

**HEALTH INSURANCE PORTABILITY AND  
ACCOUNTABILITY ACT (HIPAA)  
PRIVACY RULE  
AND  
PRESCRIPTION DRUG MONITORING  
PROGRAMS (PMPS)**

- **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.**

- **General Preemption Rule 45 C.F.R. §160.203.**

A standard, requirement or implementation specification preempts a contrary provision of State law.

- **Exceptions Relevant to a PMP That Require A Determination by the Secretary of U.S. Department of Health and Human Services (HHS).**

(1) Provision is necessary (i) to prevent fraud and abuse related to the provision of or payment for health care; or ... (iv) for purposes of serving a compelling need related to public health, safety or welfare... 45 C.F.R. §160.203(a)(1).

(2) Provision has as its principal purpose the regulation of the manufacture, registration, distribution, dispensing or other control of any controlled substance (as defined under federal or state law). 45 C.F.R. §160.203(a)(2).

- **Exception Relevant to a PMP That Doesn't Require a Determination by the Secretary of HHS.**

A provision of state law provides for reporting of disease or injury ...or for the conduct of public health surveillance, investigation or intervention.  
45 C.F.R. §160.203(c).

- **If no exception, use and disclosure of PHI must occur:**

(1) as Privacy Rule permits or requires;

or

(2) as the individual who is subject of the information or the individual's personal representative authorizes in writing

45 C.F.R. §164.502(a).

- **Privacy Rule allows disclosure of PHI without permission of individual for 12 national priority purposes. 45 CFR §164.512  
Several purposes may apply to PMPs.**

- (1) Disclosure Required by Law. 45 C.F.R. §164.512(a).
  - (a) Legal mandate compels use or disclosure of information and is enforceable in court.
  - (b) Examples are statutes or regulations, subpoenas or court orders.
- (2) Public Health Activities. 45 CFR §164.512(b), §164.501.
  - (a) Authority/agency must be responsible for public health matters as part of official mandate.
  - (b) Authority/agency must be authorized by law to collect or receive information for ... public health surveillance, public health investigation, and public health intervention.
- (3) Health Oversight Activities. 45 C.F.R. §164.512(d), §164.501.

(a) 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.

(b) Agency must use PHI for legally authorized oversight activities.

(c) 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.

(a) Disclosure to a law enforcement official for a law enforcement purpose under six circumstances, subject to specified conditions.

(b) Circumstances include disclosures as required by law.

(c) 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.

- **Disclosure is Allowed for Treatment, Payment, Health Care Operations. 45 C.F.R. §164.506. §164.501.**

(a) Covered entity's own treatment, payment or health care operations.

(b) Health care operations include:

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

(ii) fraud and abuse detection and compliance activities.

- **Minimum Necessary**

(a) General Rule: Use, disclosure or

request of PHI limited to that minimally necessary to accomplish intended purpose of the use, disclosure or request. 45 C.F.R. §164.502(b)(1).

(b) Exception applicable to PMP:  
Disclosures or uses required by law under §164.512(a). 45 C.F.R. §164.502(b)(2).

(c) Requirements of HITECH Act

(i) Covered entity in compliance with §164.502(b)(1) only if PHI limited, to the extent practicable, to the limited data set, or if needed, to the minimum necessary to accomplish the intended purpose of such use, disclosure, or request. American Recovery and Reinvestment Act (ARRA), Pub. L. No. 111-5, H.R. 1 (2009), Div. A, Title XIII, Subt. D §13405(b)(1)(A).

(ii) §13405(b)(1)(A) effective until new guidance on minimum necessary issued by Secretary of HHS. Deadline for issuance is August 17, 2010.