The Interplay Between New Rules Governing 42 CFR Part 2 and HIPAA
My Background

- JD & LL.M (Masters of Law)
- Practiced law 23 years & retired in 2000
- Veteran
- Since 2001, involved with those experiencing homelessness, veterans & those with SUDs
- Addictions Studies Certificate
- Masters in Counseling
- NCC, MAC & CADC III
- Proud grandfather

My granddaughter Tessa
“Embracing the Future”

Today we’ll be talking about:

- The recent “modernization” of treatment language in 42 CFR Part 2
- Bringing “Part 2” into the digital age
- The alignment more closely of Part 2 with HIPAA
- While carrying forward in Part 2 the privacy protections that Congress wrote into law 50 years ago for those seeking or receiving substance use treatment
“Embracing the Future”

We’ll also raise the question – what does the future hold for Part 2?

- Will it remain a stand-alone?
- Will it be subsumed more fully into HIPAA?
- Will, as some have suggested, it go away altogether, replaced entirely by HIPAA?
What We Hope You’ll Come Away with Today:

- An understanding of changes made in the updated Part 2;
- An understanding of the 3 primary rules of HIPAA;
- An understanding of the interplay between Part 2 and HIPAA;
- Familiarity with remaining and pending areas at issue between Part 2 and HIPAA.
Comprehensive Alcohol Abuse & Alcoholism Prevention, Treatment & Rehabilitation Act of 1970

- Known as the “Hughes Act” for Sen. Harold Hughes, a recovering alcoholic, who sponsored the legislation

Drug Abuse Office & Treatment Act of 1972

- Title IV, Sec. 408 is the “parent” of Part 2
- Sec. 408 contains the language that was codified into 42 U.S. Code § 290dd-2
Why the Need?

- Horror stories of police coming to treatment centers to arrest clients
- Treatment centers having to turn over records to police or government entities
- People needing treatment feared prosecution by law enforcement, so avoided treatment
- Stigma of being “outed” as an alcoholic or addict kept people away from treatment
42 CFR Part 2 - How Did We Get Here

42 U.S. Code § 290dd-2, as amended:

“Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to substance abuse education, prevention, training, treatment, rehabilitation, or research, which is conducted, regulated, or directly or indirectly assisted by any department of the United States shall... be confidential... and... disclosed only for... purposes and under the circumstances expressly authorized...”
42 CFR Part 2 - How Did We Get Here

- These laws & amendments authorized the promulgation of implementing regulations
- These have been codified at Title 42 of the Code of Federal Regulations in Part 2
- Hence, 42 CFR Part 2
  - 1st regs were effective Aug. 1, 1975
  - Later revised & updated in 1983
  - Unchanged for 33 years
  - Revised Proposed Rule published Feb. 9, 2016
  - Final Rule was published Jan. 18, 2017 and was to be effective March 21, 2017
  - After many questions/concerns raised by the treatment community, a “Supplemental Notice of Proposed Rulemaking” was issued
  - Final rule published Jan. 2, 2018, effective Feb. 2, 2018
HIPAA – How Did We Get Here?

- Introduced as the Kennedy-Kassebaum Bill of 1996
  - Passed Aug. 2, 1996 as Pub. L. 104-191
  - Signed into law by Pres. Clinton
  - Codified variously throughout U.S. Code but primarily 42 U.S. Code §m 11101, et. seq.

- Renamed the “Health Insurance Portability and Accountability Act” upon passage
HIPAA – How Did We Get Here

- **Regulatory Action:**
  - Initial proposed rule issued 1999
  - Final initial rule issued 2002
  - Last revised & updated Jan 2013
  - 2013 revisions were required by provisions amending HIPAA contained in:
    - Health Information Technology for Economic & Clinical Health (HITECH) Act
    - The Genetic Information Nondiscrimination Act (GINA)

- Regulations codified at 45 CFR Parts 160 and 164
Why The Need?

- Exponential growth of health information technology
- Expectation of better health outcomes, smarter spending, healthier people resulting from increased use & reliance on digital health information
- Growth of Use of Electronic Health Records (EHRs) systems and reliance on Health Information Exchanges (HIEs)
- BUT…fear about security and privacy risks in the confidentiality and accuracy of electronic health information
- Might cause patients to withhold disclosure of health information to providers
- And withholding health information could have life-threatening consequences
Reconciling 42 CFR Part 2 with HIPAA

The essence of the dilemma arises in the titles of the respective provisions:

- 42 CFR Part 2 – Confidentiality of Substance Use Disorder Patient Records
- HIPAA – Health Insurance Portability and Accountability Act
**Part 2**

**HIPAA**

- Promote restrictions on disclosure of Patient Identifying Information by Part 2 programs

- Promote maximum Exchange of health Information among Health care entities

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**Purposes of Each Provision**

**Patient**

- Promote restrictions on disclosure of Patient Identifying Information by Part 2 programs

- Promote maximum Exchange of health Information among Health care entities
The Respective Intentions Are Noble

- **Part 2 §2.2(b)(2):**
  
  “…to ensure that a patient receiving treatment for a substance use disorder in a part 2 program is not made more vulnerable by reason of the availability of their patient record than an individual with a substance use disorder who does not seek treatment.”

- **HIPAA Privacy Rule:**
  
  “Ensuring strong privacy protections is critical to maintaining individuals’ trust in their health care providers and willingness to obtain needed health services…at the same time…circumstances arise where health information may need to be shared to ensure the patient receives the best treatment…”
Concerns Expressed by SAMHSA

- While the goal is to make Part 2 compatible with emerging health care models that promote integrated care & patient safety
- Recognize that unauthorized disclosure can lead to a host of negative consequences such as:
  - Loss of employment
  - Loss of housing
  - Loss of child custody
  - Discrimination by medical professionals
  - Discrimination by insurers
  - Arrest, prosecution and incarceration
Commonality in Terms in Part 2 and HIPAA

**In Part 2:**
- Part 2 Programs
- Qualified Service Organizations (QSO’s)
- Third Party Payers
- Patient Identifying Information

**In HIPAA**
- Covered Entities (CE’s)
- Business Associates (BA’s)
- May be CE’s or BA’s
- Patient Health Information (PHI)
Let’s Get To It:

- First, a look at 42 CFR Part 2 and changes, updates to it
- Next, a look at HIPAA’s Privacy Rule, Security Rule and Breach Rule
- Finally, what may lie ahead in the tug of war between Part 2 and HIPAA policy makers
The recent “modernization” of treatment language in 42 CFR Part 2

- “Alcohol abuse” and “drug abuse” language is out, replaced by “Substance Use Disorder” [§ 2.11]:

- “…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.”

- Definition lifted verbatim from DSM 5, p. 483.
Bringing 42 CFR into Digital Age

**Data in Use:**
Active data under constant change stored physically in databases, data warehouses, spreadsheets etc.

**Data at Rest:**
Inactive data stored physically in databases, data warehouses, spreadsheets, archives, tapes, off-site backups etc.

**Data in Motion:**
Data that is traversing a network or temporarily residing in computer memory to be read or updated.
Bringing Part 2 Into the Digital Age

- 42 CFR Part 2, Subpart B, § 2.19, Disposition of records by discontinued programs

- Major changes here, but 1 initial example:

  - “[Patient] records which are electronic, must be…transferred, along with a backup copy, to separate electronic media, so that both the records and the backup copy have implemented encryption to encrypt the data at rest so that there is a low probability of assigning meaning without the use of a confidential key…” [§ 2.19(b)(2)]
Bringing 42 CFR into Digital Age

Data in Use:
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Summary of Key Changes to Part 2

- Expanded provisions for Maintenance Treatment, Withdrawal Management and Opioid Treatment Programs (OTPs)
- Expanded definitions of Diagnosis and Treatment and possible ethical considerations
- Expanded provisions for Discontinued Programs
- “Treating Provider Relationship(s)"
- Guidance on “lawful holder” of patient records
- Provisions for general hospitals or health care facilities that have a SUD treatment component
Summary of Key Changes to Part 2

- Acknowledging the presence of patients
- Records Security (separate provisions for paper vs. electronic records)
- Research Privilege statutes
- Disclosures with Patient Consent (General Designations)
- Shortened notice on prohibition on re-disclosure
Summary of Key Changes to Part 2

- Disclosures to Prevent Multiple Enrollments
- Disclosures without Patient Consent
  - Researchers
  - HIPAA CE’s or BA’s
  - Data Linkages and Data Repositories
  - Audits & Evaluations (Medicare, Medicaid or CHIP utilization or quality control reviews)
Summary of Key Changes to Part 2

- Court Orders
  - Researchers, Auditors & Evaluators
  - Confidential Communications
  - Court Orders in Criminal Prosecutions
  - Court Orders for noncriminal purposes
  - Procedures when the Part 2 Program is under investigation or prosecution
Now, Let’s Take a Walk Through Part 2

- Introductory Materials
- General Provisions
- Disclosures with Patient Consent
- Disclosures without Patient Consent
- Court Orders Authorizing Disclosures & Use
Introductory Materials

Part 2 imposes

- Restrictions on the disclosure and use
- Of Substance Use Disorder Patient Records
- Maintained in connection with the performance of any part 2 program

42 CFR § 2.2
The GENERAL Rule of Part 2:

- Part 2 prohibits (with the force of law)
- Disclosure and Use of Patient Records
- Unless certain circumstances exist
- If circumstances exist permitting disclosure,
- It does not compel disclosure
- THUS, the regs do not require disclosure under any circumstances

42 CFR Part 2, § 2.2(a)-(b)
“Under Force of Law”

- Criminal penalties
  - It is a violation, not a misdemeanor or felony, so only a fine – no jail time
  - Title 18 U.S. Code §3571 states:
    - Not more than $5,000 if an individual
    - Not more than $10,000 if an organization

- Reports of violations
  - Reported to local U.S. Attorney
  - If an Opioid Treatment Program, to both U.S. Attorney and U.S. Substance Abuse and Mental Health Services Administration (SAMHSA)

- Other Legal & Administrative Consequences
  - Potential lost of federal or state licensure or certification
  - Potential loss of eligibility to compete for federal contracts

42 CFR Part 2 § 2.3-2.4
General Provisions – Selected Definitions

Terms Added to Address Opioid Treatment Programs (OTPs)

- Central Registry – organization that gets Protected Patient Information (PII) from 2 or more treatment programs so that the individual is not enrolled in more than 1 program

- Member Program – a withdrawal management or maintenance treatment program that reports PII to a central registry & is in the same state as the central registry or is in a state which participates in data sharing with the central registry in question

42 CFR Part 2, § 2.11
General Provisions – Selected Definitions

Terms Added to Address Opioid Treatment Programs (OTPs) [Entities that dispense meds]

- Maintenance Treatment – long-term pharmacotherapy for those with SUDs that reduces the pathological pursuit of reward and/or relief and supports remission of SUDs-related symptoms
- Withdrawal Management – use of pharmacotherapies to treat or attenuate the problematic signs and symptoms arising when heavy and/or prolonged substance use is reduced or discontinued

42 CFR Part 2 § 2.11
OTP Member Programs in the Northwest

- Alaska (4)
- Idaho (4)
- Oregon (20)
- Washington (28)
General Provisions – Selected Definitions

Programs Covered by/Subject to Restrictions on Disclosure in Part 2

- “Federally Assisted Program” [42 CFR Part 2, §2.12(b)]
  - Operated by contract for/with any US agency
  - Operated under license, certification, registration or other authorization by US government
  - A recipient of federal funds even though the funds do not directly pay for SUD diagnosis, treatment or referral for treatment
  - Supported by US government funds through programs conducted through a state or local government that gets federal funds
  - Have tax-exempt status through the IRS
Programs Covered by/Subject to Restrictions on Disclosure in Part 2

Other Programs [42 CFR Part 2 § 2.11]

- An individual
- Or entity
- That “holds itself out”
- As providing, and provides
- Substance use disorder diagnosis, treatment or referral for treatment

NOTE – Being licensed by the state, even if the individual or entity is not tax-exempt and receives no other federal funds that would make it a “federally assisted program”, counts as “holds itself out”. Thus, a for-profit program that gets no federal funds but is state licensed comes under the Part 2 regs.
General Medical Facilities -

- An identified unit within a general medical facility that holds itself out as providing, and provides, SUD diagnosis, treatment or referral for treatment.

- Medical personnel or other staff in a general medical facility whose primary function is providing SUD diagnosis, treatment or referral for treatment, and are identified as providing such.
General Provisions – Selected Definitions

Diagnosis –

- Any reference
- To an individual’s SUD
- Or to a condition identified as having been caused by that SUD
- Which is made by for the purpose of treatment or referral for treatment

42 CFR Part 2 § 2.11
Ethical Question/Concern About Definition of “Diagnosis”

- Part 2 definition is of “diagnosis” is extremely broad
- Typically a mental health practitioner must be specially licensed or credentialed to make a diagnosis
  - NAADAC Code of Ethics V-7, Diagnosing: “Addiction professionals shall provide proper diagnosis of mental health and substance use disorders within their scope and licensure”
  - ACA Code of Ethics, Sec. E-5:
    - “Counselors take special care to provide proper diagnosis of mental disorders. Assessment techniques…are carefully selected and appropriately used.
    - “Counselors recognize historical and social prejudices in the misdiagnosis and pathologizing of certain individuals and groups…
    - “Counselors may refrain from making and/or reporting a diagnosis if they believe it would cause harm to the client or others. Counselors carefully consider both the positive and negative implications of a diagnosis.”

KEY – We now must carve out a distinction between a “Part 2 Diagnosis” and a clinical diagnosis. They are not the same and there may be ethical implications
General Provisions – Selected Definitions

- **Patient**
  - Any individual
  - Who has applied for
  - Or been given diagnosis, treatment or referral for treatment
  - By a Part 2 program
  - Special Criminal Charge Provision

42 CFR Part 2 § 2.11
Patient – Criminal Provision

- Any individual
- Who after arrest on a criminal charge
- Is identified as an individual with a SUD
- In order to determine the individual’s eligibility to be in a Part 2 program

Question – Who can do the identifying? Must it be a police officer or can it be a spouse or a parent? Can it be the individual?
Qualified Service Organization (QSO)

- Any individual or entity who
- Provides services such as
  - Data processing
  - Bill collecting
  - Dosage Preparation
  - Lab analyses
  - Legal
  - Accounting
  - Training on nutrition
  - Child care
  - Individual & Group therapy

And has entered into a written agreement with the Part 2 program for these services,

- Acknowledging that in receiving, storing, processing or otherwise dealing with patient records of the program
- That they will be bound by the Part 2 regs, and
- If necessary, will fight in any judicial proceedings against release of any PII related to SUD treatment for any patients

42 CFR Part 2 § 2.11
General Provisions – Selected Definitions

- **Treating Provider Relationship**
  - A change in the new Part 2 that may make the exchange of information easier
  - The existence of a “treating provider relationship” will permit the patient to consent
  - To disclosures of protected information using a more general description of the individuals to whom the patient’s information may be released
  - Absent such a relationship, a patient’s consent to disclose would have to specifically name the individuals or entities to whom disclosure may be made
### Treating Provider Relationship

- The relationship can be established between the individual and the Part 2 Program
  - Regardless of whether there has been an actual in-person encounter, so long as
  - The patient agrees to or is legally required to be diagnosed, evaluated and or treated,
  - Or agrees to accept consultation
  - And the Part 2 individual or entity agrees to undertake, or undertakes diagnosis, evaluation, consultation and/or treatment of the patient

- Could be a phone call, text or email exchange, etc.

42 CFR Part 2 § 2.11
Lawful Holder of Patient Records

- An individual or entity who has received PII as the result of a Part 2-compliant patient consent
- Or as the result of one of the limited exceptions to the consent requirements & is thus bound by Part 2 re-disclosure rules
- Primarily to permit payment and health care operations to re-disclose patient information more easily
- Examples lawful holders include:
  - A Treating Provider
  - Hospital emergency room
  - Insurance company
  - Individual or entity performing an audit or evaluation
  - Individual or entity conducting scientific research
Initial SAMHSA proposed to list 17 different payment & health care operations activities that would justify re-disclosure in Part 2.

But in its Jan 2018 announcement of the final rule, SAMHSA opted not to publish the list within Part 2, but left the list of 17 in the preamble to the regulation.

Also, Lawful Holders are required to enter into contracts with those payment and health care operations to whom they would re-disclose patient information:
- That specify the permitted uses of PII
- But the Final Rule gives lawful holders until Feb. 2, 2020 to get these contract provisions in place.
Restrictions on Disclosure & Use By the Part 2 Program

➢ To “Disclose” means

- To communicate any information
- Identifying a patient
- As having been diagnosed with a SUD,
- Having or having had a SUD
- Or being or having been referred for treatment of a SUD

42 CFR Part 2 § 2.11
“The restrictions on disclosure apply to any information which would identify a patient as having or having had a substance use disorder”

[42 CFR Part 2, § 2.12(e)(3)]
Restrictions on Disclosure & Use
By the Part 2 Program Apply To:

- Any information, whether or not recorded
- That would identify a patient as having or having had a SUD
- That is alcohol abuse information or drug abuse information collected in the past by a Part 2 program
- And that has been maintained by a Part 2 program
- As part of an ongoing treatment episode, or
- For purposes of treating a SUD, making a diagnosis for that treatment or making a referral for that treatment

42 CFR Part 2 § 2.12(a)(1)

NOTE – Intent here appears to be to capture any historically obtained “alcohol abuse” and “drug abuse” information (since there has now been a shift to “SUDs”) and make clear that this historical information remains subject to the disclosure prohibitions.
Further Restrictions on the Part 2 Program From Disclosure

- PII cannot be used to initiate or substantiate any criminal charges against a patient or to conduct a criminal investigation of a patient [42 CFR Part 2 § 2.12(a)(2)]

- A Part 2 program may get PII from a branch of the armed forces about a patient who was subject to the UCMJ while on active duty, but that information must be protected from disclosure. [42 CFR Part 2 § 2.12(c)(2)]
Exceptions to Restrictions on the Part 2 Program From Disclosures

- Communications about PII within the Part 2 program itself (e.g., between staff)
- Communications between a Part 2 program and an entity that have direct administrative control over the Part 2 program
- Communications between a Part 2 program and one of its QSOs with whom it has a written agreement

42 CFR Part 2 § 2.12© (2)–(3)
Exceptions to Restrictions on the Part 2 Program From Disclosures

- Crimes on Part 2 Program premises or against Part 2 program personnel or a threat to commit such a crime
  - Disclosure is limited to law enforcement personnel, and to
  - Commission of a crime on the premises by the patient, and to
  - The circumstances of the incident (not PII related to treatment)

- Reports of suspected child abuse & neglect
  - State law governs
  - Restrictions continue to apply to the original SUD patient records

[42 CFR Part 2 § 2.12(c)(5)-(6)]
Disclosure Restrictions Imposed on Recipients of Information Received From the Part 2 Program

- Third-party Payers
- Entities having direct administrative control over a Part 2 Program
- Individuals or entities who receives patient records directly from a Part 2 program and who are advised of the restrictions on re-disclosure

[42 CFR Part 2 § 2.12(d)(1)-(2)]
Disclosure Restrictions Imposed on Recipients of Information Received From the Part 2 Program

These entities that may also receive patient information created by a Part 2 program and must protect it from disclosure:

- Rehabilitation programs
- Employee Assistance Programs
- Programs within general hospitals
- School-based programs
- Private practitioners who hold themselves out as providing, and provide SUD diagnosis, treatment or referral for treatment

NOTE – There is an express exception in this section for emergency room personnel who refer a patient to an intensive care unit after an overdose (unless the ER personnel are also SUD treatment personnel & hold themselves out as such).

[42 CFR Pare 2 § 2.12(e)]
Clinical Diagnoses Done by a Part 2 Program

- A diagnosis done by a Part 2 program for purposes of identifying a patient as having a SUD and which is released to another entity
  - Must be protected from disclosure by that entity.
  - Even if the diagnosis is not so used.

- These diagnoses done by a Part 2 program are not subject to the disclosure restrictions (can be re-disclosed):
  - A diagnosis made solely for the purpose of providing evidence for use by law enforcement agencies or officials
  - A diagnosis of drug overdose or alcohol intoxication which clearly shows that the individual does not have a SUD (e.g., involuntary ingestion of alcohol or other drugs or reaction to prescribed dosages of one or more drugs).

[42 CFR Part 2 § 2.12(e)(4)]
Confidentiality Restrictions

- Acknowledging the Presence of Patients
  - If it is a treatment facility, acknowledge only if the patient has signed a written consent
  - The regulations permit acknowledgment of the presence of an identified patient in a health care facility if the health care facility is not publicly identified as a treatment facility and no information is revealed that the patient has a SUD

[42 CFR Part 2 § 2.13(c)(1)]
Confidentiality Restrictions

- Answers to requests for patient records that are not permissible
  - Any answer must be made in a way that will not affirmatively reveal that the identified individual has been or is being treated for a SUD
  - The inquiring party may be given a copy of the regs and advised that they restrict disclosure of patient SUD records
  - But may not be told affirmatively that they restrict the disclosure of the records of this particular identified patient

[42 CFR Part 2 § 2.13(c)(2)]
Disclosures Involving Minor Patients

- State law governs legal capacity
- Minor patients with legal capacity must give written consent for disclosures
- Part 2 programs can refuse to give treatment to a minor unless the minor signs consents necessary to obtain financial reimbursement (but local law may say otherwise)

[42 CFR Part 2 § 2.14(a)]
Disclosures Involving Minor Patients

- Parents, guardians or others authorized under state law to act on behalf of the minor

- May be given information if the minor is found by the Part 2 Program Director to lack capacity for rational choice and the Program Director finds:
  - That the minor’s situation poses a substantial threat to the life or well-being of the minor or another individual, and
  - That the threat may be reduced by communicating relevant facts to the minor’s parents or others

[42 CFR Part 2 § 2.14(c)]
Security for Records

- Part 2 Program must have formal policies in place to “reasonably protect” against unauthorized uses & disclosures of PII

- Security for Paper Records
  - Procedures for transferring, moving or destroying, including sanitizing hard copy media
  - When not in use maintaining records in a locked room, locked file cabinet, safe or similar container

- Security for Electronic Records
  - Procedures for creating, receiving, maintaining, transmitting and destroying such records, including sanitizing the electronic media on which the records are stored
  - Rendering the PII non-identifiable in a way that creates a very low risk of re-identification

[42 CFR Part 2 § 2.16]
Disposition of Records by Discontinued Programs

- Where a program is being discontinued but is being acquired by another, an individual patient must give written consent to the records being transferred to the acquiring program.

- There are typically legal requirements for keeping records for a set period.

- If retention is required:
  - Paper records sealed, hard copy media sanitized & a responsible party appointed who will destroy the records after the retention period ends.
  - Electronic records – extensive requirements for transfer to portable electronic devices, encryption, sanitization, etc.
Relationship to State Laws

- If a disclosure is permitted under Part 2 but is prohibited by state law, state law controls.
- Part 2 cannot be construed to authorize a violation of state law.
- However, no state law may either authorize or compel any disclosure prohibited by Part 2.

[42 CFR Part 2 § 2.20]
State laws and Substance Use Disorder Records Disclosure with Patient Consent

State Consent Requirements for Disclosure of Records as Compared with Part 2
- Light blue: Stricter than Part 2
- Purple: Same as Part 2
- Light green: Less strict than Part 2/Part 2 Controls
- Gray: No law specifying consent requirements; Part 2 controls
- Yellow: State has separate requirements for entities not governed by Part 2

Source: Healthinfolaw.org
<table>
<thead>
<tr>
<th>State</th>
<th>Consent Requirements</th>
<th>Law Reference</th>
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<tbody>
<tr>
<td>Alaska</td>
<td>No law specifying consent requirements; Part 2 controls</td>
<td>Alaska Stat. § 47.37.210: Disclosure of substance abuse treatment information with the consent of the client is not addressed.</td>
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<tr>
<td>Idaho</td>
<td>Same as Part 2</td>
<td>Idaho Admin. Code r. 16.07.50.261: A patient may consent to the disclosure of information relating to their substance abuse treatment by fulfilling all Part 2 requirements.</td>
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<tr>
<td>Oregon</td>
<td>Same as Part 2</td>
<td>Or. Admin. R. 407-014-0020: A patient may consent to the disclosure of information relating to their substance abuse treatment by fulfilling all Part 2 requirements.</td>
</tr>
<tr>
<td>Washington</td>
<td>Less strict than Part 2/Part 2 Controls</td>
<td>Wash. Rev. Code § 70.96A.150: A patient may consent to the disclosure of information relating to their substance abuse treatment by providing written permission.</td>
</tr>
</tbody>
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Research Privilege Statutes

- Several federal laws allow scientists conducting research to keep the names of their patients confidential.

- Part 2 recognizes these research statutes, even if those seeking disclosure get a Part 2 court order directing release.

[42 CFR Part 2 § 2.21]
Notice to Patients of Federal Confidentiality Requirements

Patient must be given a written summary at time of admission of confidentiality protections, that include:

- The limited circumstances for which a disclosure can be made
- That unauthorized disclosure is a crime and who to report it to
- That commission of a crime on the premises is not protected
- That suspected child abuse & neglect must be reported
- Citation to applicable federal law and regulations
- A summary also may be included about state law

[42 CFR Part 2 § 2.22]
Consent of Patient to Disclosure of Treatment Information

- **Generic elements of consent forms:**
  - Must be in writing
  - Name of program allowed to disclose info
  - Patient’s name
  - Purpose of the disclosure
  - How much and what kind of information is to be disclosed
  - Signature of patient (electronic signatures are authorized) & date patient signed
  - Statement that consent can be revoked except to the extent the program has already disclosed information
  - Date, event or condition for expiration of consent

[42 CFR Part 2 § 2.31]
More About Consent Forms

- Must include “an explicit description of the SUD information that may be disclosed”
  - Can consent to disclosure of all their SUD records, but…
  - Now must also be given options to list specific things, such as:
    - Medications
    - Substance use history
    - Employment information
    - Living situation

- Consents may be orally revoked (HIPAA revocations must be in writing)

[42 CFR Part 2 § 2.31]
Restriction on Consent Revocations in Criminal Justice Cases

- In lieu of criminal prosecution against an individual
- A court, prosecutor or probation/parole officer can refer an individual to a Part 2 program
- If so, the consent the individual signs can contain restrictions on the individual’s ability to revoke the consent
- Until the occurrence of a specified event or time (e.g., end of parole/probation)

[42 Part 2 § 2.35]
3 Types of Disclosures Without Patient Consent

1. Medical Emergencies [42 CFR Part 2 § 2.51]
   - The old reg required a medical condition posing an immediate threat to the health of an individual, which required immediate medical intervention
   - The new provision aligns more closely with statutory language and permits disclosure without patient consent in cases where a “bona fide medical emergency exists”
3 Types of Disclosures Without Patient Consent

2. Scientific Research [42 CFR Part 2 § 2.52]

- Research entities are fully bound to protect the confidentiality of the patient information they receive.
- To the point of having to agree to fight any court subpoena that tries to get the patient data.
- Special rules for:
  - Data Linkages – obtaining information via linkages to data sets from data repositories holding patient information.
  - Data Repositories – must agree to store, sanitize and destroy patient data in accordance with Part 2 security procedures.
3 Types of Disclosures Without Patient Consent

3. Audits and Evaluations of a Part 2 Program [42 CFR PART 2 § 2.53]

- Includes entities that perform audits & evaluations on behalf of federal, state or local government agencies
- Includes third-party payers and QSO’s
- Special rules audits & evaluations to meet requirements of Medicare, Medicaid and Children’s Health Insurance Program (CHIP) programs
Requests by Patient to be Notified of Who Got Their PII

- When the general designation is used the patient must confirm on the consent form their understanding that they can be provided a list of who got their PII [42 CFR Part 2 § 2.31(4)]

- If the patient thereafter requests a list:
  - It must be in writing
  - Limited to disclosures made within the last 2 years
  - Program must respond within 30 days, and
  - Provide for each disclosure
    - The name of the entity that got the information
    - The date of the disclosure
    - A brief description of the PII disclosed

[42 CFR Part 2 § 2.13(d)]
Impact of the New “Treating Provider Relationship”

- Now, a patient can consent to the disclosure of his PII without naming each entity or individual who would get the info.
- Instead, patient can consent to disclosures to the patient’s treating providers, without naming each one.
- But on the consent form the patient must be given the opportunity to request to be notified of all those entities or individuals who received the patient’s records.

[42 CFR Part 2 § 2.31(a)(4)]
Impact of the New “Treating Provider Relationship”

- Entities that are not “treating providers”:
  - Names of any third-party payers must be listed on the consent form if information will be provided to them
  - Names of Health Information Exchanges or research institutions must be listed on the consent form if information will be provided to them
  - Names of any other individuals who would not be considered “treating providers” must be listed

[42 CFR Part 2 § 2.31(a)(4)(iii)]
Prohibitions on Re-Disclosure

- When PII is disclosed to an individual or entity based on the patient’s consent, they must be advised that they are prohibited from re-disclosing absent additional consent of the patient.
“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 has 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 of any patient with a substance use disorder, except as provided at §§2.12(c)(5) and 2.65.”

[42 CFR Part 2 § 2.32]
Alternate Notice Concerning Re-Disclosure

- In the 2018 Final Rule, an abbreviated notice of the prohibition against re-disclosure was provided that “can be used in any instance in which a notice is required”

- The abbreviated notice reads: “Federal law/42 CFR part 2 prohibits unauthorized disclosure of these records”

- The abbreviated notice is less than 80 characters long so that it will fit within the standard free-text space in most electronic health record systems
Disclosures To Prevent Multiple Enrollments in OTPs

- OTP patients were enrolling in multiple OTP programs that dispensed meds
- To resolve this problem, a special Part 2 provision was created
- It allows Part 2 programs to disclose patient records under certain conditions:
  - Patient’s written consent
  - Disclosure to any WM/TM programs within 200 miles of the program
  - Disclosure to a Central Registry within the same state
  - Limits on type of information disclosed

[42 CFR Part 2 § 2.34]
Court Orders Authorizing Disclosure & Use

➢ To obtain a court order directing a part 2 program to release patient records:
  • The applicant must have a legally recognized interest
  • It must be a court of competent jurisdiction
  • The application for an order may be filed separately or as part of a pending civil case seeking evidence in the case

[42 CFR Part 2 § 2.64]
Court Orders Authorizing Disclosure & Use

- A mere subpoena issued by a court clerk is insufficient for getting patient records
- There must have been a court proceeding, either in the judge’s chambers, or in open court if the patient consents
- Following which the judge, if the evidence suffices
  - Enters an order directing release
  - Which results in a court-ordered subpoena

[42 CFR Part 2 § 2.61; 42 CFR Part 2 § 2.64]
Court Orders Authorizing Disclosure & Use

- Patient records held by research organizations and auditors/evaluators cannot be the subject of a court order for disclosure.
- But research organizations and auditors/evaluators can be court-ordered to turn over patient records when the purpose of the disclosure is to prosecute qualified personnel holding the records (i.e., the Program Director or program personnel).

[42 CFR Part 2 § 2.62]
Patient Records vs. “Confidential Communications”

- Part 2 contains a provision which might create confusion among practitioners.
- It involves a higher level of information than what might typically be found in patient records.
- This is the category of “Confidential Communications” at 42 CFR Part 2 § 2.63.
“Confidential Communications”

- Confidential communications would be information disclosed by a patient to Part 2 program personnel
- In the course of diagnosis, treatment or referral for treatment
- Via either oral or written means, paper or electronic (emails, texts, etc.)
- This information may or may not have made it into the patient’s records
“Confidential Communications”

Because of the quasi-privileged or sensitive nature of the information there are more stringent requirements:

- Disclosure only if it is necessary to protect against an existing threat to life or serious bodily injury
- Including circumstances which constitute child abuse or neglect
- Or verbal threats against third parties
“Confidential Communications”

- Disclosure is necessary in connection with the investigation or prosecution of an extremely serious crime allegedly committed by the patient.

- Such as one which directly threatens loss of life or serious bodily injury, including:
  - Homicide
  - Rape
  - Kidnapping
  - Armed Robbery
  - Assault with a deadly weapon
  - Or child abuse and neglect
A Walk Through HIPAA
HIPAA – How Did We Get Here?

- Introduced as the Kennedy-Kassebaum Bill of 1996
  - Passed Aug. 2, 1996 as Pub. L. 104-191
  - Signed into law by Pres. Clinton
  - Codified variously throughout U.S. Code but primarily 42 U.S. Code §11101, et. seq.

- Renamed the “Health Insurance Portability and Accountability Act of 1996” upon passage
HIPAA – How Did We Get Here

- Regulatory Action:
  - Initial proposed rule issued 1999
  - Final initial rule issued 2002
  - Last revised & updated Jan 2013
  - 2013 revisions were required by provisions amending HIPAA contained in:
    - Health Information Technology for Economic & Clinical Health (HITECH) Act
    - The Genetic Information Nondiscrimination Act (GINA)

- Regulations codified at 45 CFR Parts 160 and 164
More Recent HIPAA Developments that Will Impact Patient Privacy

- **21st Century Cures Act Electronic Health Record Reporting Program**
- **Dec. 14, 2018** – HHS OCR issued a Federal Register Notice seeking information on modifying HIPAA rules to improve coordinated care
  - Comment period ended Feb. 12, 2019
  - OCR analyzing comments & new guidance pending
Important HIPAA Rules

1. The Privacy Rule – Protects the privacy of individually identifiable health information

2. The Security Rule – Sets national standards for security of electronic Protected Health Information (ePHI)

3. The Breach Notification Rule – Requires CE’s and BA’s to provide notification following a breach of unsecured PHI.
Whether PHI is on a computer, in an Electronic Health Record (HER), on paper, or in other media, providers have responsibilities for safeguarding the information by meeting the requirements of the 3 Rules.
The Privacy Rule protects:

- “Individually identifiable health information”
- Held or transmitted by a CE or BA
- In any form or media
- Whether electronic, paper or oral
- That relates to:
  - The individual’s past, present or future physical or mental health or condition;
  - The provision of health care to the individual; or
  - The past, present or future payment for the provision of health care to the individual
Who Must Comply with HIPAA Rules?

- CE’s must comply with the HIPAA Privacy, Security and Breach Rules
- BA’s must comply with certain provisions of the Privacy Rule and must comply fully with the Security and Breach Rules
Who Must Comply with the HIPAA Rules

CE’s include:

- Health care providers who conduct certain standard administrative and financial transactions in electronic form, such as:
  - Doctors
  - Clinics,
  - Hospitals
  - Nursing Homes,
  - Pharmacies
  - Any health care provider who bills electronically is a CE (i.e., a current Medicare provider)

- Health Plans
- Health Care Clearinghouses
Who Must Comply with the HIPAA Rules

- Business Associates (BA’s) are persons or entities (other than a member of the office staff)
- Who perform certain functions or activities on behalf of a CE
- Or who provide certain services for a CE
- When the services involve access to or the use or disclosure of PHI
Who Must Comply with the HIPAA Rules

- BA functions or activities include:
  - Claims processing
  - Data analysis
  - Quality assurance
  - Certain patient safety activities
  - Utilization reviews
  - Billing

- BA services to a CE can be:
  - Legal
  - Actuarial
  - Accounting
  - Consulting
  - Data aggregation
  - Information Technology (IT) management
  - Financial services
Who Must Comply with the HIPAA Rules

Examples of BA’s include:

- Health Information Organizations or Exchanges (HIOs/HIEs)
- E-prescribing gateways
- Other persons that provide data transmission services involving access to PHI
- A subcontractor to a BA that creates, receives, maintains or transmits PHI on behalf of the BA
- An entity that a CE contracts with to provide patients with access to Personal Health Record (PHR) on behalf of a CE
The HIPAA Privacy Rule

Two central aspects:

- Sets national standards to protect use and disclosure of certain health care information
- Sets standards for the privacy rights of individuals
  - To understand and control how their health information is used and shared, including...
  - Rights to examine and obtain a copy of their health records (and request corrections, if needed)
The HIPAA Privacy Rule

- A CE must prominently post and distribute a “Notice of Privacy Practices” (NPP)
- CE’s must provide the NPP to patients at their initial visit
- The NPP must include the following information:
  - How the CE may use & disclose an individual’s PHI
  - The individual’s rights with respect to the information
  - How the individual can exercise these rights
  - The CE’s legal duties with regard to the information, including that the CE is required by law to maintain the privacy of PHI
  - Who the individual can contact for further information about the CE’s privacy policies
The HIPAA Privacy Rule

- Providing the NPP opens the door
- The patient’s permission is not thereafter needed
- To use or disclose
- The patient’s health care information
- To another health care provider, Health Plan or Business Associate
The HIPAA Privacy Rule

- A CE may then disclose PHI for:
  - The treatment activities of another health care provider
  - The payment activities of another CE and of any health care provider
  - Or the health care operations of another CE when:
    - Both CE’s have or have had a relationship with the individual
    - The PHI pertains to the relationship
    - The data requested is the minimum necessary
The HIPAA Privacy Rule

- "Treatment" under Part 2:
  "The care of a patient suffering from a SUD, a condition which is identified as having been caused by the SUD, or both, in order to reduce or eliminate the adverse effects upon the patient"

- "Treatment" under HIPAA:
  "The provision, coordination or management of health care and related services for an individual by one or more health care providers, including consultation between providers regarding a patient and referral of a patient by one provider to another"
The HIPAA Privacy Rule

- Other circumstances where prior patient written authorization is not required
  - With limitations, disclosures to family, friends & other involved in the care of the patient
  - Disclosures needed to ensure public health & safety (release of shot records to schools, etc.)
  - Information needed to be disclosed to prevent or lessen serious and imminent dangers threats posed by the patient to himself, the public or others
  - Child abuse or neglect
  - Patient information listed in facility directories
  - “De-identified” PHI – if the HIPAA De-Identification Methods are used
The HIPAA Privacy Rule

Disclosures to family, friends or others involved in the care of the individual:

- “Informal” permission can be obtained
- By asking the individual outright, or
- Inferring from the circumstances that the patient did not object
  - In circumstances where the patient had the opportunity to agree, acquiesce, or object, i.e.:
    - Discussing health care information with the patient in the presence of family, friends or others
The HIPAA Privacy Rule

“Serious and Imminent Threat”

- HIPAA defers to the professional judgment of the health care provider in making this assessment.
- HIPAA presumes that the health care provider is acting in good faith, whether relying on his or her actual knowledge or credible information from another who has knowledge and authority.
- OCR states that it will not second guess a health provider’s good faith belief that a patient poses a serious and imminent threat to the health or safety of the patient or others.
The HIPAA Privacy Rule

- After an NPP, there remain certain situations where a subsequent written authorization from the patient is needed.

- Written authorization is required for any disclosure of PHI that is not for treatment, payment or health care operations or as otherwise permitted by the Privacy Rule.
The HIPAA Privacy Rule

Examples of when subsequent written authorization is needed:

- Disclosures of psychotherapy notes
- Disclosures to life insurers for coverage purposes
- Disclosures to an employer to provide the results of a pre-employment physical or lab test
- Disclosures to pharmaceutical firms for their own marketing purposes
- Sale or licensing of PHI
The HIPAA Privacy Rule

- Psychotherapy Notes – A CE or BA must obtain the patient’s written consent to disclose psychotherapy notes

- Defined as: “notes recorded (in any medium) by a health care provider who is a mental health professional documenting the contents of conversation during a private counseling session, or a group, joint or family counseling session that are separated from the rest of the individual’s medical record.”

- Psychotherapy notes do not include “Progress Notes”: “Counseling session start and stop times, modalities and frequencies of treatment furnished, the results of clinical tests, medication prescription & monitoring, and any summary of these: Diagnosis, functional status, the treatment plan, symptoms, prognosis & treatment to date.”
The HIPAA Privacy Rule

Patient Access to Information
- Patients have a right to inspect and receive a copy
- Of their PHI that is contained in a “designated record set”
- A CE must grant or deny access within 30 days of receipt of the request
- Can receive the records in electronic format
- Additional rights under the “Meaningful Use” rules in the Medicare and Medicaid Electronic Health Records (EHR) program
The HIPAA Privacy Rule

“Designated Records Sets”

- A group of records that a CE (or BA, if applicable)
- Maintains to make decisions about individuals
- This includes, but is not limited to:
  - A patient’s medical records
  - Billing Records
  - CE’s are responsible for what records are to be in a designated record set
Amending Patient Information:

- Patients can request amendment or correction of information in their designated record set.
- A CE must honor the request within 60 days after receipt of the request.
  - Unless the CE determines the information in the record is accurate & complete (and so notifies the patient).
  - In which case the patient has the right to file a statement of disagreement that stays with the health record.
The HIPAA Privacy Rule

- Patients have a right to request an accounting of disclosures:
  - Names of persons or entities to whom PHI was disclosed
  - Date on which it was disclosed
  - Description of the PHI disclosed
  - Purpose of the disclosure
  - The accounting of disclosures is for 6 years prior to the date on which the accounting was requested
The HIPAA Security Rule

- Establishes a set of national standards of minimum security requirements for protecting ePHI
- That a CE or BA receive, maintain or transmit
The HIPAA Security Rule

- Security Rule has 4 safeguards/ requirements for CE’s and BA’s
  - **Administrative safeguards** – To prevent, detect, contain & correct security violations
  - **Physical safeguards** – Physical measures to protect electronic information systems and related buildings & equipment from unauthorized intrusion and physical and environmental hazards
  - **Organizational standards** - Require CE’s to have contracts or other arrangements with the BA’s that will have access to ePHI
  - **Policies & Procedures** – Written security policies & procedures and written records of required actions that comply with the provisions of the Security Rule
The HIPAA Security Rule

Other requirements for ePHR and access to it:

- Encryption
- Security of remote access
  - Email
  - Mobile devices such as smartphones, laptops and tablets

The HIPAA Security Rule

- Email and Texting
  - The Security Rule does not apply to the patient
  - But when the patient sends it to a CE or BA, it becomes subject to the Security Rule
  - EHR systems need to be certified under the Office of the National Coordinator for Health Information Technology (ONC)
The HIPAA Security Rule

- HIPAA Security Rule standards govern all forms of electronic media such as
  - Hard drives
  - Floppy discs
  - Compact discs
  - DVDs
  - Smart cards or other storage devices
  - Personal digital assistants
  - Transmission media or
  - Portable electronic media
The HIPAA Security Rule

➢ It is not just the ePHI, but also in:
  ● Practice management systems
  ● Billing
  ● Patient flow (bed management)
  ● Care and case management
  ● Document scanning
  ● Clinical portals
The HIPAA Breach Notification Rule

- “Breach” means an impermissible use or disclosure under the HIPAA Privacy Rule
- An impermissible use or disclosure of unsecured PHI is presumed to be a breach
- Unless the CE or BA conducts a risk assessment and determines that there was a low probability that the PHI was compromised
The HIPAA Breach Notification Rule

- If a breach occurs, a CE or BA is required to:
  - Notify affected individuals
  - Notify the Secretary of HHS, and
  - In some cases, the media must be notified
The HIPAA Breach Notification Rule

- Health care providers must notify HHS promptly if a breach affects 500 or more individuals.
- If a breach affects less than 500, providers must notify HHS no later than 60 days after the end of the calendar year in which the breach occurs.
- If the breach affects more than 500 in the same state, the media must also be notified.
- Breaches that are determined to be significant are investigated by the HHS OCR.
The HIPAA Breach Notification Rule

- Breaches that affect more than 500 are also reported on the OCR website:
- Breaches are kept on the OCR website for the last 2 years
- Currently
  - Oregon has 8 breaches listed, 3 already in 2019
    - From hacking, theft, unauthorized access and loss of records
    - From email, laptop, desktop, network servers and paper records totaling 48,876 records
    - Largest breach of Legacy Health in 2018, involving 38,000 records
  - Washington has 6 breaches listed, 3 already in 2019
    - All from hacking of email and network servers
    - Totaling 1,413,001 records
    - Largest breach was Univ. of Washington Medical Center in 2018 involving 973,024 records
The HIPAA Breach Notification Rule

- Violations can result in civil or criminal penalties
- Violations have different penalties for each of 4 levels of culpability:

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<thead>
<tr>
<th>Intent</th>
<th>Per Incident</th>
<th>Annual Cap</th>
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<tr>
<td>- Did not know or could not Have known</td>
<td>$100-$50,000</td>
<td>$1.5 Million</td>
</tr>
<tr>
<td>- Reasonably should have Known but not willful neglect</td>
<td>$1,000-$50,000</td>
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<tr>
<td>- Willful neglect (corrected Within 30 days)</td>
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<tr>
<td>Willful neglect (not corrected Within 30 days)</td>
<td>$50,000</td>
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Remaining Issues

- **Impact of the opioid crisis**
  - “We…find ourselves in the complicated situations of people in our behavioral health services not being able to effectively communicate with people in our primary care and dental services” [James Wilson, Quality & Data Manager, Clackamas Health Centers, quoted in Sep. 1, 2018 Bend Bulletin article]
  - Multiple cases of patients with addictions being prescribed opioids by primary care doctors or dentists in the same general health clinic who had no idea the patients were also in substance abuse treatment in a program within the same facility (same Bend Bulletin article)

- **Growing push**
  - Toward interoperability between health care systems
  - That may lessen patient protections
Remaining Issues

- The “Protecting Jessica Grubb’s Legacy Act”
  - Young West Virginia woman who died in 2016 from an opioid overdose
  - Was in recovery from an opioid addiction but following surgery was sent home from the hospital with a prescription for 50 oxycodone pills, overdosed that night and died
  - Sen. Joe Manchin’s statement:
    “The 42 CFR Part 2 regulations govern the confidentiality and sharing of substance abuse disorder treatment records within our healthcare system. Unfortunately, at a time when we are working toward greater care coordination, this regulation has acted as a barrier to communication between healthcare providers serving individuals with substance use disorders and has created silos of medical care, which can compromise both the quality of care and patient safety. Simply put, it has left patients at greater risk of overdose death and made it harder for them to access quality health care.”
  - Introduced in the U.S. Senate Sep. 25, 2017
Remaining Issues

- SUPPORT for Patients & Communities Act (Pub. L. 115-271)
  - Rep. Greg Walden of Oregon sponsored bill
  - Omnibus compilation of 116 bills related to Substance Use Disorder and the recent opioid crisis
  - Became law Oct. 24, 2018
  - Incorporated provisions of “The Protecting Jessica Grubb’s Legacy Act” as “Jessie’s Law” in Title VII, Subtitle F of the Act
Remaining Issues

- Overdose Prevention & Safety Act (Reps. Earl Blumenauer of Oregon and Markwayne Mullin of Oklahoma)
  - More expansive provisions for sharing patient information among TPO’s (Treatment, Payment & Health Care Operations), legislatively modifying 42 CFR Part 2
  - Passed the U.S. House and referred to the Senate June 21, 2018
  - But left out of the SUPPORT Act.
  - As a result, more than 220 health care organizations signed a letter dated Nov. 16, 2018 to the Senate Health, Education, Labor & Pensions Committee asking that the Committee help get the Act passed before the end of 2018:

    “Patients are required to give multiple consents, creating a barrier for integration and coordination of health care. A lack of access to the full scope of medical information for each patient can result in the inability of providers and organizations to deliver safe, high-quality treatment and care coordination. The barriers presented by Part 2 can result in the failure to integrate services and can lead to potentially dangerous medical situations for patients.”

  - But it died in committee with the expiration of the term of Congress and will have to be re-introduced
Remaining Issues

- Among the 220 signers of the letter supporting passage of the Overdose Prevention & Safety Act:
  - American Psychiatric Association
  - American Society of Addiction Medicine (ASAM)
  - Hazelden Betty Ford Foundation
  - National Alliance on Mental Illness (NAMI)
  - National Association of Addiction Treatment Providers
  - 5 Oregon medical associations, 3 from Alaska, 4 from Idaho, 7 from Washington & 1 from Hawaii

- One prominent signer was absent from this letter: NAADAC
Addiction professionals remain committed to ensuring the privacy of individuals living with substance use disorders (SUDs). Unfortunately, stigma surrounding addiction still exists and it is critical that our privacy laws protect those seeking treatment. NAADAC, the Association for Addiction Professionals believes that efforts to amend confidentiality laws must be carefully crafted to avoid any unintended consequences for those seeking SUD treatment or the addiction professionals and treatment and recovery support agencies that serve them.

Passage of the SUPPORT for Patients and Communities Act (P.L. 115-271) in the 115th Congress represented a landmark response to the opioid crisis, advancing treatment and recovery initiatives, improving prevention efforts, and bolstering research. The new law also took steps to better coordinate care for individuals with substance use disorders by directing the Department of Health and Human Services (HHS) to:

- Evaluate appropriate circumstances in which patient SUD history should be displayed in medical records;
- Identify how a patient may issue a formal request to include his/her SUD history in records and what constitutes such a request;
- Consider the benefits of displaying SUD information in the same way that other potentially life threatening information, like drug allergies or contraindications, appear; and
- Assess the importance of patient privacy and consent requirements for SUD history disclosure.

This section of the bill, known as Jessie’s Law, represents a responsible approach to delivering care to patients with a history of SUD while preserving patient confidentiality.

During the broader debate, however, many sought to advance a full overhaul of privacy protections for substance use treatment records by advocating for a bill known as the Overdose Prevention and Patient Safety Act. The bill sought to align regulations governing the confidentiality of SUD treatment records (42 CFR Part 2, or “Part 2”) with HIPAA standards. NAADAC maintains strong concerns about this approach, as HIPAA does not require patient consent to share medical records for the purposes of securing healthcare treatment or payment. The bill ultimately was not adopted in the final bipartisan package that became law, but efforts to pass the bill in 116th Congress are expected.

NAADAC remains concerned that efforts to weaken protections for individuals with SUD treatment and recovery history will discourage individuals from seeking SUD treatment due to the perceived risks associated with exposing patient records and other sensitive information. **We ask for support to allow HHS to fulfill its mandate in the SUPPORT for Patients and Communities Act while maintaining the privacy protections of individuals living with SUD. Please reject efforts to advance legislation that seeks to align 42 CFR Part 2, or “Part 2” with HIPAA standards.**
Closing Thought

Given the Interplay Between New Rules Governing 42 CFR Part 2 and HIPAA

How Will We Embrace the Future?