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Pennsylvania Enacts PBM Law

Pennsylvania is the latest state to pass legislation aimed at regulating pharmacy benefit managers (PBMs) with House Bill 1993 (HB 1993), which was signed into law by Governor Shapiro on July 17, 2024. The law generally becomes effective on **November 14, 2024**.

HB 1993 governs disclosure, reporting, and contractual requirements for PBMs doing business in Pennsylvania. It will also have some effect on insurance carriers and the administration and design of fully insured medical plans offered in the state that are subject to Pennsylvania's insurance laws. The law expressly excludes self-insured: (i) ERISA plans, (ii) non-federal governmental entity plans, and (iii) church plans.

This Alert summarizes HB 1993, with a focus on those provisions most likely to impact employer-sponsored coverage. This Alert is relevant to employers offering fully insured prescription drug benefits to Pennsylvania residents.

Summary of the law

HB 1993 fully goes into effect 120 days after being signed into law for an effective date of November 14, 2024**.** This means HB 1993's provisions impact fully insured group health plan policies approved, amended, or renewed in Pennsylvania after November 14, 2024, and any corresponding pharmacy contracts.

HB 1993, also known as the Pharmacy Benefit Reform Act, amends Pennsylvania's existing Pharmacy Audit Integrity and Transparency Act of 2016 ("the 2016 Act"). Taken together, the existing 2016 Act and the provisions enacted under HB 1993 are referred to in this Alert collectively as "the Act."

HB 1993 adds new rules governing PBM relationships with pharmacies as well as certain rules directed at health insurers that are applicable to fully insured group health plans. As a result of these changes, existing policies and contracts will likely need to be amended for any renewal dates that fall after November 14, 2024.

HB 1993 expressly provides that the Act does not generally extend or intend to extend to self-insured ERISA plans, nor to self-insured non-federal governmental entity or church plans that are exempt from ERISA. This express exclusion is a departure from other recent state PBM laws.

Highlights

Overview

Pennsylvania HB 1993 goes into effect on November 14, 2024.

The law will have some effect on the administration and design of fully insured medical plans offered in Pennsylvania that are subject to the state's insurance laws. HB 1993 expressly excludes self-insured plans.

This Alert is most relevant to employers offering fully insured prescription drug benefits to Pennsylvania residents.

Key provisions

The most significant requirements affecting coverage include:

- Required pass-through for manufacturer rebates;
- Network adequacy standards;
- A prohibition on mandatory mail order programs; and
- Limitations on steering to specific pharmacies.

Employer action items

- Confirm with the applicable insurance carrier(s) and/or pharmacy benefit manager(s) that insurance policies and contracts will comply with HB 1993; and
- Confirm that any changes will be communicated to plan participants in the appropriate form and manner.

The Act still requires any PBM or "auditing entity" conducting business in the state to comply with the 2016 Act's existing licensure requirements,[1] which applies whether those entities perform services for fully insured or self-insured plans. As defined under the Act, an auditing entity includes an insurance carrier, other third-party administrator (TPA), or managed care organization that performs a pharmacy audit in the state on behalf of a plan. This lone exception to the Act's broad exclusion for self-insured plans requires PBMs and auditing entities to register with the state and should have no meaningful impact on the plans themselves.

Key provisions affecting group health plans

Although a number of the provisions in HB 1993 are limited to internal PBM operations and interactions with pharmacies, HB 1993 will have some effect on fully insured employer-sponsored health plans providing prescription drug benefits. HB 1993 follows the trend for state PBM legislation[2] and contains many of the same requirements recently enacted in other states (e.g., Florida, Idaho, and Kentucky), so some of the following provisions may look familiar:

- **No cost sharing clawback:** A PBM and/or plan cannot charge a participant for any difference in the cost sharing paid by the participant to a pharmacy and the applicable cost sharing defined under the plan.
- **95% pass through of Rx manufacturer rebates:** For contracts delegating the negotiation of rebates to the PBM, PBMs must pass at least 95% of all Rx manufacturer rebates through to the plan.
- **Network adequacy:** The PBM contract must include a reasonably adequate and accessible retail pharmacy network for convenient access to pharmacies within a reasonable distance from a covered person's residence. This network cannot be limited solely to PBM-affiliated pharmacies and must meet or exceed the federal requirements to access covered drugs. In addition, each registered PBM is required to submit an annual network adequacy report to the state beginning April 1, 2026.
- **Mail order limitations:** A covered person cannot be required to utilize mail order delivery to receive prescription drugs. Mail order and delivery options can be available as a choice for covered individuals as long as they are permitted to opt out at any time. Auto-enrollment is permitted for maintenance medications, but not during the first 90 days of a maintenance medication, and a participant must be able to opt-out at any time.
- **Limits on steering**: Health insurers and PBMs are prohibited from certain activities limiting consumer choice of pharmacies, including the following activities:
  - Requiring participants to obtain prescription drugs exclusively through a mail-order pharmacy or PBM-affiliated retail pharmacy.
  - Requiring participants to obtain specialty drugs exclusively through a specialty pharmacy unless the specialty drug meets the definition of a specialty drug under the Act.
  - Prohibiting or limiting a covered individual from selecting an in-network pharmacy of the individual's choice.
  - Requiring covered individuals to use a PBM-affiliated retail pharmacy or using financial incentives to the exclusive benefit of a PBM-affiliated retail pharmacy.
  - Auto-transferring a prescription to another pharmacy unless expressly authorized by the covered individual.
  - Auto-enrolling covered individuals into a mail order pharmacy (except for certain maintenance medications, but only after 90 days and only if the individual can opt out of mail order at any time).

[1] Section 102(3) of HB 1993 provides: "Except for the provisions of Chapter 5, this Act shall not apply to a self-insured health benefit plan subject to ERISA or exempted from ERISA under Section 4(B) of ERISA." Presumably, the inclusion of this statement means that even PBMs and auditing entities affiliated only with a self-insured plan must continue to register with the state under Chapter 5 of the 2016 Act.

[2] Over half the states have enacted laws regulating PBMs in the past three years. More information on state PBM legislative action is available from the National Academy for State Legislative Policy here.

Penalties

Violation of HB 1993's requirements may result in fines or penalties imposed by the Pennsylvania Insurance Department (PID) of up to $100,000 for each violation (capped at $1,000,000 per year), in addition to suspension or revocation of a covered entity's license. These penalties can apply to PBMs, insurance carriers, and auditing entities. They do not apply to employer/plan sponsors.

Affected insurance policies

As written, the law only appears to affect fully insured plans subject to Pennsylvania insurance law.[3] This generally means insurance policies sitused or domiciled in Pennsylvania, but this is a determination that should generally be made by the insurance carrier.

With the lone exception of the registration requirement for PBMs and auditing entities discussed earlier, HB 1993 does not affect self-insured:

1. ERISA plans,
2. Non-federal governmental entity plans (including state, local, and certain tribal government plans); and
3. Church plans.[4]

Other ongoing PBM litigation

In general, ERISA preempts (i.e., blocks enforcement of) state laws that regulate self-insured ERISA plans. The U.S. Court of Appeals for the 10th Circuit determined that ERISA preempted portions of a similar PBM law passed in Oklahoma affecting network access and design (including limitations affecting mail order) intended to affect both fully insured and self-insured coverage.[5]

Oklahoma's Attorney General appealed the 10th Circuit's ruling to the U.S. Supreme Court on May 10, 2024. As of the date of publication, the U.S. Supreme Court has not yet agreed to hear the case, but the decision to hear or deny the appeal will provide additional guidance. A denial is implicit endorsement of the 10th Circuit's decision. If the U.S. Supreme Court does agree to hear the case, we do not expect a decision before next year.

Pennsylvania's PBM law avoids this issue by excluding self-insured ERISA coverage and should not be affected by this ongoing PBM litigation.

Employer action items

We recommend employers sponsoring fully insured medical plans providing prescription drug benefits to Pennsylvania residents seek the assistance of appropriate advisors to confirm the applicability of the new requirements under HB 1993, and assist with the action items described below, which may include a broker and/or pharmacy benefit subject matter expert, consulting firm and legal counsel.

1. Confirm with insurance carrier(s) and/or PBM(s) whether insurance policies and contracts are subject to HB 1993 and will comply by the applicable due date (see note below); and

[3] The provisions affecting plan design and administration apply when a PBM is acting on behalf of a "Health Insurer Client," which is generally an insurance carrier licensed by Pennsylvania to offer prescription drug coverage subject to Pennsylvania's insurance laws. See Sections 601(A) and 103 of the Act (HB 1933 did not revise the definition of Health Insurer found in the 2016 Act).

[4] Section 102(3) of HB 1933, which also cites ERISA Section 4(b). ERISA Section 4(b) includes additional exclusions of lesser significance.

[5] Pharmaceutical Care Management Association v. Mulready, 78 F.4th 1183 (10th Cir. 2023). The district court earlier ruled that ERISA did not preempt any portion of Oklahoma's law, and PCMA appealed the ERISA preemption ruling for four provisions. The district court did rule that several provisions were separately preempted by Medicare Part D, which may be why PCMA limited its ERISA preemption appeal.

2. Confirm that any changes will be communicated to plan participants in the appropriate form and manner.

Note: While HB 1993 appears to apply to PBMs, pharmacies, and health insurers beginning on November 14, 2024, without regard to any actual PBM contract period, it only applies to group health plans for policies and contracts entered into, offered to, issued to, or renewed with fully insured group health plan sponsors after November 14, 2024.

About the author

Andrea Sokolich, J.D., M.P.H. is a Compliance Consultant in the Employee Health & Benefits Compliance Center of Excellence for Marsh McLennan Agency.

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