



*Overview of 42 CFR Part 2
and HIPAA*

HIPAA

- Health Insurance Portability and Accountability Act of 1996
- Administrative Simplification Provisions - national standards to facilitate the electronic exchange of health information and to protect the privacy of patient identifying health information

Privacy Regulations - Deadline for Compliance

- Deadline for compliance - April 14, 2003
- Small health plans (annual receipts of \$5 million or less) - deadline for compliance is April 14, 2004

Transactions and Code Sets Regulations - Deadline for Compliance

- Deadline for compliance - October 16, 2002
- Small health plans (annual receipts of \$5 million or less) - deadline for compliance is October 16, 2003
- Extension now available - Covered entity (other than a small health plan) must submit request for extension by October 15, 2002. New deadline if extension granted is October 16, 2003
- Model extension request form and instructions
<http://www.cms.gov/hipaa/hipaa2/default.asp>

42 CFR Part 2

- Confidentiality of Alcohol And Drug Abuse Patient Records
- Also 42 U.S.C. §290dd-2

The Framework of Principles

- **Privacy** is the right of the individual to be left alone.
 - **Confidentiality** is the responsibility for limiting disclosure of private matters.
 - **Security** is the means to control access and protect information from accidental or intentional disclosure.
- * Definitions courtesy of Guardent.

Applicability

42 CFR Part 2

- Federally-assisted Substance Abuse Treatment Programs
- Definition of federally-assisted

HIPAA

- Health Plans
- Health Care Clearinghouses
- Health Care Providers that transmit electronic information

Who is considered a patient?

42 CFR Part 2

- 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 program.

HIPAA

- The person who is the subject of the protected health information
- The individuals and organizations who are subject to HIPAA regulations as a CE or BA.

Protected Health Information

Individually Identifiable Health Information which is:

- Created or received by a health care provider, health plan, employer or health care clearinghouse
- Related to the past, present or future physical or mental health or condition of an individual
- Related to the provision of health care to an individual
- Related to the past, present or future payment for the provision of health care to an individual
- Identifies the individual or there is reasonable basis to believe that the information can be used to identify the individual
- Is transmitted by electronic media or maintained in any medium

Patient Identifying Information

42 CFR Part 2

- Name
- Address
- Social Security Number
- Fingerprints
- Photograph
- Other similar info
- Does not include a number assigned to a patient by a program - different than HIPAA.

HIPAA

- Same: 42 CFR Part 2 PLUS
- Address is defined more broadly
- Names of relatives/household
- Name of employer
- Variety of dates
- Telephone/fax number
- E-mail address/URL/IP
- Medical record number
- Account/health plan number
- Vehicle or other device serial number

Prohibition on Redisclosure

42 CFR Part 2

- Can only disclose pursuant to a consent or other permitted purpose
- Prohibition against redisclosure of information to another - can only disclose to those named in consent
- Must include a written prohibition statement to accompany the consent
- Any recipient of information is subject to the rule and may not disclose the information except as permitted by the rule.

HIPAA

- No specific prohibition against redisclosure
- However, if the entity is a covered entity or a business associate, privacy protections continue to apply

Patient Access to Records

42 CFR Part 2

- No consent nor authorization required
- Also subject to restriction on use 2.23(b)

HIPAA

- Patient has right to access own records
- Exceptions:
 - Psychotherapy notes
 - Information compiled in anticipation of civil, criminal or administrative proceeding
 - Info subject to CLIA or exempt from CLIA

Subpoenas/Court Orders

42 CFR Part 2

- A subpoena alone is not sufficient to release information - a court order is also required - must be issued by judge in accordance with specific procedures and criteria

HIPAA

- Can disclose in response to a court (or administrative tribunal) order only, or a subpoena and court order, or by discovery request or lawful process alone

Patient Rights

42 CFR Part 2

- Patients must be given written summary of confidentiality provisions and notice that Federal law and regulations protect the confidentiality of alcohol and drug abuse patient records.

HIPAA

- Receive notice of covered entity's privacy practices
- Access own information
- Request corrections of erroneous/incomplete information
- Request restriction of uses and disclosures
- Request transmittal of communications in an alternative manner
- Obtain an accounting of disclosures

Child Abuse/Neglect

42 CFR Part 2

- Specific exception allows reporting of child abuse/neglect
- Restrictions on disclosure and use continue to apply to the original alcohol and drug abuse patient records maintained by the program including their disclosure or use for criminal or civil proceedings which may arise out of the report

HIPAA

- Allows a report to appropriate authorities of abuse, including child abuse

Law Enforcement

42 CFR Part 2

- Generally cannot disclose information without subpoena and court order - arrest/search warrant not sufficient
- Can disclose for crime committed by patients on program premises or against program personnel or a threat to commit such a crime

HIPAA

- Can disclose to law enforcement and jails without consent/authorization:
- As required by law
- With a subpoena
- With a warrant
- To locate missing persons
- Victim of crime
- Crime on program premises

Public Health Authorities/Disease Reporting

42 CFR Part 2

- No specific exemption for reporting - need consent, court order, or can report if done anonymously
- Can disclose to FDA if error in manufacturing e.g., labeling or sale of drug used in treatment - exclusive purpose notifying patients and their physicians of potential dangers.

HIPAA

- Authority to disclose to public health authorities for a variety of circumstances without patient authorization

Other HIPAA Privacy Mandates

- Designate a Privacy Officer
- Adopt written comprehensive policies
- Train staff routinely
- Personnel sanctions for breaches
- Establish a grievance process
- Physical safeguards
- Mitigate results of violations
- Minimum Necessary Requirement
- Privacy Notice
- Accounting of Disclosures
- Correction of erroneous/incomplete information

Enforcement, Compliance and Penalties

42 CFR Part 2

- Enforcement - United States Attorney for judicial district in which the violation occurs
- Criminal penalties - not more than \$500 for 1st offense; no more than \$5,000 for each subsequent offense

HIPAA

- Enforcement - HHS' Office of Civil Rights
- Penalties - Civil - \$100/person per violation up to \$25,000
- Criminal - \$50,000/up to 1 year imprisonment for wrongful disclosure
- Intent to sell, transfer or use PHI for gain - \$250,000/up to 10 years imprisonment