

Pharmacy Benefit Managers Update

PBM LICENSING AND COMPLIANCE DEVELOPMENTS

Pharmacy Benefit Managers Licensing and Compliance Developments

New York Enacts Legislation Regulating Pharmacy Benefit Managers

New York recently enacted legislation, SB 3762, requiring Pharmacy Benefit Managers (“PBMs”) doing business in New York to register and then become licensed with the New York Department of Financial Services (“DFS”). The law was signed by the Governor on December 31, 2021 and became effective on March 31, 2022. SB 3762 was subsequently amended by SB 7837, which was signed on February 24, 2022 and became effective immediately or otherwise on the effective date of SB 3762. The new law is codified at N.Y. Ins. Law §§ 2901 et. seq. and N.Y. Pub. Health Law § 280-a.

Under the new law as amended, PBMs are required to register with the DFS and pay a fee of \$4,000 by June 1, 2022. The new PBM registration requirement expires on December 31, 2022. Thereafter, all PBMs doing business in New York must be licensed by January 1, 2023, and licenses shall expire 36 months after date of issue. PBMs that fail to become appropriately licensed in New York by January 1, 2023 may be subject to cease and desist orders and/or monetary penalties by the DFS. The DFS has not yet published any information regarding the PBM registration or licensing process on its website.

The new law defines a PBM as “any entity that performs pharmacy benefit management services for a health plan.” “Pharmacy benefit management services” is defined under the law to mean “the management or administration of prescription drug benefits for a health plan, directly or through another entity, and regardless of whether the pharmacy benefit manager and the health plan are related, or associated by ownership, common ownership, organization or otherwise; including the procurement of prescription drugs to be dispensed to patients, or the administration or management of prescription drug benefits, including but not limited to, any of the following:

- i. mail service pharmacy;
- ii. claims processing, retail network management, or payment of claims to pharmacies for dispensing prescription drugs;
- iii. clinical or other formulary or preferred drug list development or management;
- iv. negotiation or administration of rebates, discounts, payment differentials, or other incentives, for the inclusion of particular prescription drugs in a particular category or to promote the purchase of particular prescription drugs;
- v. patient compliance, therapeutic intervention, or generic substitution programs;
- vi. disease management;
- vii. drug utilization review or prior authorization;
- viii. adjudication of appeals or grievances related to prescription drug coverage;
- ix. contracting with network pharmacies; and
- x. controlling the cost of covered prescription drugs.

The new law provides that a PMB has a duty of good faith and fair dealing with all parties and that a PBM has the same duty to a covered individual as the health plan for whom it is performing PBM services that the law also requires PBMs to perform PBM services “with care, skill, prudence, diligence and professionalism.” Additionally, the officers or directors named in the PBM application shall be responsible for the PBM’s compliance with financial services and insurance laws, rules, and regulations in New York.

The new law provides that the Superintendent of the DFS to establish by regulation, minimum standards for issuance and maintenance of a PBM license, including: (1) the conflicts of interest between PBMs and health plans; (2) deceptive practices; (3) anti-competitive practices; and (4) unfair claims practices; (5) pricing models used by PBMs; (6) standards and practices used in creation of pharmacy networks and pharmacy contracting; and (7) protection of consumers. The DFS has not promulgated any regulations yet.

New York is just one of an increasing number of states which have recently enacted legislation regulating PBMs. [See Polsinelli e-alert of January 31, 2021](#) for additional information.

Pharmacy Benefit Managers Licensing and Compliance Services

Polsinelli’s Pharmacy Benefit Managers Team has significant experience representing PBMs and TPAs on a national basis regarding a variety of business and compliance issues. The group includes attorneys who were formerly in-house counsel for TPAs, as well as attorneys who were formerly insurance regulators and members of the Federation of Regulatory Counsel.

Polsinelli’s experience in the pharmacy benefit managers industry is demonstrated by these representative examples:

- National and multi-state PBM and TPA licensing projects.
- Assistance with investigations, market conduct examinations and formal regulatory actions brought by state insurance departments.
- Monitor regulatory and legislative activity affecting our PBM clients and provide periodic reports regarding such activity.
- Maintain licensure as a PBM or TPA through periodic renewal and annual report filings.

To learn more about Polsinelli’s Pharmacy Benefit Managers Licensing and Compliance Services practice, contact a member of the Pharmacy Benefit Managers Licensing and Compliance Services team.

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