New York to regulate pharmacy benefit managers

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Feb. 9, 2022; updated Mar. 3, 2022

In this article

Effective June 1, 2022, pharmacy benefit managers (PBMs) operating in New York must register with the state Insurance Department. Beginning in 2024, PBMs must obtain licenses and adhere to state regulations. Legislation (2021 Ch. 828, SB 3762) enacted on Dec. 31, 2021, amends the state's insurance and public health laws. This GRIST has been updated to reflect subsequent legislation (2022 Ch. 128, SB 7837) — enacted on Feb. 24, 2022 — that further amends the new law.

Health law amendment

New health provisions (N.Y. Pub. Health Law § 280-a) impose "duty, accountability and transparency" on PBMs. Under the 2022 amendment, a "health plan" is defined as an entity for which a PBM provides PBM services "and that is a health benefit plan or other entity that approves, provides, arranges for, or pays or reimburses in whole or in part for health care items or services, to include at least prescription drugs, for a substantial number of beneficiaries who work or reside in New York." Regulations will outline what constitutes "a substantial number of beneficiaries who work or reside in" New York.

A PBM must disclose to health plans any conflicts of interest and the terms and conditions of any contract or arrangement between the PBM and any party relating to the PBM services. In addition, the PBM must disclose any pricing discounts, rebates, inflationary payments, credits, clawbacks, fees, grants, chargebacks, reimbursements or other benefits it receives. The law generally protects proprietary information or trade secrets, except in reports to state regulators.

Health plans also have the right to access financial and utilization information from the PBM. To what extent insurers will share this information with plan sponsors is unclear, although regulations might address this issue.

The law places certain restrictions on requiring prescription drug substitutions and gag clauses. Contracts with pharmacies must include a reasonable process to appeal, investigate and resolve disputes about multisource generic drug pricing. Some PBMs have expressed concern about possible inconsistencies in network composition. Some pharmacies may join the network by agreeing to financial terms but without agreeing to certain quality criteria, such as providing 24/7 patient access or meeting the guidelines of third-party quality assurance organizations.

A statement by Gov. Kathy Hochel observed, “This landmark law creates the most comprehensive regulatory framework in the country for pharmacy benefit managers, increasing transparency for consumers and shedding light on the cost of prescription drugs.”

Regulatory oversight, liability and penalties

A new insurance law section (N.Y. Ins. Law art. 29) retroactively required PBMs to register with the Department of Financial Services (DFS). The 2022 amendments delayed the mandatory registration date to June 1, 2022. The registration requirement will apply to PBM contracts made or renewed on or after that date. As of Dec. 31, 2023, all registrations will expire; PBMs will have to obtain a state license by Jan. 1, 2024.

Insurance and health regulators must develop PBM regulations on prescription drug substitutions, disclosure obligations — including any spread pricing — and appeal processes. While agencies have yet to draft these regulations, they could increase plan sponsor costs in the short run. Issues the regulations may address include:

- Conflicts of interest between PBMs and health plans or insurers
- PBM practices that may be deceptive or anti-competitive or involve unfair claims processing
- Pricing models
- Standards and practices used in creation of pharmacy networks and contracting with network pharmacies
- Consumer protections
- Compliance verification procedures
- Minimum registration and licensing standards

DFS has the authority to suspend or revoke a registration or license or issue penalties for violations. In addition to any penalties for noncompliance levied by state regulators, the law gives pharmacies and plan participants the right to sue a PBM for restitution and compensatory damages up to $4,000 for the first violation of the law and $10,000 for subsequent violations, or (if greater) the aggregate economic gross receipts attributable to all violations.

Reporting

Annual reports due by July 1 must disclose to state regulators:

- Any pricing discounts, rebates, reimbursements and other financial incentives the PBM receives
- The terms and conditions of any contract or arrangement, between the PBM and any other party relating to PBM services provided to a health plan, including dispensing fees paid to pharmacies

Regulators may ask for additional quarterly reports.

Mail-order reimbursement

Additional legislation (Ch. 827, SB 3566) effective when enacted on Dec. 31, 2021, clarifies reimbursement amounts group health insurers pay to non-mail-order network pharmacies under the state's any willing pharmacy law (N.Y. Ins. Law § 3221(18)(A)). A plan must apply the same benchmark index — including the same average wholesale price, maximum allowable cost and national prescription drug codes — to reimburse all participating network pharmacies, whether mail-order or not. This law does not apply directly to PBMs but to insured health plans in New York.

Like some other provisions, these protocols may increase plan costs by 3%–5% (or more in some cases), depending on utilization. Mail-order costs are typically lower than retail pharmacy costs, so a plan with higher mail-order utilization could see higher costs due to the required parity in retail and mail-order reimbursements.

Plan sponsor considerations

These laws don't apply directly to self-funded ERISA plans. However, some PBM changes to comply with SB 3762 and any ensuing regulations could affect a plan sponsor's prescription drug coverage, whether insured or self-funded. These potential changes may not only increase transparency but also increase administrative costs. PBM regulation has grown among states after a 2020 US Supreme Court decision holding ERISA does not preempt a state law regulating PBM pharmacy reimbursements (*Rutledge v. Pharm. Care Mgmt. Ass'n*, 140 S. Ct. 474 (2020)). Affected plan sponsors will want to discuss the impact with their PBM and factor into their medical plan any potential changes in cost or coverage.

Related resources

Non-Mercer resources

- 2021 Ch. 828, SB 3762 (New York Senate, Feb. 24, 2021)
- 2021 Ch. 827, SB 3566 (New York Senate, Dec. 31, 2021)

- N.Y. Public Health Law § 280-a
- N.Y. Ins. Law art. 29
- N.Y. Ins. Law § 3221(l)(18)(A)

Mercer Law & Policy resources

- Mercer, ERIC provide more input on CAA prescription drug reporting (Jan. 28, 2022)
- Roundup of selected state health developments, fourth-quarter 2021 (Jan. 21, 2022)
- States seek to rein in Rx costs and pharmacy benefit managers (Oct. 26, 2021)
- Top 10 compliance issues for health, fringe and leave benefits in 2022 (Sept. 7, 2021)
- Supreme Court upholds Arkansas law regulating PBMs (Dec. 10, 2020)

Other Mercer resources

- Managed pharmacy consulting

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