

## State Prescription Drug Monitoring Programs And HIPAA Privacy Requirements

HIPAA regulations are very detailed and specific in their definition of actors, what information is affected, what types of disclosure are being discussed, and what procedures must be followed. This brief overview is not intended as legal guidance or to provide a roadmap to HIPAA/PMP interplay. Rather, it is intended to provide a sketch of how HIPAA regulations may affect PMP operations.

- **HIPAA Privacy Regs., generally:** HIPAA regulations limit under what circumstances and to what extent individually identifiable information can be disclosed by “**covered entities**” -- health plans, health care clearinghouses (entities that transform nonstandard health care data into standard data and vice versa) and health care providers (which includes **providers and dispensers**). **45 CFR §160.103**
- **HIPAA-PMP privacy issues** arise because state Prescription Drug Monitoring Programs (“PMPs”) typically require a variety of players, including providers and dispensers, to transmit detailed health care information regarding individuals to the state PMP.
- Although the PMP is not a covered entity subject to HIPAA privacy rules, providers and dispensers who are required under state PMP laws to provide information to the PMP, are covered entities subject to HIPAA, so **State PMP requirements may potentially be in conflict with HIPAA privacy rules** that apply to **providers and dispensers**. In other words, disclosure of information under State PMP laws by providers or dispensers may place those parties in violation of HIPAA.
- **HIPAA Preemption Rule, generally:** HIPAA expressly provides that its provisions preempt any contrary provisions of state law, unless one or more listed conditions are met. So, if a state PMP law requires disclosure that is not permitted under HIPAA, HIPAA will preclude providers and dispensers from complying with such state PMP requirements. **45 CFR §160.203**

There are two categories of exceptions to this preemption rule – those requiring a predetermination by HHS that the exception applies, and those that do not require such a determination.

- **Relevant Exceptions to HIPAA Preemption, subject to HHS determination:** These include an HHS determination that the provision of state law:
  - is necessary (i) to prevent fraud and **abuse related to the provision of . . . health care**; or (ii) for the purposes of serving a **compelling need related to public health**; **45 CFR §160.203(a)(1)** or
  - Has as its principal purpose the **regulation of the . . . distribution, dispensing or other control of any controlled substance** (as defined under federal or state law). **45 CFR §160.203(a)(2)**

These are effective only once HHS determination is obtained.

- **Relevant Exception to HIPAA Preemption, not requiring HHS determination:**
  - Provision of State law provides for **reporting of disease or injury . . . or for the conduct of public health surveillance, investigation or intervention. 45 CFR §160.203(c)**
- **There are no blanket exceptions:** The exceptions are intended to apply to individual requirements of HIPAA. Since state PMP's typically cover a large range of activities, to determine whether HIPAA compliance is required by covered entities disclosing information to the PMP, a state PMP needs to find exceptions for each aspect of its operations (such as monitoring of fraud or abuse; criminal referrals or assistance with criminal investigations; disciplinary action by a licensing board; treatment/referrals for treatment, etc.). **45 CFR §160.203**
- **Where no exceptions apply:** In this case HIPAA privacy rules will apply to all disclosures by covered entities (including providers and dispensers) to a state PMP. HIPAA has different rules and limitations depending mostly on the purpose of the disclosure and who's requesting the information. If a PMP requires disclosure for multiple purposes where there is no HIPAA exception, then the **disclosure must comply with HIPAA disclosure provisions applicable to each type of intended use. Requirements range** from obtaining the individual's **pre-authorization (45 CFR §164.508)**, to giving the individual the **right to object (45 CFR §164.510)**, to **no authorization required (45 CFR §164.512)**. A listing of provisions where no authorization is required, most likely to apply to disclosure to a PMP, follows:
  - **Disclosure required by law.** A mandate contained in law compels an entity to make a disclosure, and is enforceable in a court of law (including civil or authorized investigative demand, and regulations that require the production of information). (Appears to be limited to child abuse situations, judicial or administrative proceedings, or **disclosures for law enforcement purposes.**) **45 CFR §164.512(a)**
  - **Public Health Activities.** Disclosure must be to an **agency or authority** responsible for **public health matters as part of its official mandate**, if the public health authority is authorized by law to collect or receive such information **for the purpose of** preventing or controlling disease, . . . and the **conduct of public health surveillance, public health investigations, and public health intervention. 45 CFR §164.512(b)**
  - **Health Oversight Activities.** Disclosure must be to an **agency or authority authorized by law to oversee the health care system** (whether public or private) or **government programs in which health information is necessary to determine** eligibility or **compliance . . . . 45 CFR §164.512(d)**
  - **Law Enforcement.** Disclosure for law enforcement purpose **to law enforcement official** "as required by law including laws that require reporting of certain types of . . . injuries . . .", but "**law enforcement purpose is limited** to "investigation or conduct of an official inquiry into a potential violation of law . . . ." **Treatment purposes.** Disclosures permitted for covered person's

own treatment, payment or health operations, for treatment activities of a health care provider, and for health care operations activities of the entity that receives the information (if the recipient has a relationship with the individual whose information is being released). **45 CFR §164.506**

- **Minimum Necessary Rule.** With respect to all of the above disclosures, except the “required by law” provision, the **covered entity must make reasonable efforts to limit disclosed information** to the “minimum necessary to accomplish the intended purpose of the . . . disclosure.” **45 CFR §164.502(b), §164.514 (d)(3)(i)**