

PBM Regulations

Pharmacy benefit managers (PBMs) are regulated by each state in which they operate and must comply with state licensing requirements. While it may vary from state to state, PBMs may be licensed and regulated as third-party administrators (TPAs) and/or utilization review agents (URAs) in appropriate states. In addition to licensing requirements, federal HIPAA and state privacy requirements also apply because PBMs act as business associates of their covered entity clients.

PBMs in Texas:

PBMs are not insurance companies; they are third-party administrators (TPAs). Typically, they do not sponsor benefit plans for an enrolled population but rather primarily perform certain services for health plans and employers. The Texas Department of Insurance (TDI) is authorized under Chapter 4151, Texas Insurance Code, to license and regulate PBMs as administrators. These provisions are geared more toward basic financial practices and business controls than toward PBMs' operations.

PBMs are subject to areas of specific oversight. Chapters 843 and 1301, Texas Insurance Code, govern the operation of Health Maintenance Organizations (HMOs) and Preferred Provider Benefit Plans (PPOs) and also provide some regulatory authority over PBMs. Most notable are the sections related to the prompt payment of claims. The law imposes a more stringent standard for timely payment of pharmacy claims than for other medical claims.

TDI regulates PBMs through laws that govern specific pharmacy benefit standards. Chapter 1369, Texas Insurance Code, governs benefits related to prescription drugs and devices and related services. This chapter addresses prescription drug coverage requirements and the regulation of formularies. This includes consumer notice requirements regarding which drugs are on a formulary (covered by the plan), and how those drugs were chosen, and requirements for continuation of coverage when drugs fall off a formulary in the middle of a plan year. An appeals process for coverage denials is also set forth.¹

PBMs Fall Under the Insurance Code and TDI Regulations

The regulatory requirements applicable to HMOs and insurers carry over to any activities delegated to a PBM. Therefore, PBMs' actions relating to network contracting and terminations, network access, use of formularies, payment of pharmacy claims, pre-authorization and utilization review, etc.—in the context of insured members—are subject to the requirements of the Insurance Code and TDI regulations.

The Office of the Attorney General recently issued an opinion highlighting this issue; Opinion No. KP-0036 addresses the responsibilities of a PBM contracting with an HMO or a PPO issuer. The opinion concludes that when an HMO or PPO plan issuer delegates provider contracting to a PBM, the PBM must comply with the applicable notice requirements when terminating a pharmacist or pharmacy provider.

¹Senate Committee on Health and Human Services and Senate Committee on State Affairs Joint Interim Report to the 80th Legislature

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