

INFORMATION EXCHANGE IN PRESCRIPTION DRUG MONITORING PROGRAMS (PMPS)

LEGAL ISSUES REGARDING ACCESS AND DISCLOSURE

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LAWS**

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- INFORMATION PROVIDED IN THIS DOCUMENT AND PRESENTATION IS FOR EDUCATIONAL PURPOSES ONLY AND DOES NOT CONSTITUTE LEGAL ADVICE OR OPINION.

- **HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) PRIVACY RULE**

- **FEDERAL CONFIDENTIALITY RULE**

- **DETERMINATION OF AUTHORIZED USERS AND RULES OF INFORMATION USAGE**

HIPAA PRIVACY RULE

45 C.F.R. PARTS 160 AND SUBPARTS A AND E OF PART 164

- Addresses use and disclosure of protected health information by covered entities.
- Protected health information (PHI) 45 C.F.R. §160.103.
- General Definition: Individually identifiable health information that is transmitted or maintained electronically or in any other form or medium.

- Covered entities 45 C.F.R. §160.103.
- A health plan, a health care clearinghouse, or a health care provider who electronically transmits health information to carry out financial or administrative activities related to health care covered under HIPAA.
Examples: health care payments, coordination of benefits, health care claims.
- Most PMPs **are not** considered to be covered entities subject to the HIPAA Privacy Rule.
- Dispensers (pharmacists and dispensing prescribers) **are** considered to be covered entities.

- Dispensers must comply with the HIPAA Privacy Rule when disclosing prescription information to PMPs.
- Section 164.512 of the Privacy Rule allows disclosure of PHI without permission of the individual:
 - To certain types of agencies/officials
 - For 12 designated public interest purposes
- PMPs should distribute the collected PMP information to authorized users consistent with the purposes for which the dispenser was allowed to disclose the information to the PMP.

- Public interest purposes under §164.512 applicable to PMP activities:

- (1)Disclosure Required by Law. 45 C.F.R. §164.512(a).

- Legal mandate compels use or disclosure of information and is enforceable in court.

- Examples are statutes or regulations, subpoenas or court orders.

§164.501.

- Authority/agency must be responsible for public health matters as part of official mandate.
- Authority/agency must be authorized by law to collect or receive information for ... public health surveillance, public health investigation, and public health intervention.

(2) Public Health Activities. 45 CFR §164.512(b), (3) Health Oversight Activities. 45 C.F.R. §164.512(d), §164.501.

- Agency must be authorized by law to oversee the health care system or certain government programs or to enforce civil rights for which health information is relevant.
- Agency must use PHI for legally authorized oversight activities.
- Oversight includes audits; civil, administrative, or criminal investigations; inspections; licensure or disciplinary actions; civil, administrative, or criminal proceedings.

(4) Law Enforcement. 45 C.F.R. §164.512(f), §164.501.

- Disclosure to a law enforcement official for a law enforcement purpose under six circumstances, subject to specified conditions.
- Circumstances include disclosures as required by law.
- Law Enforcement Official – officer/employee authorized to investigate or conduct official inquiry into potential violation of law, prosecute or otherwise conduct civil, administrative or criminal proceedings arising from alleged violation of law.

- Disclosures are also allowed for Treatment, Payment, Health Care Operations. 45 C.F.R. §164.506. §164.501.

- Covered entity's own treatment, payment or health care operations.

- Health care operations include:

- (i) quality assessment and improvement activities, including case management and care coordination.

- (ii) fraud and abuse detection and compliance activities.

FEDERAL CONFIDENTIALITY RULE

**U.S.C.A. §290DD-2 and
42 C.F.R. PART 2**

Federal Confidentiality Rule

- **General Rule - §290-dd-2:**

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 or agency of the United States shall, with designated exceptions, be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under this section.

Federal Confidentiality Rule

- **The Federal confidentiality rule shapes the prescription information that a PMP may collect and that is available for distribution to authorized users.**

U.S. Department of Health and Human Services interpretation of the Federal Confidentiality Rule as applied to PMPs:

- Most Dispensers (pharmacists and most physicians or other prescribers) **are not** considered substance abuse treatment programs.
- Most Dispensers may report dispensing information to PMPs.
- Physicians authorized to prescribe narcotic drugs for addiction treatment under the Drug Addiction Treatment Act of 2000 **are substance abuse treatment programs and cannot report the dispensing of the drugs to PMPs.**
- Opioid treatment programs that dispense narcotic drugs (e.g., methadone, buprenorphine) to patients for addiction treatment **are substance abuse treatment programs and cannot report the dispensing of the drugs to PMPs.**

**DETERMINATION OF AUTHORIZED USERS
AND RULES OF USE**

Authorized Users of Shared Information in State Requesting the Information

- Two primary options being discussed by States.
 - ❖ Consensus on categories of authorized users that can access shared PMP information. Usually categories common to the states sharing PMP information. E.g, prescribers, dispensers
 - ❖ Disclosing state determines categories of authorized users in the requesting state that can access PMP information shared by the disclosing state.

Rules of Use of Shared Information in State Requesting the Information

- Two primary options being discussed by States.
 - ❖ Consensus on which usage rules of states sharing PMP information will apply.
 - ❖ Usage rules of state requesting information will apply to PMP information shared by the disclosing state.

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