



**PRESCRIPTION DRUG MONITORING PROGRAMS (PMPs)
AND
THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)**
(Pub. L. No. 104-191 (Aug. 21, 1996), 45 C.F.R. parts 160 and 164 (HIPAA Privacy and Security Rules))

BRIEF OVERVIEW

A. PMP ≠ COVERED ENTITY

The Privacy Rule of HIPAA applies to the use and disclosure of protected health information (PHI) by a covered entity or business associate (45 C.F.R. §164.502). HIPAA defines a covered entity as a health plan, a health care clearinghouse, or a health care provider who transmits health information electronically in connection with a transaction covered by HIPAA (45 C.F.R. § 160.103). A covered provider may include an institutional provider of services, e.g., hospital, or a non-institutional provider of medical or health services, e.g., physician, dentist, pharmacist (45 C.F.R. § 160.103).

A review of HIPAA’s definitions indicates that a PMP is clearly not a covered health plan or health care provider. A more detailed review reveals that a PMP is also not a health care clearinghouse under HIPAA. A health care clearinghouse for HIPAA purposes is “a public or private entity that processes or facilitates processing of information received from another entity in nonstandard format or containing nonstandard data content into standard data elements or a standard transaction”, or vice versa (45 C.F.R. § 160.103).

Format under HIPAA means “data elements that provide or control the enveloping or hierarchical structure, or assist in identifying data content of, a **transaction**” (45 C.F.R. § 162.103). Data content means “all the data elements and code sets inherent to a **transaction**, and not related to the format of the **transaction**” (45 C.F.R. § 162.103). Data element means “the smallest named unit of information in a **transaction**” (45 C.F.R. § 162.103).

The relevant format, data content, and data elements for HIPAA’s definition of health care clearinghouse are those that pertain to a transaction under HIPAA. A transaction is a “transmission of information between two parties to carry out **financial or administrative activities related to health care**” (45 C.F.R. § 160.103). Eleven information transmissions that HIPAA includes as transactions are (1) health care claims or equivalent encounter information, (2) health care payment and remittance advice, (3) coordination of benefits, (4) health care claim

status, (5) enrollment and disenrollment in a health plan, (6) eligibility for a health plan, (7) health plan premium payments, (8) referral certification and authorization, (9) first report of injury, (10) health claims attachments, and (11) health care electronic funds transfers and remittance advice. HIPAA authorizes the U.S. Secretary of Health and Human Services (Secretary) to identify other types of transactions by regulation (45 C.F.R. § 160.103).

For an entity to satisfy the definition of health care clearinghouse under HIPAA, the entity must process data format, data content, and data elements for the purpose of carrying out financial or administrative activities related to health care. Additionally, the processing must be from non-standard information into standard information, or vice versa. A standard under HIPAA is a rule, condition, or requirement describing certain information for products, systems, services, or practices with respect to the privacy of PHI (45 C.F.R. § 160.103). A standard transaction is an information transmission to carry out financial or administrative activities related to health care that satisfies a standard adopted by the Secretary (45 C.F.R. § 162.103).

A PMP collects, maintains, and discloses information for multiple public health and safety purposes:

- Support access to controlled substances for legitimate medical purposes;
- Facilitate detection and deterrence of diversion of controlled substances;
- Identify and create opportunities for intervention with individuals who may be abusing or are addicted to prescription controlled substances; and
- Inform public health initiatives by outlining drug trends.

No PMP transmits information to carry out a financial or administrative activity related to health care. The Secretary has issued no regulation identifying the collection, maintenance or disclosure of PMP data as a transaction subject to HIPAA. Additionally, the Secretary has issued no rule, condition, or requirement that governs how states collect, maintain, or disclose PMP data. A PMP is not a health care clearinghouse for HIPAA purposes and is therefore not a covered entity subject to the Privacy Rule or other requirements, standards, and specifications of HIPAA.

B. PMP ≠ BUSINESS ASSOCIATE

(1) A person may become a business associate under HIPAA by creating, receiving, maintaining, or transmitting PHI, **on behalf of a covered entity**, for a function or activity regulated by HIPAA (45 C.F.R. § 160.103). A person includes a public or private entity. A function or activity is a **financial or administrative activity related to health care** and includes (1) claims processing or administration; (2) data analysis, processing or administration; (3) utilization review; (4) quality assurance; (5) certain patient safety activities; (6) billing; (7) benefit management; (8) practice management; and (9) repricing (45 C.F.R. § 160.103).

A PMP takes no action regarding PMP data as an agent, contractor or other representative of a covered entity. A PMP takes no action regarding PMP data on behalf of a covered entity.

A PMP collects, maintains, and discloses PMP data to fulfill its legal requirements under state law and regulation. Additionally, a covered entity has the authority to define the scope and nature of what someone does on its behalf. Such details of scope are described in a legally binding agreement. A covered entity has no authority to control how a PMP collects, maintains, and discloses PMP data. Such parameters of PMP data processing are controlled by the statutes and regulations that govern the activities of the PMP. A PMP is therefore not a business associate as that role is described in this subsection.

(2) A person may also become a business associate under HIPAA by providing **certain services** to or for a covered entity. The services must involve the disclosure of PHI from the covered entity, or from another business associate of the covered entity, to the person (45 C.F.R. § 160.103). HIPAA **specifically delineates the services** that a person must provide to qualify as a business associate: (1) legal, (2) actuarial, (3) accounting, (4) consulting, (5) data aggregation, (6) management, (7) administrative, (8) accreditation, or (9) financial (45 C.F.R. § 160.103).

Data aggregation means the combining of PHI from multiple covered entities for whom the person serves as a business associate. The data combining is done on behalf of the multiple covered entities to assist with their quality assessment and improvement, underwriting, premium rating, cost-management, business management and general administration, and other health care operations identified under HIPAA (45 C.F.R. § 164.501).

A PMP provides none of the delineated services that a business associate under HIPAA must provide and is therefore not a business associate as that role is described in this subsection.

A PMP collects, maintains, and discloses PMP data pursuant to state statute and rule. The activities of a PMP are designed to benefit the public through achievement of one or more public health and safety goals. As members of the public, covered entities undoubtedly reap benefits for their individual operations. However, the individual benefits resulting from a PMP's public activities does not transform a PMP into a business associate for any individual covered entity.

For questions or more detailed discussion about the information in this brief overview, please contact Sherry L. Green, President, NAMSDL, by email at sgreen@namsdl.org or by phone at 505-692-0457 (cell).

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