Protecting Patient Privacy While Working in an Integrated Care Environment

Changes to CFR 42

My Background

- National Council Senior Medical Adviser
- Distinguished Professor of Science, MIMH
- Missouri 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

So, what is PHI really?

Health information:

- That is individually identifiable
- Relates to past, present, or future health care
- Relates to the person's physical and/or mental wellbeing
- Relates to treatment received/to be received and/or **payment** for that **treatment** and/or **operations** supporting treatment and payment

Individually Identifiable

Based on the information presented, you can reasonably determine the identity of the specific person

Allowable Uses - TPO

Core Health Care Activities for which health information can be used/shared with or without patient consent under HIPAA to avoid unnecessary interference with access to quality health care:

- **Treatment**
- **Payment**
- Healthcare **Operations**

TPO Disclosures Do <u>Not</u> Have To Be Tracked!

Treatment (45 CFR 164.5010)

- Treatment means the
  - provision,
  - coordination, or
  - management
- Of health care and related services by one or more health care providers, including
  - coordination or management of health care by a health care provider with a third party;
  - consultation between health care providers relating to a patient; or
  - referral of a patient for health care from one health care provider to another.

Treatment

- Authorizations are not needed to use or disclose Personal Health Information (PHI) for treatment purposes.
- Treatment, by design, is broadly defined.
- Treatment covers the coordination or management of health care among providers or a third party “related service”.

Treatment

- Treatment includes not just health care, but, also, “related services.”
- “Related services” can include social, rehabilitative or other services associated with health care.
- HHS believes disclosures for treatment purposes are appropriate for timely and quality treatment.

Treatment

- Treatment can only be provided to an individual or particular patient.
- PHI about a prospective patient to a health care provider may be disclosed.
- Minimum necessary disclosure does not apply to treatment.
- Treatment does not generally apply to therapy notes.

Treatment

The following, when undertaken on behalf of a single consumer (not a population) are treatment activities:

- Case management;
- Care coordination;
- Disease management;
- Health promotion; and
- Outreach programs

Health Care Operations

- Quality assessment and improvement,
- Staff evaluation,
- Insurance related activities,
- Administrative functions,
- Business planning and development,
- Business management

Health Care Operations

- Are activities in support of treatment and payment functions.
- Are often population-based activities.
- Covered entities may use any PHI it maintains for its operations.
- PHI may be disclosed without authorization.
- Minimum necessary applies to both requests for and disclosure of PHI.

Health Care Operations

The following, when population-specific rather than individual-specific are health care operations activities:

- Case management;
- Care management;
- Disease management;
- Health promotion; and
- Outreach programs.

Payment

- Payment encompasses the various activities of health care providers to obtain payment or be reimbursed for their services.

Payment

Common payment activities include:

- Determining eligibility or coverage adjudicating claims;
- Risk adjustments;
- Billing and collection activities;
- Reviewing health care services for medical necessity, coverage, etc.;
- Utilization review.

Payment

- Payment can only be related to an individual and the covered entity.
- Covered entities may disclose PHI to any other entity, regardless of its HIPAA status, related to its payment activities for care rendered.
- Minimum necessary applies to disclosure for purpose of payment.

Surprising Truth about Treatment, Health Care Operations, and Payment

- Individuals have the right to request restrictions on how a covered entity will use and disclose PHI about them for treatment, health care operations, and payment.
- A covered entity is not required to agree to an individual's request for restriction, but is bound by any restrictions to which it agrees. (45 CFR 164.522(a))

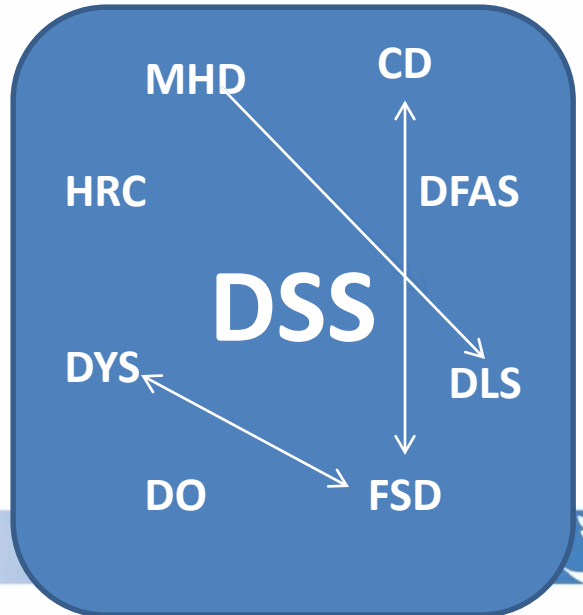
Sharing Information With External Partners

Covered Entity (CE) Status

- A CE must comply with HIPAA.
- A CE is:
  - A health plan;
  - A health care clearinghouse; or
  - A health care provider who transmits any health information in electronic form in connection with a transaction covered by HIPAA.
    - 45 CFR 160.103

Single Covered Entity Status

- When an organization has declared itself to be a single covered entity, PHI may be freely shared among it's components because, in the eyes of HIPAA, the PHI has not been disclosed outside of the covered entity.
- This is sometimes called the "**Bubble Rule**" – information can bounce around freely inside the bubble, but not outside of the bubble.



Business Associate (BA)

- A person/company/firm that *performs a function for the CE* that requires the creation, receipt, maintenance, or transmission of PHI.
- If the function or activity the contractor does involves the use or disclosure of PHI, and is not part of treatment by a health care provider, the contractor is our “business associate”, or BA.
- A BA may also be a CE.
  - 45 CFR 160.103

Business Associate Agreement (BAA)

- Not required for sharing PHI for Treatment
- Only required for Health Operations and Payment
- With the BAA in place, you can disclose the PHI in our possession necessary for them to perform the duty or function you have contracted with them for.

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

Current 42 CFR Part 2 Regulation adds additional Requirements

- 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

42 C.F.R. Part 2 - Generally

- Disclosure of info that identifies patient (directly or indirectly) as having a current or past drug or alcohol problem (or participating in a drug/alcohol program) is generally PROHIBITED,
- UNLESS:
  - Patient consents in writing, or
  - Other exception applies

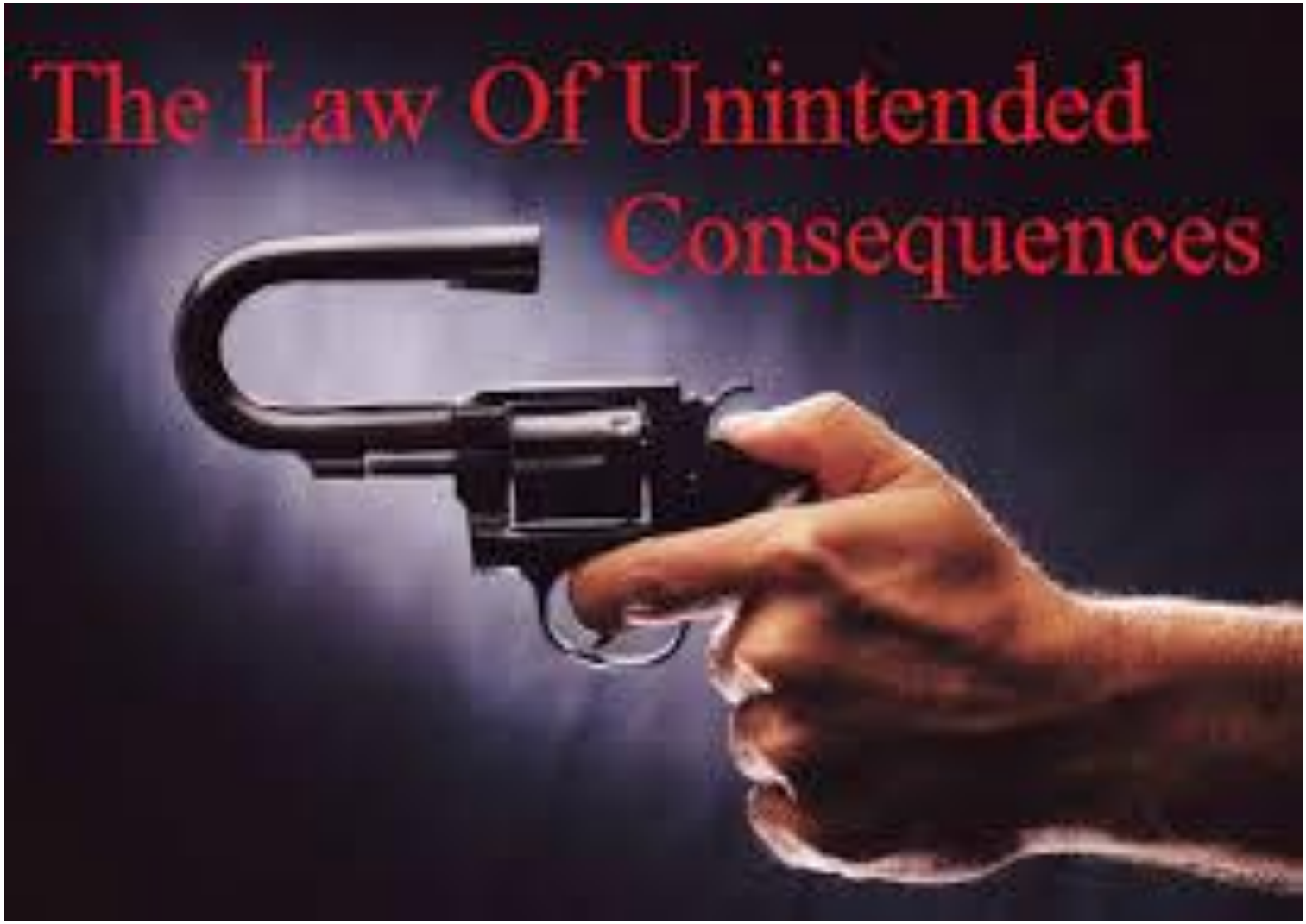
Exceptions to Rule Prohibiting Disclosure

- 10 EXCEPTIONS:
- Written Consent
- Medical Emergency
- Qualified Service Organization Agreement
- Research
- Internal Communications
- Crime on Program Premises/Against Program Personnel
- No Patient-Identifying Information
- Audit
- Court Order
- Reporting Child Abuse/Neglect

HIPAA is Much Broader

- Allows Disclosure for
  - Treatment
  - Operations
  - Payment

- Allows Disclosure without Consent for Treatment


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

Minimizing Harm Due to 42CFR Part 2

- You are not a covered entity if you do not "hold yourself out to the public "as providing substance abuse treatment
- Diagnoses of SUD by providers who do not hold themselves out to the public as treating substance abuse disorders are not subject to 42CFR part 2
- Treatment of SUD by providers who do not hold themselves out to the public as treating substance abuse disorders are not subject to 42CFR part 2
- Treatment of the medical complications of SUD is not the same as treatment of SUD and does not fall under 42 CFR part 2
- Recommendation - provide integrated care that includes substance abuse treatment but **never advertise that you provide substance abuse treatment**

42 CFR part 2 and Medications

- If you don't hold yourself out to the public is providing substance abuse treatment the medication she prescribed do not come under 42 CFR part two
- Only liquid methadone falls under 42 CFR part 2 because it is illegal to use non-liquid methadone for the treatment of opiate dependence

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

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?

Main Points

Proposed Rule amending 42 CFR Part 2:

Proposed Rule – 42 CFR Part 2: Main points

- Consent:
- New option for general designation in “to whom” section of consent form
- Limited to those who have “treating provider relationship” with patient
- Can include past, present, and/or future treating providers
  - Example: Consent to HIE & “all my treating providers” (who are members of the HIE)

Proposed Rule – 42 CFR Part 2: Main points

- Prohibition on re-disclosure remains.
- “From whom” section of consent form would now need to name specific individual/entity.
- New patient right: Can request & receive list of individuals/entities to whom their info has been disclosed pursuant to a general designation consent.

Proposed Rule – 42 CFR Part 2: Main points

- Medical Emergencies

- A patient's SUD info can be disclosed w/o consent to medical personnel to meet a "bona fide medical emergency" in which the patient's prior consent cannot be obtained."

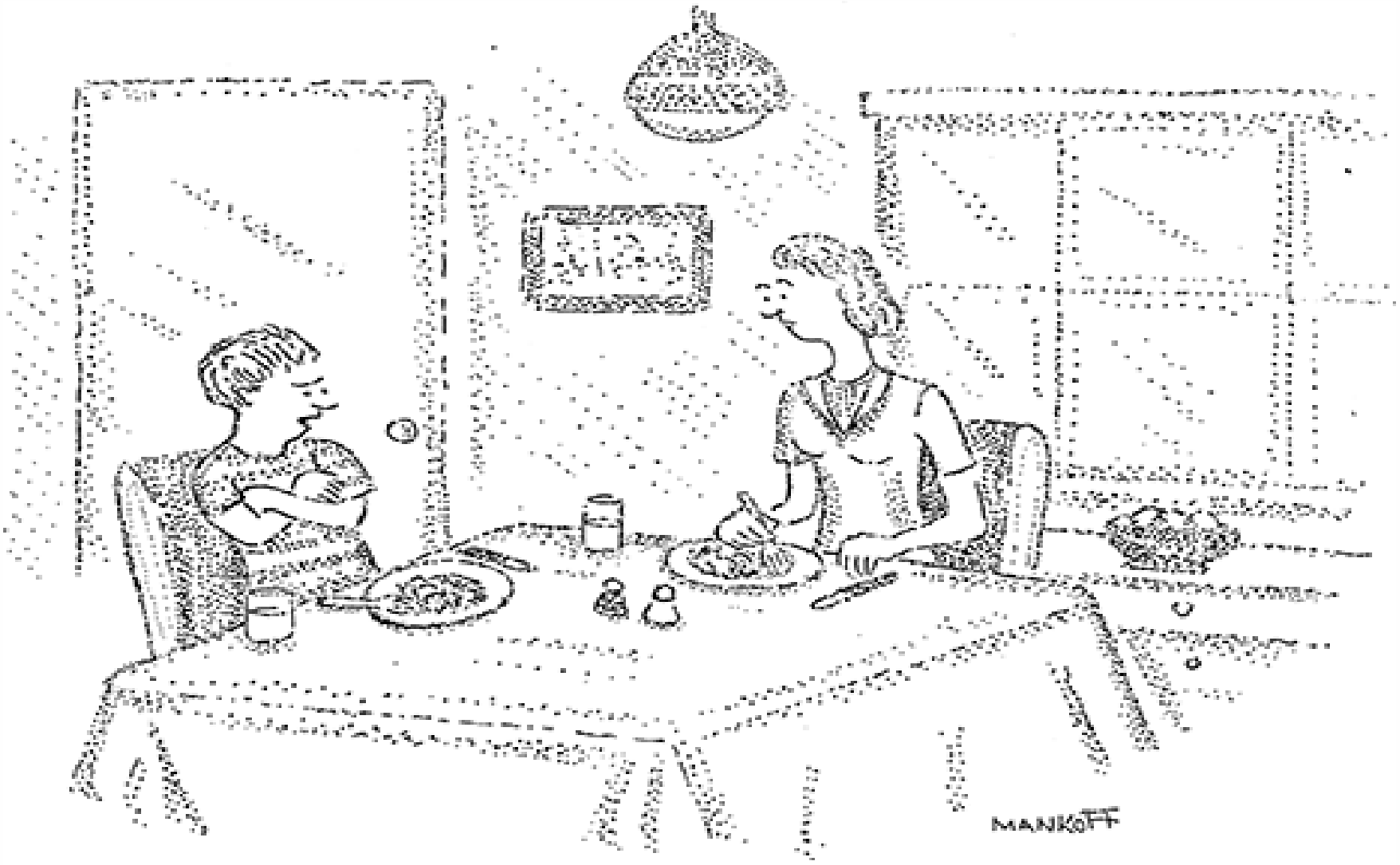
- Currently - SUD information could be disclosed w/o consent "for the purpose of treating a condition which poses an immediate threat to the health of any individual and which requires immediate medical intervention."

Proposed Rule – 42 CFR Part 2: Main points

- Research
- Changes make it more consistent with HIPAA research requirements (e.g., Institutional Review Board).
- Maintains core protections of 42 CFR Part 2 (including prohibition on re-disclosure).

Proposed Rule – 42 CFR Part 2: Main points

- Security of Records
- Updated - more in line with HIPAA.
- Significant Administrative Burdens remain
  - Re-disclosure prohibited (except for Methadone Treatment Registries)
  - New Requirement to provide list of disclosures



"I say it's government-mandated broccoli, and I say the hell with it."