CFR Part 2** regulations
- Authorized under Title 41 U.S.C. 290dd-2

RELIAS LEARNING 5

Introduction Substance Use Disorder

- 42 CFR part 2 was passed to protect the confidentiality of the records containing the identity, diagnosis, prognosis, or treatment of any patient that were maintained in connection with the performance of any **federally assisted program** or activity relating to substance abuse education, prevention, training, treatment, rehabilitation, or research
  - Amended **14** major provisions and received 376 comments on the rule
- Promulgated by **SAMHSA** or the Substance Abuse and Mental Health Administration
  - Will issue sub-regulatory compliance guidance in 2017

RELIAS LEARNING 6

Introduction

- First, issued the proposed rules on February 9, 2016
- Next, published the final rules on January 18, 2017
- 76 pages long
- For questions contact **Danielle Tarino** at 240 276-2857 or email to **PrivacyRegulations@samsha.hhs.gov**
- Purpose was to update and modernize the confidentiality of drug and alcohol records and to facilitate information exchange within healthcare models while addressing patient privacy concerns

Proposed Rule Feb 9, 2016

Confidentiality of Substance Use Disorder Patient Records

A Rule by the Health and Human Services Department on 01/18/2017

PUBLISHED DOCUMENT

AGENCY:

Substance Abuse and Mental Health Services Administration, HHS.

ACTION:

Final rule.

SUMMARY:

The Department of Health and Human Services (HHS) is issuing this final rule to update and modernize the Confidentiality of Alcohol and Drug Abuse Patient Records regulations and facilitate information exchange within new health care models while addressing the legitimate privacy concerns of patients seeking

DOCUMENT DETAILS

Printed version: PDF

Publication Date: 01/18/2017

Agencies: Department of Health and Human Services; Office of the Secretary

Dates: Effective date: This final rule is effective February 17, 2017.

Effective Date: 03/21/2017

Document Type: Rule

https://www.federalregister.gov/documents/2017/01/18/2017-00719/confidentiality-of-substance-use-disorder-patient-records

Final Law PDF January 18, 2017 76 Pages

5354 Federal Register / Vol. 82, No. 11 / Wednesday, January 18, 2017 / Rules and Regulations

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

12 CFR Parts 25 and 195

FEDERAL RESERVE SYSTEM

12 CFR Part 228

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Part 345

https://www.gpo.gov/fdsys/pkg/FR-2017-01-18/pdf/2016-31928.pdf

Final Law Text Copy


[Federal Register Volume 82, Number 11 (Wednesday, January 18, 2017)]
[Rules and Regulations]
[Pages 6052-6127]
From the Federal Register Online via the Government Publishing Office [www.gpo.gov]
[FR Doc No: 2017-00719]

[[Page 6051]]
Vol. 82
Wednesday,
No. 11
January 18, 2017
Part VII

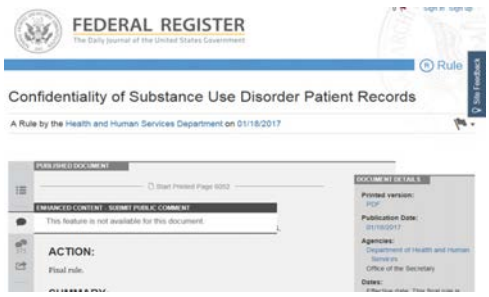
Department of Health and Human Services

42 CFR Part 2

Confidentiality of Substance Use Disorder Patient Records; Final Rule

www.gpo.gov/fdsys/pkg/FR-2017-01-18/html/2017-00719.htm

Easy To Read Version Final Federal Law



www.federalregister.gov/documents/2017/01/18/2017-00719/confidentiality-of-substance-use-disorder-patient-records

Final Law Available at e-CFR

www.ecfr.gov/cgi-bin/text-idx?c=ecfr&sid=b7e8d29be4a2b815c404988e29c06a3e&rgn=div5&view=text&node=42:1.0.1.1.2&idno=42

Substance Abuse & Mental Health Services

www.samhsa.gov/

Effective Date 2/17 to 3/21/2017??

- The Substance Abuse and Mental Health Services Administration **postponed** the effective date of its **final rule** on confidentiality of substance use disorder patient records for 60 days, to March 21
- The Office of Management and Budget issued a **memorandum** calling for heads of executive departments and agencies to postpone for review for 60 days most regulations that have been published in the Federal Register but not yet taken effect.
  - If it raises substantial questions of law or policy then need to take further appropriate action in consultation with the OMB director

Memo Freezing Pending Review

www.gpo.gov/fdsys/pkg/FR-2017-01-24/pdf/2017-01766.pdf

OFFICE OF MANAGEMENT AND BUDGET

Memorandum for the Heads of Executive Departments and Agencies; Regulatory Freeze Pending Review

January 20, 2017.

FROM: Reince Priebus, Assistant to the President and Chief of Staff.

SUBJECT: Regulatory Freeze Pending Review.

The President has asked me to communicate to each of you his plan for managing the Federal regulatory process at the outset of his Administration. In order to ensure that the President's appointees or designees have the opportunity to review any new or pending regulations, I ask on behalf of the President that you immediately take the following steps:

1. Subject to any exceptions the Director or Acting Director of the Office of Management and Budget (the "OMB Director") allows for emergency situations or other urgent circumstances relating to health, safety, financial, or national security matters, or otherwise, send no regulation to the Office of the Federal Register (the "OFR") until a department or agency head appointed or OFR for review and approval as described in paragraph 1, subject to the exceptions described in paragraph 1. This withdrawal must be conducted consistent with OFR procedures.

3. With respect to regulations that have been published in the OFR but have not taken effect, as permitted by applicable law, temporarily postpone their effective date for 60 days from the date of this memorandum, subject to the exceptions described in paragraph 1, for the purpose of reviewing questions of fact, law, and policy they raise. Where appropriate and as permitted by applicable law, you should consider proposing for notice and comment a rule to delay the effective date for regulations beyond that 60-day period. In cases where the effective date has been delayed in order to review questions of fact, law, or policy, you should consider potentially proposing further notice-and-comment rulemaking. Following the delay in effective date:

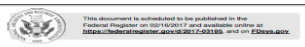
(a) For those regulations that raise no substantial questions of law or policy, no further action needs to be taken; and

(b) for those regulations that raise substantial questions of law or policy, agencies should notify the OMB regulations affect critical health, safety, financial, or national security matters, or for some other reason. The OMB Director will review any such notifications and determine whether such exclusion is appropriate under the circumstances.

6. Continue in all circumstances to comply with any applicable Executive Orders concerning regulatory management.

As used in this memorandum, "regulation" has the meaning given to "regulatory action" in section 3(e) of Executive Order 12866, and also includes any "guidance document" as defined in section 3(g) thereof as it existed when Executive Order 13422 was in effect. That is, the requirements of this memorandum apply to "any substantive action by an agency (normally published in the **Federal Register**) that promulgates or is expected to lead to the promulgation of a final rule or regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking," and also covers any agency statement of general applicability and future effect "that sets forth a policy on a statutory, regulatory,

Delay of Effective Date



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of the Secretary
42 CFR Part 2
[SAMHSA-4162-20]
RIN 0930-AA21
Confidentiality of Substance Use Disorder Patient Records; Delay of Effective Date

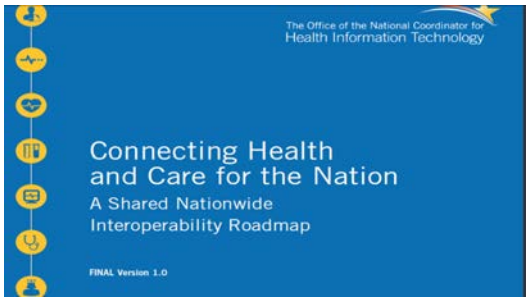
https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-03185.pdf

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.
ACTION: Final rule; delay of effective date.
SUMMARY: On January 18, 2017, the Substance Abuse and Mental Health Services Administration (SAMHSA) published a final rule on Confidentiality of Substance Use Disorder Patient Records. That rule is scheduled to take effect on February 17, 2017. In accordance with the memorandum of January 20, 2017, from the Assistant to the President and Chief of Staff, entitled "Regulatory Freeze Pending Review," published in the Federal Register on January 24,

Introduction

- We also have new models of integrated care that rely on information sharing
- This is necessary to coordinate the care of the patient
- The law needed to be revised because of the need to have an electronic infrastructure for the exchange of information
- Recently, there is a new focus on performance measurement and the need for outcome measures

Connecting Health and Care for the Nation



www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf

Resources HIE and Confidentiality

Frequently Asked Questions

Applying the Substance Abuse Confidentiality Regulations to Health Information Exchange (HIE)[1]

www.samhsa.gov/sites/default/files/faqs-applying-confidentiality-regulations-to-hie.pdf

RELIAS LEARNING 19

Substance Use Disorders Incidences in America

RELIAS LEARNING 20

Substance Use Disorders

- SAMHSA says substance use disorders occur when the recurrent use of alcohol and/or drugs causes clinically significant impairment
- This includes health problems, disability, and failure to meet major responsibilities at work, school, or home
- In 2014 there were 21.5 million Americans who were classified as substance use disorders in the past year
  - This was Americans age 12 or older

RELIAS LEARNING 21

Substance Use Disorders SUDs

- 4.5 million had problems with drugs
- 14.4 million had problems with alcohol
- 2.6 million had problem with both
- There was also 7.9 million adults with co-occurring disorders in 2014
  - This means they had both a substance use disorder and a mental health disorder
- Rates are highest for adults ages 26-49 (42.7%)

Substance Use Disorders SUDs

- Diagnostic and Statistical Manual of Mental Disorders (DSM-5) no longer uses the term substance abuse and substance dependence
- Instead it refers to substance use disorders
- Defined as mild, moderate, or severe
- Most common is alcohol use disorder (AUD) at 17 million, Tobacco use disorder with 25.2% Americans who use tobacco (not included in SUD), cannabis use disorder of 4.2 million, stimulant use disorder at 913,000, hallucinogen use disorder at 246,000, and opioid use disorder at 1.9 million

Behavioral Health Trends

AHA Recommendations and Comment Letter

RELIAS LEARNING 25

AHA Initiatives

- AHA had urged SAMHSA to align the substance abuse confidentiality requirements with HIPAA
- AHA does not believe the law eliminates current barriers to sharing of information for clinical care coordination
- AHA sent a letter to SAMHSA before it was finalized
- AHA did not think the new law was an improvement over the past regulation
- It does nothing to eliminate the barriers that significantly impede the sharing of information

RELIAS LEARNING 26

AHA Initiatives

- AHA urged full alignment of the substance abuse law with HIPAA as the proper way to eliminate the barriers for sharing patient information that is;
  - Essential for care coordination
  - Compatible with the electronic exchange of information
  - And supportive of performance measurement and improvement
- Felt they could have done more to align these two sets of requirements

RELIAS LEARNING 27

AHA Letter to SAMHSA

American Hospital Association

www.aha.org/advocacy-issues/letter/2016/160405-cl-samhsa4162-20.pdf

April 5, 2016

Ms. Kana Enomoto
Principal Deputy Administrator
Substance Abuse and Mental Health Services Administration
U.S. Department of Health and Human Services
Attn: SMAHSA-4162-20
5600 Fishers Lane, Room 13N02B
Rockville, MD 20857

RE: SAMHSA-4162-20; Confidentiality of Substance Use Disorder Patient Records, Proposed Rule

Dear Administrator Enomoto:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 43,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the proposed revision to the regulation governing the confidentiality of substance use disorder patients' records. According to the Substance Abuse and Mental Health Services Administration (SAMHSA), the proposed revision will allow greater flexibility in sharing patient information to support new models of integrated care that require information exchange for care coordination, rely on an electronic infrastructure for managing and exchanging patient information, and focus on performance measurement and improvement within the delivery system.

The AHA believes that the proposed revision would not be an improvement over the current requirements as it does nothing to eliminate the barriers that significantly impede the robust sharing of patient information necessary for effective clinical integration contained in the 42 CRF Part 2 regulation (Part 2 regulation). **Instead, we urge full alignment of the Part 2 regulation with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulation as the proper and effective solution to eliminating the existing barriers to the sharing of patient information essential for care coordination, compatible with electronic**

RELIAS LEARNING 28

Purpose and Need of New Law

RELIAS LEARNING 29

Purpose of Federal Law

- The main reason for the confidentiality law is to encourage patients with substance abuse to get treatment
  - Need to facilitate electronic exchange of information also
- Some individuals did not seek treatment because of fear their medical records would be made public especially if a politician or a public figure
- The regulations protect the identity of the patient in a drug or alcohol treatment program
- First, started off with two statutes (laws) in the early 1970's

RELIAS LEARNING 30

Purpose of Federal Law

- This included the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970
- And the Drug Abuse Prevention, Treatment, and Rehabilitation Act of 1972
- Originally implemented by the Department of Health, Education and Welfare (HEW) in 1975
- Revised in 1987 by its successors, the Department of Health and Human Services (HHS)
- Congress merged the laws into one act known as 42 CFR Part 2

Purpose of Federal Law

- Inappropriate disclosure could also lead to loss of employment, loss of housing, loss of child custody, discrimination by medical professionals and insurers, arrest and incarceration
- Now more than 29 years after the last substantial amendment, the final rule makes changes to better align them with the advances in the health care delivery system
- So the final rule revises 42 CFR Part 2, Confidentiality of Alcohol and Drug Abuse Patient Records (USC Section 290dd-2)

Purpose of Federal Law

- The final rule imposes restrictions on what can be disclosed and how the information can be used
- Organized into the following sections:
  - Purpose and effect
  - General provisions including definitions
  - Disclosures with patient consent
  - Disclosures without patient consent
  - Court orders authorizing disclosure

Purpose and Effect of Federal Law

- So the bottom line is the law imposes restrictions on using or disclosing the use of substance use disorder patient records which are maintained in connection with a part 2 program
- This regulation is not intended to direct the manner in which research, treatment, and evaluation is carried out
- Rather, it is intended to make sure that the patient who receives treatment for a substance use disorder in a part 2 program was not more vulnerable by reason of their record

Federally Assisted
Who Does 42 CFR Part 2 Apply to?

Federally Assistance 2.12

- Healthcare facilities that receive federal assistance and provide substance abuse treatment must be aware of these changes
- Not every provider who prescribes controlled substances to treat substance use disorders (SUDs) meets the definition of program under Part2
- A private for profit hospital that does accept Medicare or Medicaid and any federal assistance would not be subject to the 42 CFR Part 2
- Same for a private physician or practitioner who does not receive federal assistance of any kind

Federally Assisted 2.12

- An exception is when the state law or state licensing or certification agency requires compliance
- Part 2 applies to any individual or entity that is not only federally funded but must **holds itself** out as providing substance use disorder (drug and alcohol) diagnosis, treatment, or referral for treatment
  - Most drug and alcohol programs are federally assisted
- It applies to an identified unit within a general medical facility that holds itself out and provides SUD diagnosis, treatment, and referral

Federally Assisted 2.12

- For example, the hospital has a substance abuse department for patients with SUDs
  - They are a program under the rule
- Any clinician who uses a controlled substance (methadone, benzodiazepine, buprenorphine etc.) for detoxification or maintenance treatment of a substance use disorder requires a federal DEA registration becomes subject to the regulations because of the **DEA license**
  - This includes Medicare providers
- It includes those authorized to conduct maintenance treatment of withdrawal

Federally Assisted

- It includes recipients who receive federal financial assistance in any form
- It includes recipients who have a program conducted by a state unit who receives federal funds
- Or is assisted by the IRS through allowance of income tax deductions or who grants tax exempt status
- An exception is that these regulations do NOT apply to the **VA department** as their medical services are governed by another law (38 USC 7332)

Federally Assisted

- Does apply to the Armed Forces with exception
  - Applies if information was obtained when the patient is subject to the Uniform Code of Military Justice
  - Except for information discussed between the Armed Forces and the VA furnishing the health care to the veteran
- Communications are permitted between or among staff who need the information to do their jobs
- This includes communication with an entity that has direct administrative control over the part 2 program

Federally Assisted

- Regulations do not apply to the emergency department when admitting a patient to ICU for an overdose
- If the patients SUD diagnosis and treatment or referral is **not** provided by a part 2 program then the patient's records are not covered by this law
- The definition of federally assisted is the only one that does not appear in the definition section of 2.11
- The definition of federally assisted was modernized to be consistent in the regulation

More Rules in Round 2
Confidentiality of SUD Patient Records

SAMHSA More Rules in the Future

- There were many questions raised during the rule making process
- Such as restriction on lawful holders and their contractors and subcontractors
- In consideration of the feedback and critical role of third party payers and other lawful holders
- SAMHSA issued supplemental notice of rulemaking
- To seek further comments and information on this topic
- In Federal Register on 1/18/2017

Second Proposed Rules


Confidentiality of Substance Use Disorder Patient Records

A Proposed Rule by the Health and Human Services Department on 01/18/2017

PUBLISHED DOCUMENT

AGENCY:

Substance Abuse and Mental Health Services Administration, HHS.

ACTION:

Supplemental notice of proposed rulemaking.

SUMMARY:

On Feb. 9, 2016, the Substance Abuse and Mental Health Services Administration (SAMHSA) published a Notice of Proposed Rulemaking (NPRM) that proposed policy changes to update and modernize the Confidentiality of Alcohol and Drug Abuse Patient Records (42 CFR part 2). SAMHSA explained in

DOCUMENT DETAILS

Printed version: PDF

Publication Date: 01/18/2017

Agencies: Department of Health and Human Services, Office of the Secretary

Dates: To be assured consideration, comments must be received at one of

Document Type: Proposed Rule

Site Feedback

www.federalregister.gov/documents/2017/01/18/2017-00742/confidentiality-of-substance-use-disorder-patient-records

PDF Version 6 Pages


Federal Register / Vol. 82, No. 11 / Wednesday, January 18, 2017 / Proposed Rules 5485

Dated: December 13, 2016.
Anthony J. Cerada,
Captain, U.S. Coast Guard, Captain of the Port San Francisco.

BILLING CODE 9110-04-P

DEPARTMENT OF THE INTERIOR
National Park Service
36 CFR Parts 1 and 2
[NPS–WASO–REGS–17326; GPO Deposit Account 4311H2]
RIN 1024–AE30
Withdrawal of the Proposed Rule To Revise General Provisions; Electronic Cigarettes

AGENCY: National Park Service; Interior.
ACTION: Proposed rule; withdrawal.

SUMMARY: The National Park Service withdraws the proposed rule that would revise the regulation that defines smoking to include the use of electronic cigarettes and other electronic nicotine

menu and selecting "Smoking" from the list of policy subjects.

Michael Reed,
Principal Deputy Assistant Secretary for Fish and Wildlife and Parks.

BILLING CODE 4310–52–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of the Secretary
42 CFR Part 2
[SAMHSA–4162–20]
RIN 0930–ZA07
Confidentiality of Substance Use Disorder Patient Records

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.
ACTION: Supplemental notice of proposed rulemaking.

SUMMARY: On Feb. 9, 2016, the Substance Abuse and Mental Health Services Administration (SAMHSA) published a Notice of Proposed Rulemaking (NPRM) that proposed

clarify these matters before establishing any appropriate restrictions on disclosures to contractors, subcontractors and legal representatives.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on February 17, 2017.

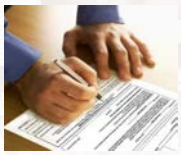
ADDRESSES: You may submit comments, identified by Regulatory Information Number (RIN) 0930–AA21, by any of the following methods:
Electronically: Federal eRulemaking Portal: Go to *http://www.regulations.gov* and follow the instructions for submitting comments.
Regular, Express or Overnight Mail, or Hand Delivery or Courier. Written comments sent by hand delivery, or mailed by regular, express, or overnight mail must be sent to the following address ONLY: The Substance Abuse and Mental Health Services Administration, Department of Health and Human Services, Attn: Danielle Tarino, SAMHSA, 5600 Fishers Lane, Room 13E09A, Rockville, Maryland 20857.
Please allow sufficient time for mailed comments to be received before the close of the comment period.
Instructions: To avoid duplication, please submit only one copy of your

www.gpo.gov/fdsys/pkg/FR-2017-01-18/pdf/2017-00742.pdf

Clarification in the Future

- So SAMHSA is seeking additional clarification to part 2 regulations
  - Questions were also asked about carrying out payment, healthcare operations, and other related activities
  - Asked if Qualified Service Organization patient identifying information disclosure provisions apply to third party payers and other lawful holders to support healthcare operations and payment
- Comment period ended February 17, 2017
- For more information contact **Danielle Tarino**, 240 276-2857 or danielle.tarina@samhsa.hhs.gov

Confidentiality Requirements



Notice to Patient of Confidentiality 2.22

- The patient must be given a written summary of the federal law and regulation
- This can be done in paper or electronic format
- The patient must also be given information on how to report a violation
  - This must include contact information to the proper authorities
- The notice must be given to the patient when they gain capacity if they were not competent on admission

Notice to Patient of Confidentiality

- Must tell the patient that the federal law protects the confidentiality of SUD records
- The written summary to the patient must include the following:
  - A written description that the program may acknowledge that the patient is present in the facility
  - Notice that a crime may be reported to the police along with contact information
  - Provide the patient with a summary of the law and regulation

Notice to Patient of Confidentiality

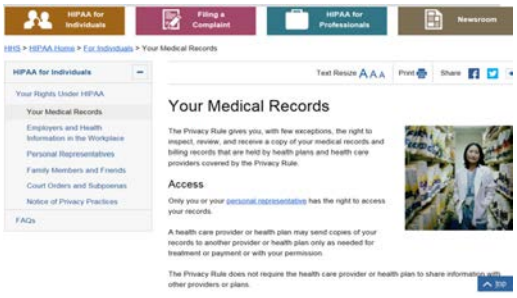
- The written summary to the patient must include the following (continued):
  - Statement that suspected child abuse and neglect is not protected
  - Cite the federal law and regulations
  - The written summary to the patient may include any state requirements, if any
  - It can also include information on the facility's policy and procedures which must be consistent with the regulations

Patient Access to Medical Records and Restrictions on Use

Patient Access to Medical

- Regulations do not prohibit providing a patient access to their own medical records
- This includes the right to inspect and copy any records
- You are not required to have the patient's written consent for the patient to do this but many do
- Access to medical records is one of the top 10 reasons of complaints to the OCR
- OCR has a website where patients can complain if they do not get timely access to their records

OCR Medical Records

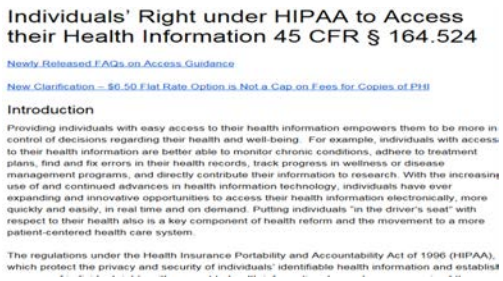


www.hhs.gov/hipaa/for-individuals/medical-records/index.html

OCR Complaint Portal

https://ocrportal.hhs.gov/ocr/smartscreen/main.jsf

OCR Guidance on Access to Medical Records



Individuals' Right under HIPAA to Access their Health Information 45 CFR § 164.524

Newly Released FAQs on Access Guidance

New Clarification – $6.50 Flat Rate Option is Not a Cap on Fees for Copies of PHI

Introduction

Providing individuals with easy access to their health information empowers them to be more in control of decisions regarding their health and well-being. For example, individuals with access to their health information are better able to monitor chronic conditions, adhere to treatment plans, find and fix errors in their health records, track progress in wellness or disease management programs, and directly contribute their information to research. With the increasing use of and continued advances in health information technology, individuals have ever expanding and innovative opportunities to access their health information electronically, more quickly and easily, in real time and on demand. Putting individuals "in the driver's seat" with respect to their health also is a key component of health reform and the movement to a more patient-centered health care system.

The regulations under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which protect the privacy and security of individuals' identifiable health information and establish

www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html

Restrictions on Use of Information

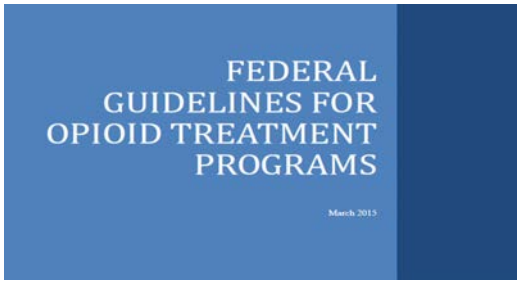
- Any medical record information that the patient accesses is subject to the restrictions on the use of information
- So for example, a patient is reviewing their medical records and takes a picture of the record on their smart phone
- This information cannot be used to initiate or substantiate any criminal charges against the patient
- It cannot be use to conduct any criminal investigation either

OCR Guidance on Access to Medical Records

Reports of Violations

- The new law revises the requirements for reporting violations of these regulations by methadone programs to the FDA
- Methadone programs are now referred to as **opioid treatment programs**
- This change was made because authority over these programs was transferred from the FDA to SAMHSA in 2001
- SAMHSA has a free book on Federal Guidelines for Opioid Treatment Programs which covers the guidelines for opioid treatment programs

Guidelines for Opioid Treatment Programs



http://store.samhsa.gov/shin/content//PEP15-FEDGUIDEOTP/PEP15-FEDGUIDEOTP.pdf

Reports of Violations

- Any person who violates this regulation shall be fined in accordance with title 18
  - Title 18 lists all the fines for the different crimes
- SAMHSA has authority to promulgate the regulations but the Department of Justice (DOJ) has the authority to enforce
- Any violations of these regulations can be directed to the US Attorney's office in the judicial district in which the violation occurred

Reports of Violations

- Any violations of this regulation by an opioid treatment program must be reported to SAMHSA since they now have oversight of opioid treatment centers
- A report must also be made to the United States Attorney for the judicial district in which the violation occurred

General Provisions
Minors, Security, Restrictions, Access to Medical Records

RELIAS LEARNING 64

Definitions

- The first section under general provisions addresses definitions
- There were five revised definitions in the law: central registry, patient, person, treatment, and QSO (quality service organization)
- There were also new definitions of key terms
- These should be included in the policy and training of staff
  - The definitions were put into a single section under 2.11 with one exception
    - The definition of "Federally assisted" is in section 2.12

RELIAS LEARNING 65

All Definitions

- Provides definitions for:
  - Central registry, Diagnosis, Disclose,
  - Federally assisted, Informant, Maintenance treatment
  - Member program, Minor, Part 2 program director
  - Patient Identifying Information
  - Person, Program,
  - Qualified Service Organization, SUD, Third-party Payer,
  - Treating Provider Relationship, Treatment
  - Undercover Agent and Withdrawal Management

RELIAS LEARNING 66

Definition Part 2 Program

- Replaced “program” to “part 2 program”
- **A part 2 director** is an individual or individual designated as director or managing director vested with authority to act as CEO of the part 2 program
  - Deleted definition of program director
- Replaced drug abuse and alcohol abuse with **substance use disorder** (SUD)
  - Note they are still terms used in the statute so you will see the definition but now SUD used

Definitions

§2.11 Definitions.

For purposes of these regulations:

Alcohol abuse means the use of an alcoholic beverage which impairs the physical, mental, emotional, or social well-being of the user.

Drug abuse means the use of a psychoactive substance for other than medicinal purposes which impairs the physical mental, emotional, or social well-being of the user.

Diagnosis means any reference to an individual's alcohol or drug abuse or to a condition which is identified as having been caused by that abuse which is made for the purpose of treatment or referral for treatment.

Disclose or disclosure means a communication of patient indentifying information, the affirmative verification of another person's communication of patient identifying information, or the communication of any information from the record of a patient who has been identified.

Informant means an individual:

(a) Who is a patient or employee of a program or who becomes a patient or employee of a program at the request of a law enforcement agency or official: and

(b) Who at the request of a law enforcement agency or official observes one or more patients or employees of the program for the purpose of reporting the information obtained to the law enforcement agency or official.

Patient means any individual who has applied for or been given diagnosis or treatment for alcohol or drug abuse at a federally assisted program and includes any individual who, after arrest on a criminal charge, is identified as an alcohol or drug abuser in order to determine that individual's eligibility to participate in a program.

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

Definition Substance Use Disorder

- **Substance use disorder** means a cluster of cognitive, behavioral, and physiological symptoms
- Indicating that the individual continues using the substance despite significant substance-related problems
- Such as impaired control, social impairment, risky use, and pharmacological tolerance and withdrawal
- For the purposes of the regulations in this part, this definition does not include tobacco or caffeine use

Definitions 2.11

- The individual or entity undertakes or agrees to undertake diagnosis, evaluation, and/or treatment of the patient, or consultation with the patient, for any condition.
- Note that SAMHSA considers the entity to have a treating provider relationship if it employs that individual
- Removed definition of "detoxification treatment" and replaced it with **"withdrawal management"**
  - As indicated in American Society of Addiction Medicine (ASAM) Principles of Addiction Medicine

ASAM Principles of Addiction Medicine

www.asam.org/quality-practice/essential-textbooks/principles-of-addiction-medicine

Definition of Disclose

- Modified definition of "**disclose**" to cover diagnosis, treatment, and referral for substance use disorder
- **"Disclose** means to communicate any information identifying a patient as being or having been diagnosed with a substance use disorder, having or having had a substance use disorder, or being or having been referred for treatment of a substance use disorder either directly, by reference to publicly available information, or through verification of such identification by another person."
  - If diagnosed with SUD but never treated then part 2 regulations do not apply

Definition Central Registry 2.11

- **Central registry** means an organization which obtains from 2 or more member programs patient identifying information about individuals applying for withdrawal management or maintenance treatment for the purpose of avoiding an individual's concurrent enrollment in more than one treatment program

Definition of Record

- **Record** means any information, whether recorded or not, created by, received, or acquired by a part 2 program relating to a patient
  - e.g., diagnosis, treatment and referral for treatment information, billing information, emails, voice mails, and texts
- For the purpose of the regulations in this part, records include both paper and electronic records.
- **Records**, added "created by" and "received or acquired by" a part 2 program:
  - Added examples of what constitutes a record

Definition Maintenance Treatment

- **Maintenance treatment** means long-term pharmacotherapy for individuals with substance use disorders that reduces the pathological pursuit of reward and/or relief and supports remission of substance use disorder-related symptoms.
  - Replaced the term "pharmacotherapy" with "long term pharmacotherapy" for clarity
- **Member program,** replaced a reference to a specific geographic distance

Definition of a QSO 2.11

- The new law defines a QSO or a qualified service organization agreement
- This definition was revised
- The types of services provided are listed
  - For example, a Part 2 program may enter into a contract to provide on-call coverage
- It references QSO agreements or QSOA
- Only information necessary for the QSO to do their job should be disclosed
- Added population health management

Definition of a QSO

- **Qualified service organization** means 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

Definition of a QSO

- (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
- 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

ASSOCIATE AGREEMENT (BA/QSO AGREEMENT)

XYZ Service Center ("the Center") and the ABC Alcohol/Drug Program (the Program") hereby enter into an agreement whereby the Center agrees to provide _____.
(Nature of services to be provided to the program)

Furthermore, the Center:

1. acknowledges that in receiving, transmitting, transporting, storing, processing, or otherwise dealing with any information received from the Program identifying or otherwise relating to the patients in the Program ("protected information"), it is fully bound by the provisions of the federal regulations governing the Confidentiality of Alcohol and Drug Abuse Patient Records, 42 C.F.R. Part 2; and the Health Insurance Portability and Accountability Act (HIPAA), 45 C.F.R. Parts 142, 160, 162 and 164;
2. agrees to resist any efforts in judicial proceedings to obtain access to the protected information except as expressly provided for in the regulations governing the Confidentiality of Alcohol

2. agrees to resist any efforts in judicial proceedings to obtain access to the protected information except as expressly provided for in the regulations governing the Confidentiality of Alcohol and Drug Abuse Patient Records, 42 C.F.R. Part 2;
3. agrees that it will not use or disclose protected health information except as permitted or required by this Agreement or by law;
4. agrees that, when the Center uses, discloses, or requests protected health information, it will limit the use, disclosure, or request to the minimum necessary;
5. agrees that if the Center enters into a contract with any agent, including a subcontractor, the agent will agree to comply with 42 C.F.R. Part 2 and HIPAA, and, if the Center learns of a pattern or practice by the agent that is a material breach of the contract with the Center, to take reasonable steps to cure the breach or terminate the contract, if feasible;
6. agrees to comply with HIPAA's security provisions with regard to electronic protected health information, and to use appropriate safeguards *(can define with more specificity)* to prevent the unauthorized use or disclosure of the protected information;

Patient Identifying Information

- **Patient identifying information (PII)** means the name, address, social security number, fingerprints, photograph, or similar information by which the identity of a patient, as defined in this section, can be determined with reasonable accuracy either directly or by reference to other information.
- In the HIPAA law it is referred to as protected health information
- Need to make sure there is no way to identify the patient in a part 2 program
- This definition has 2 revisions

Primary Care Providers

- Primary care providers could be considered a general medical facility and subject to part 2 if they are federally assisted **and** meet the definition of a program (2 part test)
- References the current FAQs
- Physicians who prescribe these must have a DEA license so meets the test for federally assisted
  - So this is the first part of the test
- Not every primary care doctor who prescribes controlled substances meets the definition of program and mentions three ways to do this

Primary Care Providers

- If the provider is not a general medical care facility but the provider holds itself out as providing SUD care (drug and alcohol treatment, diagnosis or referral) then it is a program and subject to part 2
- If the provider is an identified unit with a general medical care facility (like a hospital) that holds itself out as providing SUD care (as above) then it is subject to part 2
- If the provider consists of medical personnel and other staff in a general medical facility it is a program if primary function is SUD care (as above)

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.

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

SUDs FAQs- Will Update Later

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

RELIAS LEARNING 85

Minors and Deceased Patients

RELIAS LEARNING 86

Minor Patients

- If a minor patient is allowed under state law to legally obtain substance abuse treatment
  - Then any written consent for disclosure can only be made by the minor
- This restriction includes, but is not limited to, any disclosure of patient identifying information to the parent or guardian of a minor patient for the purpose of obtaining financial reimbursement
- This does not prohibit a part 2 program from refusing to treat the minor until the minor consents to the necessary disclosure to obtain reimbursement

RELIAS LEARNING 87

Minor Patients

- A refusal to provide treatment may be prohibited under some state laws which would require treatment irrespective of ability to pay
- If the state law requires parental consent to treatment then it must be signed by the parent and minor
- If state law requires parental consent then the fact of the minor's application for treatment can be shared with the parent
  - If the minor has given consent or the minor lacks capacity to consent as judged by the program director

Minor Patients

- A substantial threat to life or physical well-being of a minor can be disclosed to the parent or guardian if the program director determines the following:
- First, the minor applicant lacks capacity because of extreme youth or physical condition to make a rational decision to consent and
- The minor's situation poses a substantial threat to the life or physical well-being of the minor applicant which may be reduced by communicating relevant facts to the minor's parent
  - Minor is an individual who has not attained the age of majority in state law and if none then the age of 18

Deceased and Incompetent Patients

- If patient lacks the capacity to manage their own affairs
- Any consent must be given by the guardian or person authorized under state law to act on the patient's behalf
- If a patient has been adjudicated incompetent and suffers from a medical condition that prevents effective action
- Then the program director may exercise disclosure to consent for the sole purpose of obtaining payment from a third-party payer

Deceased and Incompetent Patients

- These regulations do not restrict the disclosure of patient identifying information related to the cause of death
- This includes the collection of vital statistics
- Any other disclosure of information of a deceased patient having a SUD is subject to this regulation
- If consent is needed then it may be given by the executor or personal representative who is appointed under state law
- If none, then by the spouse and if none the family

Security of Medical Records

HIPAA Privacy and Mental Health

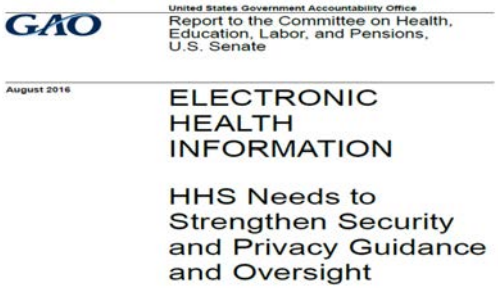
- SAMHSA said they have aligned the definition of patient identifying information with HIPAA to the extent feasible
- SAMHSA revised security for records to closely align with HIPAA
- HIPAA Security rules are enforced by the Office of Civil Rights (OCR)
- Hospitals, physicians, and other covered entities must be in compliance with the HIPAA security rules already
  - Will probably already have many of the required P&Ps

OCR HIPAA Security Website

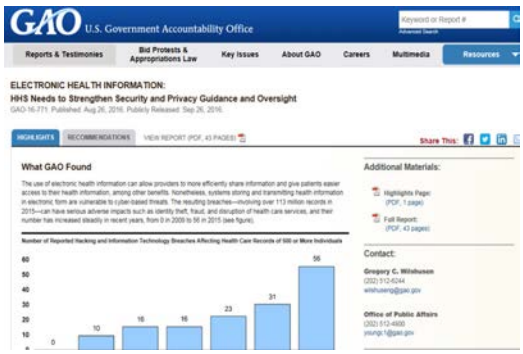
www.hhs.gov/hipaa/for-professionals/security/index.html

Security Rule Toolkits and Resources

GAO Report Need Privacy Oversight



www.gao.gov/assets/680/679260.pdf



RELIAS LEARNING 97

Security P&Ps Required

- Part 2 programs or other lawful holders of patient identifying information (protected health information) must have a formal P&P in place
- This is to protect against the unauthorized disclosure or use of patient identifying information
- **P&P** must address the following for paper records; transferring or removal of records, destroying records, sanitizing the hard copy media, maintaining records in a secure room or locked cabinet, using and accessing workstations or secure rooms, and removing direct identifiers

RELIAS LEARNING 98

Security EHRs

- P&P for electronic records includes:
  - Creating, maintaining, and securing the records to prevent unauthorized disclosure,
  - Destroying the records,
  - Sanitizing electronic media on which records are stored,
  - Using and accessing records to prevent authorized disclosure,
  - And removing direct identifiers

RELIAS LEARNING 99

Security EHRs

- So the bottom line is that part 2 programs and lawful holders of patient identifying information (PII) have to have in place security P*Ps
- These need to address security which includes sanitization of associated media
- This includes both paper and electronic records
- Media sanitation is a process that renders access to target data on the media infeasible for a given level of effort
- There are several suggest resources to use

identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule

This page provides guidance about methods and approaches to achieve de-identification in accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule. The guidance explains and answers questions regarding the two methods that can be used to satisfy the Privacy Rule's de-identification standard: Expert Determination and Safe Harbor[1]. This guidance is intended to assist covered entities to understand what is de-identification, the general process by which de-identified information is created, and the options available for performing de-identification.

In developing this guidance, the Office for Civil Rights (OCR) solicited input from stakeholders with practical, technical and policy experience in de-identification. OCR convened stakeholders at a workshop consisting of multiple panel sessions held March 8-9, 2010, in Washington, DC. Each panel addressed a specific topic related to the Privacy Rule's de-identification methodologies and policies. The workshop was open to the public and each panel was followed by a question and answer period. Read more on the Workshop on the HIPAA Privacy Rule's De-Identification Standard. Read the Full Guidance - PDF.

General **www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html**

1.1 Protected Health Information
1.2 Covered Entities, Business Associates, and PHI

NIST Special Publication 800-88
Revision 1

Guidelines for Media Sanitization

http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-88r1.pdf

64 pages

Richard Kissel
Andrew Regenscheid
Matthew Scholl
Kevin Stine

This publication is available free of charge from:
http://dx.doi.org/10.6028/NIST.SP.800-88r1

Two Types of Media From NIST

NIST SP 800-88 Rev. 1 Guidelines for Media Sanitization

2.2 Types of Media

There are two primary types of media in common use:

- **Hard Copy.** Hard copy media are physical representations of information, most often associated with paper printouts. However, printer and facsimile ribbons, drums, and platens are all examples of hard copy media. The supplies associated with producing paper printouts are often the most uncontrolled. Hard copy materials containing sensitive data that leave an organization without effective sanitization expose a significant vulnerability to "dumpster divers" and overcurious employees, risking unwanted information disclosures.
- **Electronic (i.e., "soft copy").** Electronic media are devices containing bits and bytes such as hard drives, random access memory (RAM), read-only memory (ROM), disks, flash memory, memory devices, phones, mobile computing devices, networking devices, office equipment, and many other types listed in Appendix A.

RELIAS LEARNING 103

Applicability Section 2.12 Restrictions on Disclosure

RELIAS LEARNING 104

Restrictions on Disclosure

- When are you restricted from disclosing information?
- It the information that would identify the patient as having a substance use disorder and
- The drug abuse information was obtained in a **federally assisted** drug abuse program
- There must be no way to identify the patient directly or indirectly
- Can't use this information to initiate or conduct any criminal investigation of a patient

RELIAS LEARNING 105

Restrictions on Disclosure

- It doesn't matter if the information is written down or not
- The restrictions on disclosure apply to any information that would identify the patient has having or having had a SUD
- It does not include a diagnosis of drug overdose or alcohol intoxication when the patient does not have a SUD

Request for Medical Records

- If a request for medical records has been made for a patient treated with a SUD without the proper patient consent
- The facility may not release the records
- Instead the inquiring party is given a copy of this regulation and advised that they restrict the disclosure of SUD patient records
- They may NOT be told affirmatively that the regulations restrict the disclosure of the records of an identified patient

Acknowledging the Presence of Patients

- In a healthcare facility which is identified by the public where **only** SUD is treated or diagnosed the written consent of the patient is needed to acknowledge that they are in the facility
- Can acknowledge the presence of patients in a hospital or facility that is not publicly identified as place to treat SUD patients as long as the acknowledgment does not reveal the patient has a SUD
  - Example, patient is admitted for SUD to an acute care 800 bed hospital that offers many other services and is not just a SUD facility

Crimes on the Premises and Child Abuse Reports

RELIAS LEARNING 109

Crimes on the Premises

- The restrictions on disclosure do not apply to crimes committed on the premises or against the personnel of a part 2 program
- Includes a threat to commit the crime
- Law enforcement can be notified
- Is limited to the circumstances of the incident
- Is limited to name, address, and last known whereabouts
- Can include status as a patient in the program

RELIAS LEARNING 110

Reports of Child Abuse and Neglect

- The restriction on disclosures do not apply to the reporting of child abuse and neglect under state law
- This is when the report is made to the appropriate state or local authority such as children services
- However, Part 2 restrictions continue to apply to the original alcohol or drug abuse patient records maintained by the program
- This includes their disclosure and use for civil or criminal proceedings which may arise out of the report of suspected child abuse and neglect

RELIAS LEARNING 111

Prohibition on Re-disclosure

RELIAS LEARNING 112

Prohibition on Re-disclosure

- Clarifies the prohibition on re-disclosure
- The idea was that there would be a notice made with each release of medical records pursuant to the patient's written consent
- It would state that the information disclosed to you were records protected by federal confidentiality rules (42 CFR Part 2)
- The federal rules prohibit you from making any further disclosure of the information unless further disclosure is expressly permitted by the written consent of the patient

RELIAS LEARNING 113

Prohibition on Re-disclosure 2.32

- It made it clear that a general authorization was not sufficient
- The federal rules also restricted the use of the information to criminally investigate or prosecute any SUD patient
- The prohibition on re-disclosure only applies to information that would identify the patient either directly or indirectly
  - Other health related information could be shared such as patient receives treatment for HTN since it is unrelated to their SUD as long as patient is not identified

RELIAS LEARNING 114

§ 2.32 Prohibition on re-disclosure.

(a) *Notice to accompany disclosure.* 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 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.

Relationship to State Laws

Relationship to State Laws

- A federal law preempts any inconsistent state law
- A state law cannot authorize or compel any disclosure prohibited by this law
- A state could be more stringent
- A state licensing or certification agency could require a program or private practitioner to comply with part 2 even if not federally assisted
- So states can pass laws in this area as long as does not do of any of the above

Disclosures with Consent

RELIAS LEARNING 118

Disclosures with Consent

- Discusses when a disclosure of information needs the patient to sign a consent form
- Section 2.31 has been revised to allow a patient to include a general designation in the "to Whom" section of the consent form
  - Example; my treating provides, past, present, or future
- Patients who have a included a general designation in the **"To Whom"** section of the consent form must be provided a list of entities, called the list of disclosures., to whom their information has been disclosed

RELIAS LEARNING 119

Need Release of Information Form

Appendix D Consent to Release of Information Under Title 42, Part 2, Code of Federal Regulations

The privacy and confidentiality of individually identifiable drug or alcohol treatment information is protected by SAMHSA confidentiality regulation Title 42, Part 2 of the Code of Federal Regulations (42 C.F.R. Part 2). This regulation requires that physicians providing opioid addiction treatment obtain signed patient consent before disclosing individually identifiable addiction treatment information to any third party. Below is a sample consent form containing all the data elements required by 42 C.F.R. Part 2.

This form is provided for educational and informational purposes only. It is not intended to establish a legal or medical standard of care. Physicians should use their personal and professional judgment in interpreting this form and applying it to the particular circumstances of their individual patients and practice arrangements. The information provided in this form is provided "as is" with no guarantee as to its accuracy or completeness. ASAM will strive to update this form from time to time, but cannot ensure that the information provided herein is current at all times.

1. I (name of patient) _____
2. Authorize: Dr. _____
3. To disclose: (kind and amount of information to be disclosed)
4. To: (name or title of the individual or organization to which disclosure is to be made)
5. For (purpose of the disclosure)

RELIAS LEARNING 120

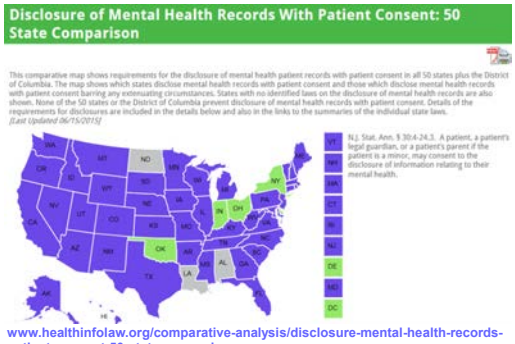
Disclosures with Consent

- The patient's request for the list of disclosures made must be in writing
  - It is limited to disclosures made in the past two years
  - Must respond in 30 days or less of written request
  - Must be provided the name of entity to which disclosure was made, date, and brief description of what was disclosed
- The consent form must include an explicit description of the amount and kind of substance abuse disorder treatment information that may be disclosed

Disclosures with Consent

- The information needs to be understandable to the patient as to what information was disclosed
- The part 2 program is not responsible for the list of disclosures but rather the entity that serves as the intermediary
  - So the names of the individuals to whom their name is on the consent form may be asked if their information has been disclosed
- Will allow an electronic signature as long as not prohibited by any state law or other law
- SAMHSA will issue sub-regulatory guidance on this

State by State Comparison



www.healthinfolaw.org/comparative-analysis/disclosure-mental-health-records-patient-consent-50-state-comparison

Consent Requirements

- The written consent for disclosure may be paper or electronic and must include:

1. The name of the patient
2. The name of the part 2 program or individual permitted to make the disclosure
   - Or general designation
3. 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

Consent Requirements

- The written consent must include (continued):
- The name of the individual to whom a disclosure is to be made or entity such as a hospital, health care clinic, or private practice
  - These are entities are ones with a treating provider relationship
- If there is **not** a treating provider relationship then
  - The name of the entity if it is a third party payor
  - Or the name of the entity that facilitates the exchange of health information or research facility along with the name of the entity that is treating the patient

Consent Form Should Comply with Rule

CONSENT FOR THE RELEASE OF CONFIDENTIAL INFORMATION

I, _____, authorize
(Name of patient)

_____
(Name or general designation of alcohol/drug program making disclosure)

to disclose to _____ the
(Name of person or organization to which disclosure is to be made)

following information: _____
(Nature and amount of information to be disclosed; as limited as possible)

The purpose of the disclosure authorized in this is to :

_____
(Purpose of disclosure, as specific as possible)

I understand that my alcohol and/or drug treatment records are protected under the Federal regulations governing Confidentiality and Drug Abuse Patient Records, 42 C.F.R. Part 2, and the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), 45 C.F.R. pts 160 & 164, and cannot be disclosed without my written consent unless otherwise provided for by the regulations. I also understand that I may revoke this consent at any time except to the extent that action has been taken in reliance on it, and that in any event this consent expires automatically as follows:

Consent Requirements

- The purpose of the disclosure must be limited as is necessary to carry out the stated purpose
- Need a statement in the consent form that the consent is subject tor revocation at any time
  - Unless the part 2 program or lawful holder has already acted in reliance on it
- Need the date, event, or condition which the consent will expire if not revoked
- Must date and sign the consent form

Consent Requirements

- You cannot disclose information if the consent has been revoked
- You cannot disclose information if the consent has expired
- You cannot disclose information if the consent form substantially fails to conform to the consent requirements
- You cannot disclose if you know or should have known the records to be materially false

Consent Requirements 2.33

- Records can be disclosed to the program listed in the patient's consent form
- An exception is disclosures to central registries and in connection with criminal justice referrals
- The later must meet the below requirements
  - The central registry or withdrawal management or maintenance treatment program must not be more than 200 miles away
  - This is to prevent multiple enrollments if the disclosure is made when the patient is accepted for treatment and the treatment is interrupted, resumed or terminated or
  - The type or dosage of the drug is changed

Central Registries

- Regarding central registries or criminal justice referrals
- Disclosure is limited to as follows:
  - Patient identifying information
  - Types and dosage of the drug and relevant dates
- The consent form must list the name and address of each central registry, withdrawal management, or maintenance treatment program to which a disclosure is made
  - These 3 cannot re-disclose for any purpose other than to prevent multiple enrollment unless authorized by the court

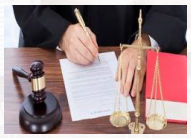
Withdrawal Management

- The consent may authorize a disclosure to any withdrawal management or maintenance treatment program established within 200 miles of the program
  - No need to individually name all programs
- When a member program asks a central registry if an identified patient is enrolled in another member program and the registry determines that the patient is so enrolled, the registry may disclose:
  - Name, address and phone number of the program the patient is enrolled in and the same information of the inquiring program

Central Registry

- This can help prevent or eliminate multiple enrollments
- The withdrawal or maintenance treatment program which has received a disclosure and has determined the patient is already enrolled may communicate as necessary to prevent or eliminate any multiple enrollments

Disclosures to Criminal Justice System Who Referred Patients



RELIAS LEARNING 133

Drugs & the Criminal Justice System

- A JAMA article found that half of all the prisoners met the criteria for drug abuse
- 7.1 million adults are under some form of criminal justice supervision
- Molecular and imaging studies have revealed addiction as a brain disorder so it is treatable
- Finding a genetic component has advanced research on new pharmacological treatments
- Study shows 80% of prisoners could benefit from drug abuse treatment

RELIAS LEARNING 134

JAMA Article

Treating Drug Abuse and Addiction in the Criminal Justice System

Improving Public Health and Safety

Redonna K. Chandler, PhD
Bennett W. Fletcher, PhD
Nora D. Volkow, MD

Despite increasing evidence that addiction is a treatable disease of the brain, most individuals do not receive treatment. Involvement in the criminal justice system often results from illegal drug-seeking behavior and participation in illegal activities that reflect, in part, disrupted behavior ensuing from brain changes triggered by repeated drug use. Treating drug-involved offenders provides a unique opportunity to decrease substance abuse and reduce associated criminal behavior. Emerging neuroscience has the potential to transform traditional sanction-oriented public safety approaches by providing new therapeutic strategies against addiction that could be used in the criminal justice system. We summarize relevant neuroscientific findings and evidence-based principles of addiction treatment that, if implemented in the criminal justice system, could help improve public heath and reduce criminal behavior.

JAMA. 2009;301(2):183-190 www.jama.com

THE PAST 20 YEARS HAVE SEEN significant increases in the numbers of individuals incarcerated or under other forms of criminal justice supervision in the United States. These numbers are staggering—approximately 7.1 million adults in the United States are under some form of criminal justice supervision.[1] The large increase in the criminal justice population reflects in part tougher laws and penalties for drug offenses.[2] An estimated one-half of all prisoners (including some sentenced for other than drug offenses) meet the cri-

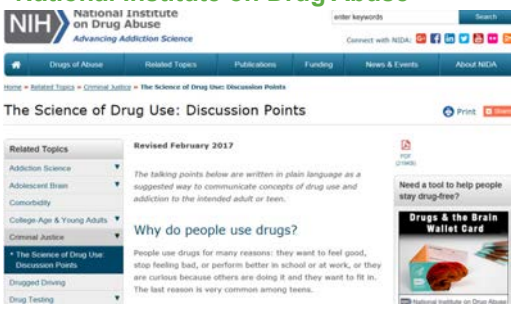
and hepatitis C[3] and frequently have co- leased returned to prison within 3 years

RELIAS LEARNING 135

Drugs & the Criminal Justice System

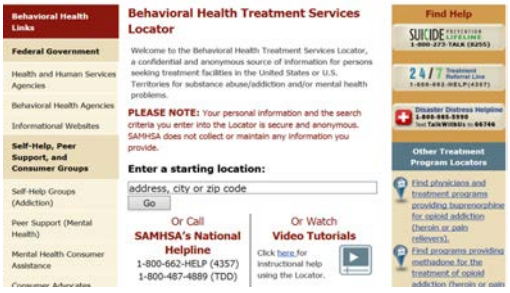
- The authors state that not treating a drug-abusing offender is a missed opportunity to improve health and safety
- One study of 15 states showed 25% of released individuals will return to prison within 3 years and most had positive drug screens
  - Treatment with methadone has reduced drug use (and also buprenorphine and naltrexone ER)
- One dollar spent on drug courts save $4 in avoided costs of incarceration and healthcare
- Prison based treatment saves $2 to $6 dollars

National Institute on Drug Abuse



www.drugabuse.gov/related-topics/criminal-justice/science-drug-use-discussion-points

Treatment Locator



https://findtreatment.samhsa.gov

Pr of Drug Abuse Treatment for CJ Population

Criminal Justice Referrals

- A part 2 program can disclose information about a patient to those within the criminal justice system who made participation a condition of the disposition of the criminal proceeding against the patient
- This also includes if it is a condition of parole or release from custody
- The disclosure is made for those who need to monitor the patient's progress such as prosecuting attorney who is withholding charges, a court granting a pretrial or post trial release, parole officers AND the patient has signed a release consent form

Criminal Justice Referrals

- The release consent form must state the period during which it remains in effect such as:
  - The anticipated length of treatment
  - Type of criminal proceedings involved and the need for information with the final disposition of the proceeding
  - And when the final disposition will occur
- This written consent must state that it is revocable upon the passage of a specific amount of time or the specified event
- Those in criminal justice system can only re-disclose it to carry out their official duties

Drug Courts

THE SUPREME COURT of OHIO & THE OHIO JUDICIAL SYSTEM

SCO HOME » JCS » SPECDOCKETS » DRUG_COURTS » DRUG COURTS

Drug Courts

Upon request, courts can receive written resource materials and/or personal assistance regarding any topics associated with drug courts—from resolving issues of random judicial case assignment to identifying minimum standards for drug court programs. The Specialized Docket Section is also available to assist courts in resolving legal issues and court procedural issues that arise in creating a drug court program.

If you are interested in starting a drug program at your court, please contact:

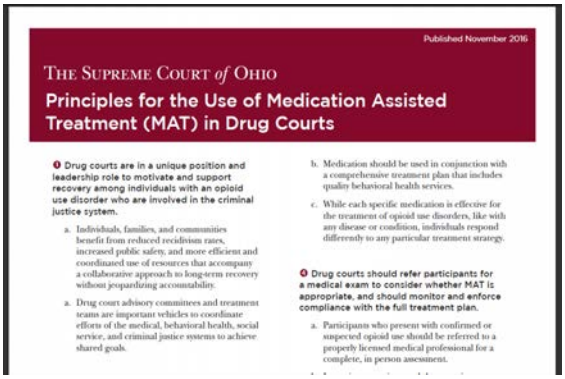
Specialized Dockets Section
Phone: 614.387.9425
Email: specdocs@sc.ohio.gov

Principles for the Use of Medication Assisted Treatment (MAT) in Drug Courts

Supreme Court Specialized Docket Certification Procedures

Related Links

All PDF files may be viewed, printed, and searched using the free Acrobat® Reader
Acrobat Reader is a trademark of Adobe Systems Incorporated.



Published November 2016

THE SUPREME COURT of OHIO

Principles for the Use of Medication Assisted Treatment (MAT) in Drug Courts

Drug courts are in a unique position and leadership role to motivate and support recovery among individuals with an opioid use disorder who are involved in the criminal justice system.

a. Individuals, families, and communities benefit from reduced recidivism rates, increased public safety, and more efficient and coordinated use of resources that accompany a collaborative approach to long-term recovery without jeopardizing accountability.

a. Drug court advisory committees and treatment teams are important vehicles to coordinate efforts of the medical, behavioral health, social service, and criminal justice systems to achieve shared goals.

b. Medication should be used in conjunction with a comprehensive treatment plan that includes quality behavioral health services.

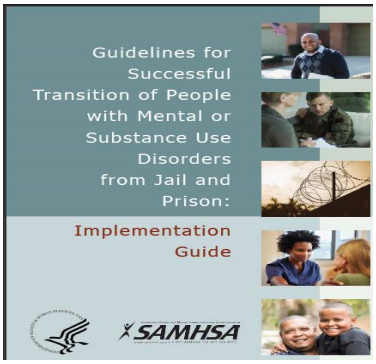
c. While each specific medication is effective for the treatment of opioid use disorders, like with any disease or condition, individuals respond differently to any particular treatment strategy.

Drug courts should refer participants for a medical exam to consider whether MAT is appropriate, and should monitor and enforce compliance with the full treatment plan.

a. Participants who present with confirmed or suspected opioid use should be referred to a properly licensed medical professional for a complete, in person assessment.

Guide to Aid in Transition from Jail

- Free guide to help prisoners make the transition when they get out of jail or prison
- Many have mental health and substance use disorders
- This consistently produces poor outcomes for both the individuals and the correction agencies
- Has 10 guidelines including individual treatment plans, universal screening, follow up of positive screens with comprehensive assessments, policies to facilitate continuity of care, cross training, collect and analyze data, match risk with need, etc.



RELIAS LEARNING 145

Disclosure without Consent

RELIAS LEARNING 146

Disclosures with Consent

- Discusses when you can discuss protected health information or medical record information when a consent form is **not** needed
- This includes disclosure for medical emergencies
- The proposed changes were finalized to allow this exception
- Made it more consistent with the statutory language
- Gives providers more discretion to determine when a bona fide medical emergency exists
  - Will issue sub-regulatory guidance on this also

RELIAS LEARNING 147

Medical Emergencies

RELIAS LEARNING 148

Medical Emergencies 2.51

- So can the medical records of the substance use disorder patient be released in an emergency?
- The answer is yes when a bona fide emergency exists and can be given without the patient's consent
- Providers are given more discretion to determine when this exists
- A medical emergency is a situation that poses an immediate threat of health of an individual and which requires immediate medical intervention
  - It does not need to be the patient

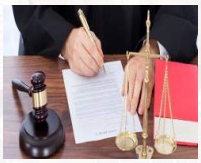
RELIAS LEARNING 149

Medical Emergencies 2.51

- Patient identifying information can be given to the FDA if they believe the health of any individual may be threatened by an error in manufacturing, labeling, or the sale of product under their authority
  - This is for the purpose to notify the patient or physicians of the potential dangers
- Immediate after disclosure, the part 2 program must document in the medical record the name of the person who made the disclosure and what was disclosed
  - The date and time of disclosure must also be documented

RELIAS LEARNING 150

Court Orders Authorizing Disclosure and Use



RELIAS LEARNING 151

Court Orders 2.61

- Discusses when a court order is needed to share protected health information
- Discusses the scope of the court order
- A general court order alone has never been sufficient in the past because a court order with good cause shown was required
- Now a subpoena and a court order are required
- For example, a person holding records receives a subpoena and the records could not be released unless a court authorized a court order

RELIAS LEARNING 152

Court Orders 2.61

- If a person gets a court order and no subpoena, or the subpoena has expired or been quashed, and the person does not want to make the disclosure then the person may refuse
- If the person is then given a valid subpoena then the person must disclose
- A court order may not authorize a qualified person who has received the information without consent for the purpose of doing research to disclose information or use it to conduct a criminal investigation or prosecute a patient (2.62)

RELIAS LEARNING 153

Court Orders 2.63

- A court order may authorize information to be released if necessary to protect against a threat of life or seriously injury
- This includes suspected child abuse and neglect
- It includes threats against third parties (Tarasoff progeny of cases)
- Disclosure is necessary in investigation of very serious crime such as kidnapping, rape, homicide, armed robbery, assault with a deadly weapon or child abuse

Court Orders 2.63

- Disclosure can also be made in connection with litigation if the patient offers testimony or other evidence pertaining to the confidential communication
- An order disclosing records for the purposes other than criminal investigation may be applied for by any person having a legally recognized interest
  - The application can be filed separately
  - It could be filed as part of the civil action
  - Must use fictitious name such as John Doe and not disclose any patient identifying information

Court Orders 2.64

- The patient and person holding the records must be given adequate notice
- Must be given opportunity to file a written response
- Or the person can appear in person for limited purpose of discussing the court order
- Any oral argument or review of evidence must be held in the judge's chambers so that the patient identifying information is not disclosed
- An order under this section may be issued only if the court determines that **good cause exists**

Court Orders 2.64

- The court must find that there other way to obtain the information
- The public interest and the need for disclosure outweighs the potential injury to the patient
- It describes the content of the order so attorneys need to make the order contains this information which is shown on the next slide

Content of Order 2.64

An order authorizing a disclosure must:

1) Limit disclosure to those parts of the patient's record which are essential to fulfill the objective of the order;
2) Limit disclosure to those persons whose need for information is the basis for the order; and
3) Include such other measures as are necessary to limit disclosure for the protection of the patient, the physician-patient relationship and the treatment services; for example, sealing from public scrutiny the record of any proceeding for which disclosure of a patient's record has been ordered.

Court Orders Should Comply with New Rule

ORDER TO DISCLOSE PROTECTED HEALTH INFORMATION

The court, having reviewed all relevant regulations and procedures, hereby finds:

1. One of the purposes of the _____ [Name of Drug Treatment Court] (the "Drug Treatment Court") is to monitor closely the progress of defendants ("Participants") appearing in the Drug Treatment Court in their substance abuse treatment.

2. Participants' enrollment in a substance abuse treatment program is a condition of Participants' continued participation in the Drug Treatment Court.

3. The Drug Treatment Court requires timely and accurate information concerning Participants' attendance and progress in treatment in order to adequately monitor the effectiveness and progress of Participants' participation in treatment.

4. From time to time, the Drug Treatment Court may direct a Participant to receive additional health-related services in connection with the Participant's involvement in the Drug

Disclosure for Criminal Investigation 2.65

- Law enforcement or the prosecutor can ask for an order authorizing disclosure of patient records to investigate or prosecute the patient
- It can be filed separately
- It can filed as part of the pending criminal action
- It must use a fictitious name like John Doe or disclose any identifying information
- Unless the court has ordered the records sealed from public scrutiny

Disclosure for Criminal Investigation 2.65

- Adequate notice must be given to the person holding the records
- An opportunity to appear and provide evidence
- A right to be represented by independent counsel
- Hearings shall take place in Judge's chambers to ensure no identifying information is disclosed to anyone other than a party to the procedure
- A judge may authorize the court only if he or she finds all of the following

Disclosure for Criminal Investigation 2.65

- It is a serious crime as previously discussed that threatens loss of life or serious injury
- Reasonable likelihood that the records will disclose information of substantial value in the investigation or prosecution
- Other ways of obtaining the information is not available
- The potential injury to the patient, to the physician-patient relationship and the ability of the part 2 program to provide services is outweighed by the public interest

Disclosure for Criminal Investigation 2.65

- If the applicant is a law enforcement then the person holding the records has a right to be represented by independent counsel
- It also specifies what must be in the order authorizing the release of the medical records
- This is discussed in the next slide
- It is important that the court order include all of this information
- Similar process if investigation or prosecution of part 2 program or their employees

Content of Order Must Include

1) Limit disclosure and use to those parts of the patient's record which are essential to fulfill the objective of the order;

2) Limit disclosure to those law enforcement and prosecutorial officials who are responsible for, or are conducting, the investigation or prosecution, and limit their use of the records to investigation and prosecution of the extremely serious crime or suspected crime specified in the application; and

- 3) Include such other measures as are necessary to limit disclosure and use to the fulfillment of only that public interest and need found by the court.

Unauthorized Agents and Informants and ID Cards

Agents and Informants 2.17

- You cannot knowingly employ, enroll as a patient, or place any undercover agent or informant in the facility to try and get information on patients
- Unless authorized by court order
- No information obtained by an undercover agent or informant may be used to criminally investigate or prosecute a patient
- Even if done pursuant to a court order

Definition of Informant

- **Informant** means an individual:
- 1) Who is a patient or employee of a part 2 program or who becomes a patient or employee of a part 2 program at the request of a law enforcement agency or official; and
- (2) Who at the request of a law enforcement agency or official observes one or more patients or employees of the part 2 program for the purpose of reporting the information obtained to the law enforcement agency or official.

ID Cards

- You cannot require the patient to carry an ID card identifying them as a patient having a substance abuse disorder while away from the premises
- This does not prohibit a person from requiring patients to use or carry cards or other identification while on the premises of a part 2 program
- Section 2.18

Court Order for Informant

- A court order can be applied for by law enforcement or prosecutors to place an undercover agent or informant in the part 2 program
- It could be as a patient or an employee
- If there is reason to suspect that the employees or agents of a part 2 program are engaged in criminal conduct
- The director of the program must be given adequate notice and the opportunity to be heard
  - Unless the allegation is that director is involved in the criminal activity

Court Order for Informant

- The director of the program will also not be notified if there is an allegation that the director will intentionally or unintentionally disclose the placement of the informant or undercover agent
- An order will be issued only if the court determines good cause exists
- The court must find there is reason to believe there is criminal activity, other ways to obtain evidence is not available and there is a public interest and need for the informant
- Specifies what must be in the court order

Closing a Program

Closing a Program 2.19

- If the hospital or other part 2 program closes it must remove patient identifying information from the medical records or destroy them
  - In HIPAA law called protected health information or PHI
- Same is true if the program is taken over by someone else
- Unless the patient gives written consent to transfer the records to the acquiring program
- This includes sanitizing any associated hard copies or electronic media so the PHI is non-retrievable

Closing a Program 2.19

- Need a P&P
- Patient can also give written consent to transfer the medical records to another program
- What do you do if you are required to by law to retain the medical records for a specified period of time?
- For example, CMS in the hospital CoPs says must keep records for 5 years and 6 years for CAHs
- Paper medical records can be sealed in an envelop with a label on it

Closing a Program 2.19

- The label can read “Records of Jane Doe are required to be maintained under (insert state or federal law, court order, or other legal requirement) until a date not later than December 17, 2018
- All hard copy media from which the paper copies were produced have to be sanitized
- At the end of the retention period the medical records should be destroyed
- Should be done consistent with your P&P
- What about electronic records?

Closing a Program 2.19

- Electronic records can be transferred to a portable electronic device with encryption
- Can also be transferred with a back up copy to a separate electronic media with encryption
- Must also implement access controls so unauthorized people do not have access
- Above must be done within one year of discontinuing or acquiring a program
  - So the original records and all back up electronic media, including email and any other communications must be sanitized to remove all PHI

Closing a Program 2.19

- The portable electronic devise or the original and backup medical must be sealed in a container with the same message as the paper copies
- Also must store in a container to protect the information such as a climate controlled environment
- The person responsible for doing this must be on the access control list and be provided a mean or way to decrypt it which must be at a different location
- Need to endure total destruction of PII

Sanitizing Electronic Media

- SAMHSA notes that sanitizing electronic media is distinctly different from deleting electronic files
- It may involve **clearing** such as using software or hardware products to overwrite media with non-sensitive date
- It may include **purging** the information from the electronic media such as degaussing or exposing the media to a strong magnetic field in order to disrupt the recorded magnetic domains
- It could include shredding, melting, pulverizing, disintegrating, or incinerating the media

Research

RELIAS LEARNING 178

Research 2.52

- Revises the research exception to permit data to be disclosed to qualified personnel for the purpose of conducting scientific research
- Will allow the lawful holders of patient identifying information (protected health information) to disclose Part 2 patient information to qualified personnel without consent
- For the purpose of conducting scientific research
- If director, managing director, CEO, or their designee meets certain conditions

RELIAS LEARNING 179

Research 2.52

- If the researcher meets certain requirements
  - The HIPAA covered entity or business associate has a HIPAA compliant authorization (research participants' authorization)
  - The Institutional Review Board (IRB) or privacy board has issued a waiver
  - Or the other HHS human subject protection requirements are met such as the researcher is subject to the HHS regulation such as the common Rule (45 CFR part 46, subpart A)
  - Must provide documentation that the researcher is in compliance with the Common Rule including informed consent requirements or a waiver of consent

RELIAS LEARNING 180

Research 2.52

- If neither a HIPAA covered entity or a business associate or not subject to the HHS regulations, then this section does not apply
- Any researcher is fully bound by this section which includes resisting any judicial procedure trying to get access to the patient's records
- Data in the research must only include information in aggregate form so patient identifying information is not use
- Patient identifying information must be maintained and destroyed according to security P&Ps

45 CFR Part 46, Subpart A - Basic HHS Policy for Protection of Human Research Subjects

eCFR | Authorities (U.S. Code) | Rulemaking

prev | next

§ 46.101 To what does this policy apply?

§ 46.102 Definitions.

§ 46.103 Assuring compliance with this policy - research conducted or supported by any Federal Department or Agency.

§§ 46.104-46.106 [Reserved]

§ 46.107 IRB membership.

§ 46.108 IRB functions and operations.

§ 46.109 IRB review of research.

§ 46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

§ 46.111 Criteria for IRB approval of research.

§ 46.112 Review by institution.

§ 46.113 Suspension or termination of IRB approval of research.

Research and the Common Rule

- The Common Rule is a rule of ethics regarding biomedical and behavioral research involving human subjects
  - It is the baseline standard of ethics by which any government funded research in the US is held
  - Nearly all academic teaching institutions hold their researchers to these standards of rights regardless of funding
  - It includes the requirements for obtaining and documenting consent
  - It includes the requirements for the IRB membership, function, operations, review of research and record keeping

Research 2.21

- The research privilege law allows a researcher to withhold the names of individuals who are the subject of the research from all persons not connected with the research
  - This may be authorized by the secretary of HHS and the attorney general
  - This is concurrent coverage since protected by several different federal laws
- The person who is doing the research cannot be compelled to disclose any identifying characteristics of subjects of that research

Research Data Linkages

- This section was changed in the final rule
- Researchers holding part 2 data can link to data sets from federal and non-federal data repositories provided certain conditions are met
  - This will support more advanced research, including studies of longitudinal effects of patient treatments
- SAMHSA addressed the retention and disposal of part 2 data in the section on security of medical records
- Will issue additional sub-regulatory guidance on the research provision

Research Data Linkages

- The request must be approved by the IRB that is registered with the HHS to make sure patient privacy is considered and the need for identifiable data is justified
- The researcher must make sure the identifying information is not provided to law enforcement
- The linked data from the records must be destroyed or deleted when done to make sure patient identifying information is non-retrievable

Audit and Evaluation

RELIAS LEARNING 187

Audit and Evaluation 2.53

- SAMHSA recognizes the importance of audits and evaluations and finalized the proposed sections
- Federal, state, or local government agencies that provide funding to Part 2 programs can now have access to the patient records
- When done to audit and evaluate the activities
- A patient consent is not needed
  - For example; disclosures of information to ACO's and similar CMS-regulated entities to carry out Medicare, Medicaid, and added Children's Health Insurance Program (CHIP) audit and evaluation activities are permitted

RELIAS LEARNING 188

Audit and Evaluation

- Permits the part 2 **program,** not just the part 2 program director, to determine who is qualified to conduct an audit or evaluation
- Revised the requirements for destroying records and this is contained in section 2.16 on security
- Sometimes the auditor may not copy or get copies of the medical records
- Must still agree in writing to comply with the limitations on non-disclosure

RELIAS LEARNING 189

Audit and Evaluation 2.53

- This includes any individual or entity that provides financial assistance to the part 2 program, which is a third-party payer covering the patients in the program
  - Or the QIO performing utilization or quality control review
- If any get copies of records, either paper or electronically, must agree in writing
  - To maintain and destroy patient identifying information with the P&Ps discussed previously under 2.16
  - Comply with federal and state laws
  - Comply with limitation on redisclosure

Audit and Evaluation 2.53

- An audit or evaluation necessary to meet requirements for a CMS-regulated ACO or similar CMS-regulated organization (including a CMS regulated QE) must follow additional rules
  - This includes having administrative or clinical systems in place
  - This requires a leadership and management structure, which includes a board and CEO with oversight responsibility
  - Must make sure participation agreement is followed
  - See section for more information

Frequently Asked Questions FAQs

Frequently Asked Questions FAQs

- SAMHSA has previously drafted frequently asked questions regarding substance abuse confidentiality regulations
- These were very helpful
- Has 17 questions
- Including information on audits, evaluation, qualified service organization agreements, on call providers, consent issues, and more
- Last updated August 9, 2016
- SAMHSA said will update to reflect new law changes

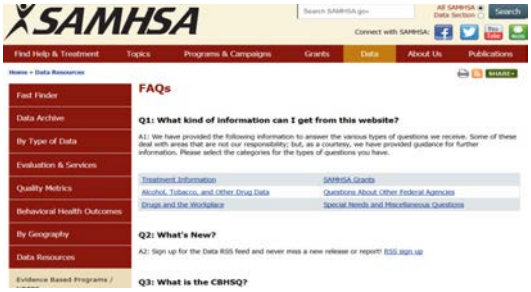
Previous FAQs

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

SAMHSA FAQs

- There is also a frequently asked question web page on what kind of information can be obtained off their website on general information
- Drug data is available and discusses the Center for Behavioral Statistics and Quality (CBHSQ)
  - Include 5 major data collection systems
- It includes treatment information
  - Includes information on how to find a treatment program and how to get listed
- Information on drug testing and SUDs in the workplace

General FAQs



SAMHSA Confidentiality Previous Documents

SAMHSA Confidentiality Document

- SAMHSA published a 25 page document in June of 2014
- It was called "The Confidentiality of Alcohol and Drug Abuse Patient Records Regulations and the HIPAA Privacy Rule: Implications for Alcohol and Substance Abuse Programs"
- It was an excellent document that discussed how the privacy rules affected disclosure
- Discussed what programs the privacy rules applied to and what information was protected

SAMHSA Confidentiality Document

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

June 2004

www.samhsa.gov/sites/default/files/part2-hipaa-comparison2004.pdf

SAMHSA Confidentiality Document

- SAMHSA also published two additional documents in the past
- The first was the confidentiality of alcohol and drug abuse records regulations under 42 CRF Part 2
- The second was applying the substance abuse confidentiality regulations to health information exchange 2010
  - 11 page document
  - Discussed if federal law protects the confidentiality of alcohol and drug records to be included in electronic health information exchange systems

Confidentiality and HIE

Frequently Asked Questions

Applying the Substance Abuse Confidentiality Regulations to Health Information Exchange (HIE)[1]

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.

www.samhsa.gov/sites/default/files/faqs-applying-confidentiality-regulations-to-hie.pdf

OCR HIPAA and Mental Health

RELIAS LEARNING 202

HIPAA Privacy and Mental Health

- The Office of Civil Rights (OCR) enforces the privacy rule
- OCR has a 11 page PDF document on the HIPAA privacy rule and sharing information related to mental health
- Recognizes circumstances where health information may need to be shared as for the health and safety of the patient or others
- Clarifies that HIPAA would allow health care providers to communicate with the patient's family or friends who are involved in his care

RELIAS LEARNING 203

HIPAA Privacy and Mental Health

- Can communicate with the parent of a minor patient
- Will consider the patient's capacity to agree or object to the sharing of his information
- Communicate with the family or law enforcement if the patient presents a serious and imminent threat of harm to self and others and
- Communicate to law enforcement about the release of a patient brought in for an emergency psychiatric hold
- Published February 20, 2014 and has FAQs

RELIAS LEARNING 204

HIPAA Privacy Rule and Sharing Information Related to Mental Health

Download PDF version - PDF

www.hhs.gov/hipaa/for-professionals/special-topics/mental-health/index.html

Background

The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule provides consumers with important privacy rights and protections with respect to their health information, including important controls over how their health information is used and disclosed by health plans and health care providers. Ensuring strong privacy protections is critical to maintaining individuals' trust in their health care providers and willingness to obtain needed health care services, and these protections are especially important where very sensitive information is concerned, such as mental health information. At the same time, the Privacy Rule recognizes circumstances arise where health information may need to be shared to ensure the patient receives the best treatment and for other important purposes, such as for the health and safety of the patient or others. The Rule is carefully balanced to allow uses and disclosures of information—including mental health information—for treatment and these other purposes with appropriate protections.

In this guidance, we address some of the more frequently asked questions about when it is appropriate under the Privacy Rule for a health care provider to share the protected health information of a patient who is being treated for a mental health condition. We clarify when HIPAA permits health care providers to:

- Communicate with a patient's family members, friends, or others involved in the patient's care;
- Communicate with family members when the patient is an adult;

who is being treated for a mental health condition. We clarify when HIPAA permits health care providers to:

- Communicate with a patient's family members, friends, or others involved in the patient's care;
- Communicate with family members when the patient is an adult;
- Communicate with the parent of a patient who is a minor;
- Consider the patient's capacity to agree or object to the sharing of their information;
- Involve a patient's family members, friends, or others in dealing with patient failures to adhere to medication or other therapy;
- Listen to family members about their loved ones receiving mental health treatment;
- Communicate with family members, law enforcement, or others when the patient presents a serious and imminent threat of harm to self or others; and
- Communicate to law enforcement about the release of a patient brought in for an emergency psychiatric hold.

HIPAA and Sharing Mental Health Information

- OCR has published an 11 page document on the HIPAA privacy rule and sharing information related to mental health
- Recognizes that health information may need to be shared for the health and safety of the patient or others
- Clarified when providers can communicate with the patient's family or friends
- Communicate with law enforcement if patient presents a serious harm to or self or others

HIPAA Privacy Rule and Sharing Information Related to Mental Health

Background www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/special/mhguidancepdf.pdf

The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule provides consumers with important privacy rights and protections with respect to their health information, including important controls over how their health information is used and disclosed by health plans and health care providers. Ensuring strong privacy protections is critical to maintaining individuals' trust in their health care providers and willingness to obtain needed health care services, and these protections are especially important where very sensitive information is concerned, such as mental health information. At the same time, the Privacy Rule recognizes circumstances arise where health information may need to be shared to ensure the patient receives the best treatment and for other important purposes, such as for the health and safety of the patient or others. The Rule is carefully balanced to allow uses and disclosures of information – including mental health information – for treatment and these other purposes with appropriate protections.

The End! Questions???

- Sue Dill Calloway RN Esq. CPHRM, CCMSCP, AD, BA, BSN, MSN, JD
- President Patient Safety and Healthcare Consulting
- 5447 Fawnbrook Lane Dublin, Ohio 43017
- 614 791-1468 (Call with questions, no emails)
- sdill1@columbus.rr.com
- Email questions to CMS at hospitalscg@cms.hhs.gov

THANK YOU