Time to Change 42 CFR Part 2

Separate is Never Equal

My Background

- Distinguished Professor of Science, MIMH
- Medicaid Director
- Practicing Psychiatrist
- Previously - MO Department of Mental Health Medical Director – 20 years

Brief History

- 42 CFR Part 2 was enacted as the Drug Abuse Office and Treatment Act of 1972
  - Intended to encourage people to seek treatment
  - Regulations – Effective August 1, 1975
  - Last revised and updated 1983

- HIPAA was enacted as the Kennedy-Kassebaum Bill of 1996
  - Intended as “administrative simplification”
  - Proposed rule issued 1999
  - Final rule issued 2002
  - Last revised and updated 2013

42 U.S. Code § 290dd–2 - Confidentiality of records

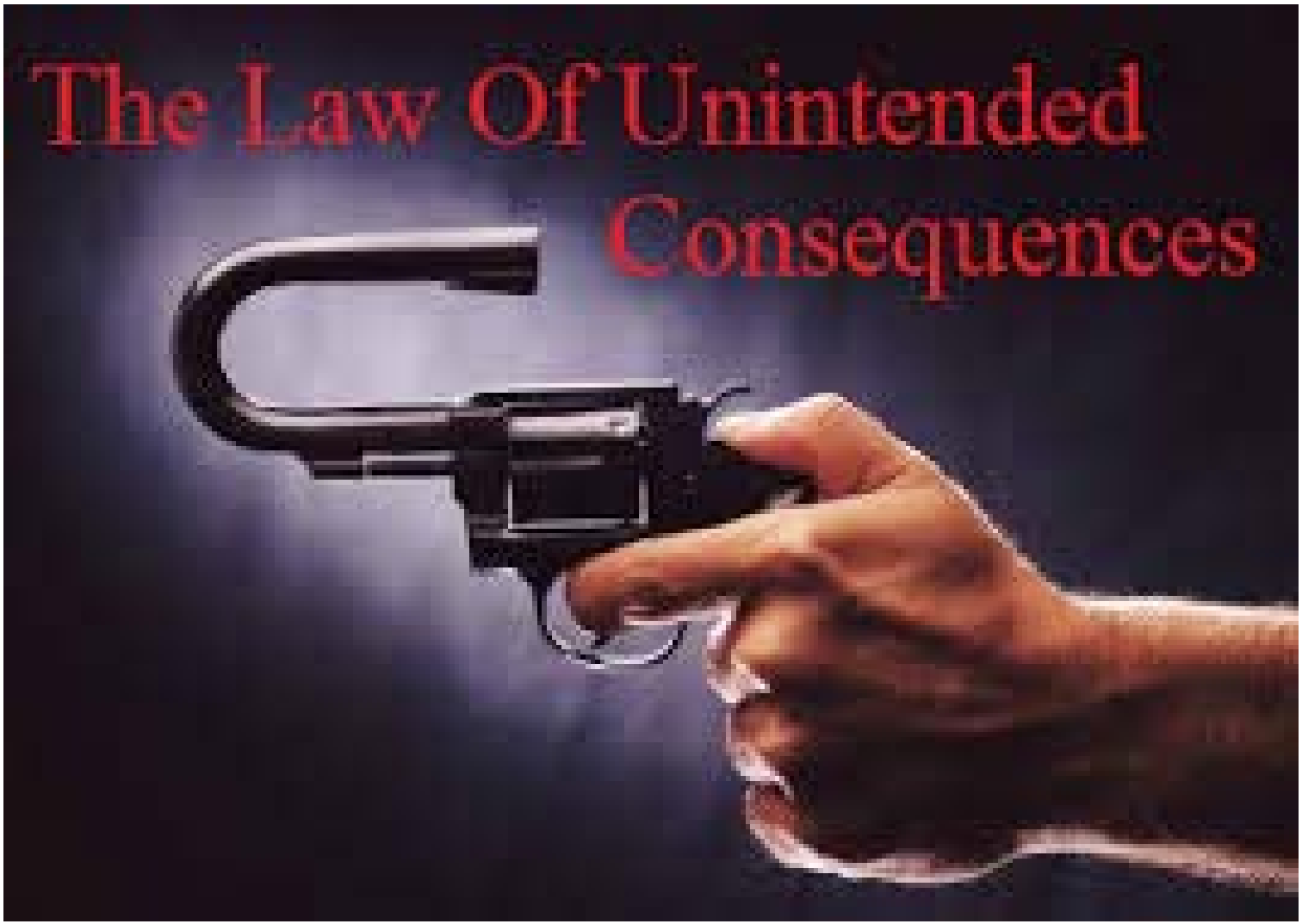
- The Federal Statute behind 42 CFR part 2
- Short and Simple – only 474 words!
- Only 2 Requirements stricter than HIPAA
  - Patient Consent required for all releases of identifiable patient information for treatment except in a medical emergency
  - Prohibits use of patient information for criminal charges or investigation unless there is a substantial risk of death or bodily harm

42 CFR Part 2 is Much More restrictive than Federal Statute Requires

- Consent for a specific purpose
- Consent to a specific organization
- Consent must be time limited
- Consent is limited to minimum necessary for the specific purpose
- Prohibits Re-disclosure

HIPAA is Much Broader

- Allows Disclosure for
  - Treatment
  - Operations
  - Payment
- Allows Disclosure without Consent


The Law Of Unintended
Consequences

Disadvantages Persons with Substance Abuse Disorder

- Have to anticipate what care they will need from who in the future
- Must constantly update expiring consents
- Do not get extra attention and supports
  - That providers give to any patient with a known chronic disorder
  - That Health Care systems arrange for high risk and high utilized patient groups

Disadvantages Substance Use Treatment Providers

- Expense of constantly updating and re-doing consents
- Expense of EMR that can track and manage the complicated 42 CFR Part 2 consent requirements
- Public relations cost of being seen as non-responsive and obstructive by other Health care Providers

Keeps SUD Treatment System Small and Isolated

- General Health Care Providers
  - Less likely to add SUD treatment
  - Less likely to partner or do projects with SUD treatment providers
- Health Information Exchanges all say they will work out later how to manage 42 CFR part 2 and just exclude SUD treatment
- Excludes SUD providers and conditions from care coordination and care management initiatives

Increases Overdose Deaths

- Methadone is reported by the Centers for Disease Control and Prevention to be involved in 30 percent of prescription overdose deaths
- CDC also reports that the death rate from methadone overdoses was 6 times higher in 2009 than in 1999.
- While buprenorphine abuse and overdose deaths are much rarer, they are rapidly increasing in number.

Prescription Drug Abuse

- Prescription drug abuse in general has become a national epidemic.
- While individuals who have received specialized substance abuse treatment are less likely to abuse prescription medications than substance abusers who have not received treatment, they remain more likely to abuse prescription medications.
- Some persons who have received specialty substance abuse treatment relapse to prescription drug abuse and
- Some subsequently die of prescription drug overdoses.

False Promise of Magical IT Solutions and "Segmented Consent"

- IT vendors wanting new contracts say it's "do-able"
- Nobody has done yet
- IT Experts who are not vendors looking for contracts say "Sure, We can do anything….given enough time and money"
  - Who loves SUD treatment enough to give that money?
  - Who has put their initiatives on hold to give the SUD field time to catch up?
  - We will be Billions of dollars short and decades late
- Even if it gets built where are the staff to help patients continuously update their consents? Will Treatment providers re-contact all previous patients for every new regional project and annually to get new consents?

42 CFR Part 2 Makes SUD Patients and Providers Miss Out On

- The better Electronic Medical Records
- Health Information Exchanges
- Prescription Drug Monitoring and Improvement Systems
- Care Coordination
- Population Management

Time for Change

- **Best Option**
  - Repeal Federal Statute 42 U.S. Code § 290dd–2 - Confidentiality of records **except for prohibition on use for investigation or criminal charges**
  - Repeal 42 CFR Part 2
- **Easier Option Revise 42 CFR Part 2**
  - As consistent with HIPAA as Statute allows
  - Applied as narrowly as Statute allows except **for prohibition on use for investigation or criminal charges**

Helpful Changes

- Eliminate all parts of 42 CFR part 2 not required by statute that restrict more than HIPAA Consent for a specific purpose
  - Consent to a specific organization
  - Consent must be time limited
  - Consent is limited to minimum necessary for the specific purpose
  - Prohibition on Re-disclosure
- Incorporate HIPAA definitions and details into new 42 CFR Part 2 by reference to HIPAA wherever possible

Helpful Changes

- Limit 42 CFR Part 2 to substance abuse specialty treatment programs and providers who are specifically licensed, credentialed, or accredited by generally recognized state and national bodies.
- It should not apply to programs and individual treatment providers who have no specialty license, credential,, or accreditation specific to specialty substance abuse treatment.
- This would more clearly define what providers can be considered covered entities.
- It would assure the protected status is only attached to programs and providers that is not a minimum quality standard.
- It is not appropriate to consider a service to be specialty substance abuse treatment unless it is being performed by a provider organization with a specialty credentials.

Helpful Changes

- The regulation should not apply to individual certified or licensed specialty substance abuse treatment providers who are practicing within a larger organization unless the larger organization is also accredited, certified, or licensed as a specialty treatment provider.

- Requiring any healthcare organizations that hires an individual employee with specialty substance abuse treatment credentials to be considered a covered entity is a substantial disincentive for general healthcare organizations to integrate substance abuse treatment services into their predominant treatment operations and significantly restricts integration of substance abuse treatment with general healthcare

Helpful Changes

- Special protections should not apply to the transmission of pharmacy data to Prescription Drug Monitoring Programs (PDPMs)
- Or at least, should not apply to transmitting pharmacy data about the prescription opiates, especially methadone to PDMPs.
- If 42 CFR Part 2 is applied to PDMPs it should only be applied to medications that are used **solely** for specialized substance abuse treatment.

Separate is Never Equal

- Any health information privacy requirements related to substance abuse treatment that differ from the privacy requirements related to general medical care will :
  - Always be a barrier to increasing access to substance abuse services
  - Always be a barrier to the coordination of substance abuse services with the rest of healthcare
  - Always be a barrier to providing high-quality substance abuse treatment in general medical care treatment settings.
  - make it much less likely that persons with substance abuse disorders will receive the additional attention and time required to support continuing remission and identifying early recurrence that is routinely provided for persons with other chronic medical conditions.

42 CFR Part 2 Discriminates Against Persons with SUD and SUD Treatment Providers

- Persons with SUD can't get the same coordination of care, early interventions, protection from medical risks, and extra condition specific supports as a person with Diabetes
- SUD providers end up excluded from the new data driven healthcare world – You're invisible and unworkable if you can't show and share data

“Liability” Through Inaction

- What Liability is there when a provider fails to share patients information and they could have and the patient comes to harm because of unshared information?
- What Liability is there when a provider fails to offer the patient the opportunity to have their information shared and they could have and the patient comes to harm because of unshared information?