State Update: New York Releases Major Market Conduct Regulations for Pharmacy Benefit Managers

On November 21, the New York Department of Financial Services (DFS) announced sweeping market conduct regulations for pharmacy benefit managers (PBMs) serving health plans in the state. The DFS rule implements a landmark 2021 bill, S. 3762/A. 1396, which imposed restrictions on PBM contracts with health plans and pharmacies and established consumer protections. This action follows previous DFS rulemaking that created a broad definition of pharmacy benefit management services, required PBMs operating in the state to obtain a license, and established annual reporting requirements.

The DFS rule establishes standards for pharmacy network contracts, creates pharmacy network and formulary transparency requirements, prohibits certain activities that may harm consumers, and establishes protections for pharmacies subject to an audit. The rule also requires parties to obtain permission from the DFS before acquiring a licensed PBM. Finally, the DFS applied the rule to self-insured health plans regulated under the Employee Retirement Income Security Act (ERISA).

Below are additional details on these provisions:

Pharmacy Network Contracts:

PBMs are prohibited from:

1) Reimbursing in-network unaffiliated pharmacies at a lower rate than affiliated pharmacies for the same covered service.
2) Retroactively denying a claim or reducing reimbursement after adjudicating and paying a claim unless the claim was submitted fraudulently, done to correct a claim as part of a pharmacy audit, or an adjustment was agreed upon with the pharmacy prior to the denial or reduction.
3) Prohibiting a pharmacist from communicating information about the PBM with elected officials or regulators.
4) Reducing any reimbursement payment to a pharmacy for a prescription drug's ingredient cost or dispensing fee.

PBMs must also adhere to certain requirements designed to facilitate a pharmacy's access and participation in the PBM's pharmacy network. PBMs must allow pharmacies to apply to participate in a pharmacy network electronically, provide a physical copy of the network contract to each pharmacy, and include a direct telephone and email address for inquiries. All pharmacy network contracts must disclose the sources used to determine a drug's reimbursement rate. PBMs may only make unilateral changes to a network contract at the time of renewal and must provide at least 60-day notice of a change in the contract or a decision not to renew a pharmacy's contract. The rule prohibits PBMs from terminating a pharmacy's contract without at least 60-day notice unless they meet one of 12 criteria (see the full regulation below).

The DFS rule also establishes standards for pharmacy credentialing requirements. PBMs must notify a pharmacy of any credentialing requirement to participate or enroll in a network upon request within 14 days and notify network pharmacies of any re-credentialing requirement at

least 30 days prior to the deadline to submit the required information. PBMs may not require pharmacies to re-credential more frequently than every three years, and they may not change their credentialing or re-credentialing requirements more frequently than 12 months.

Pharmacy Network and Formulary Transparency:

The DFS rule requires PBMs to publish a formulary directory and a network pharmacy directory on their website by July 1, 2025. If a covered individual reasonably relied on either directory in obtaining a prescription drug, the PBM shall not impose a greater cost-sharing or deductible charge than the amount posted in the directory.

- Formulary Directory: PBMs shall publish an accurate, up-to-date, and complete list of all covered drugs on each health plan's formulary, including the applicable tier and any applicable restrictions for each covered drug. The formulary drug list must identify all covered drugs available without annual deductible, copayment, or coinsurance. This requirement applies to any PBM that provides clinical or other formulary or preferred drug list development or management services on behalf of health plans.
- Network Pharmacy Directory: PBMs shall publish a list for each health plan that identifies each pharmacy within each network, which includes each pharmacy's name, address, telephone number, and email address. The PBM must update the directory within 5 days of adding or terminating a pharmacy from a network. This requirement applies to any PBM that performs retail network management services on behalf of health plans.

Consumer Protection:

PBMs may not charge a covered individual an amount more than the lesser of:

1) The cost-sharing amount under the terms of the health plan,
2) The maximum allowable cost for the drug, or
3) The amount the covered individual would pay for the drug if the covered individual were paying the cash price the pharmacy would charge to a person without health plan coverage.

The DFS rule prohibits PBMs from engaging in unfair or deceptive practices or false or misleading advertising. PBMs are also prohibited from removing a drug from a formulary or denying coverage of a drug to incentivize a covered individual to seek coverage from a different health plan. PBMs may not prevent a pharmacy from offering mail-order or home delivery services or charging a fee for providing such services, discussing the cost of prescription drugs, the availability of therapeutic alternatives, dispensing cheaper alternatives, or offering a covered individual the option of paying the cash price for a drug rather than use their insurance benefit.

PBMs are prohibited from actions that may steer patients to affiliated pharmacies, including:

- Providing incentives to a covered individual to use an affiliated pharmacy when unaffiliated pharmacies are available within the same network,
- Including affiliated pharmacies in any materials provided to covered individuals unless the materials also include unaffiliated pharmacies,

- Transferring or sharing records relative to prescription information containing a covered individual's identifiable or prescriber-identifiable data to an affiliated pharmacy,
- Requiring a covered individual to purchase prescription drugs exclusively through a mail-order pharmacy or referring a covered individual to a mail-order pharmacy or an affiliated pharmacy unless contractually required to do so by the health plan,
- Penalizing a covered individual for using an in-network unaffiliated pharmacy, including by requiring a covered individual to pay the full cost for a prescription, or
- Prohibiting or limiting any covered individual from selecting an in-network pharmacy of the individual's choice unless specifically required by the health plan.

Pharmacy Audits:

The DFS rule establishes standards regarding how PBMs conduct pharmacy audits, process pharmacy appeals of audit reports, and recoup overpayments identified by an audit. Key provisions of the pharmacy audit standards include:

- A PBM shall include in the notice of audit to the pharmacy the reason for the audit and a list of documents, records and claims, including specific prescription numbers and the number and date of any refills, that are to be audited.
- A PBM may not audit a pharmacy more frequently than once every 6 months except to address an identified problem or where fraudulent activity or other intentional or willful misrepresentation is reasonably suspected.
- A PBM shall establish a written process for audit report finalization and appeal of the findings of a preliminary audit report and shall include such written process in every pharmacy contract.
- A PBM shall not include dispensing fees in calculations of overpayments unless the claim is determined to not have been dispensed at all or to have been dispensed in error. The PBM may not recoup funds for clerical or record-keeping errors, including typographical errors, scriveners' errors, and computer errors on a required document or record unless a pattern of such errors exists.
- A PBM shall not recoup by setoff any money for an overpayment or retroactive denial of a claim until the pharmacy has an opportunity of not less than 30 business days to review the audit findings. If a pharmacy appeals a PBM's finding of overpayment or retroactive denial, the PBM may not recoup by setoff any money until after all appeals have been exhausted.

For more information, read the full regulation here: https://www.dfs.ny.gov/system/files/documents/2024/11/rf-ins-a3reg219-text.pdf.