Pharmacy Benefit Managers

TEMPLATE LEGISLATION

Definitions:

Insurer: Any individual or entity authorized to provide health benefit plans or insurance services in the province.

Payer: Any entity that provides, administers, or finances pharmacy benefits, directly or through an intermediary.

Pharmacy: A licensed establishment in [province] that provides pharmaceutical services and dispenses medication under a licensed pharmacist's supervision.

Pharmacy Benefit Manager (PBM): Any entity that contracts with insurers, health benefit plan providers, or pharmacies to inform, manage or administer pharmacy benefits.

Preferred Provider Network (PPN): A contractual arrangement between a payer, including but not limited to insurers, health benefit plan sponsors, or employers, and a designated group of pharmacies for the provision of pharmacy services, including the dispensing of prescription medications, to covered individuals.

Patient choice

WHEREAS the health and well-being of patients depend on the ability to access care and services that align with their individual needs and preferences;

AND WHEREAS patient choice is a fundamental principle of a fair and equitable healthcare system, ensuring that decisions regarding care remain independent of undue influence by third parties;

AND WHEREAS maintaining a clear and distinct separation between payers, PBMs and regulated health professionals is critical to upholding the integrity, quality, and impartiality of patient care;

This legislation establishes provisions to protect and enshrine patient choice as a central pillar of healthcare delivery, ensuring transparency, fairness, and the independence of care decisions.

1. **Prohibition:** No insurer, pharmacy benefit manager (PBM), or other payer providing pharmacy benefits shall, directly or indirectly, require, coerce, or unduly influence a patient to fill prescriptions or obtain pharmacy services from a specific pharmacy or group of pharmacies, including pharmacies owned or affiliated with the PBM or insurer, such as in-house mail order pharmacies, by means such as:
    - Penalizing patients financially (e.g., higher copays or out-of-pocket costs if they choose a non-preferred pharmacy).
    - Restricting reimbursement or denying coverage for prescriptions filled at non-preferred pharmacies.
    - Providing misleading or incomplete information to steer patients toward a specific pharmacy.
2. **Transparency:** Any PBM, insurer or plan sponsor establishing a PPN must:
    - Disclose the specific clinical, geographic, or patient-care considerations used to select pharmacies within the network.
    - Ensure that the selection criteria prioritize patient access, quality of care, and affordability, and are not based primarily on financial incentives.
    - Disclose any financial arrangements between the PBM, insurer, and pharmacies within the PPN, including rebates, discounts, or service fees.

3. **Review of PPN Practices:** The regulatory authority shall review the use of PPNs by PBMs and insurers on an annual basis to ensure compliance with the following:
    - PPNs must not reduce access to necessary medications or services.
    - PPNs must demonstrate a tangible benefit to patients, such as improved care coordination or faster access to therapy.
4. **Right to Pharmacy Choice Notification:** All insurers, health benefit plan sponsors, and PBMs must clearly and explicitly inform beneficiaries that they retain the right to select their preferred pharmacy for dispensing medications and pharmacy services.
    - **Mandatory Disclosure:** Any communication, promotional material, or messaging related to pharmacy networks, coverage, or plan benefits must include a clear statement that patients have the right to choose their pharmacy, regardless of network status.
    - **Prohibition of Misleading Language:** Insurers, PBMs, and plan sponsors shall not use language or marketing tactics that suggest or imply that a patient is required to use a specific pharmacy or is at risk of losing coverage or benefits if they select an out-of-network pharmacy.

Prohibiting interference with the pharmacist-patient relationship

1. A PBM shall not interfere with the exercise of professional responsibilities to a patient by a pharmacist and shall not take any retaliatory actions against a pharmacist/pharmacy because of the exercise of such responsibility.

2 A PBM shall not take any retaliatory actions against a pharmacist or pharmacy for exercising their professional responsibilities or advocating for patient care. Retaliatory actions include, but are not limited to:

- Removing a pharmacy from the PBM's network without cause or due process.
- Reducing reimbursement rates, imposing excessive payment delays, or introducing arbitrary clawbacks on claims submitted by a pharmacy.
- Subjecting a pharmacy to repeated or excessively burdensome audits.
- Imposing sudden and unjustified contract amendments that place financial or operational hardship on a pharmacy.
- Restricting a pharmacy's participation in preferred pharmacy networks (PPNs) in retaliation for business practices or patient advocacy.
- Implementing policies that redirect patients away from a specific pharmacy as a punitive measure.

3. PBMs must comply with statutory provisions regarding the substitution of one drug for another. Any substitution policies must be transparent and based on clinical evidence, rather than financial incentives, to ensure the pharmacist's ability to make appropriate recommendations for patient care.

Transaction Fees

1. **No Fees for Electronic Claims:**
    - PBMs are prohibited from charging pharmacies any fees, including but not limited to transaction or service fees, for the submission, reversal or processing of electronic claims made on behalf of patients.
    - This provision applies to all types of claims submissions, including initial claims, adjustments, reversals, resubmissions, or any other related transactions.

Regulation of Audits

1. **Fair Audit Timing:**
    - In-person/onsite audits of pharmacies by PBMs or insurers shall not be conducted during the first seven days of the month.
    - Audits are prohibited from being conducted on federal or provincial holidays, or during weekends unless the pharmacy specifically agrees to the timing in advance.
2. **Auditor Independence:**
    - Auditors must not receive any financial incentives, bonuses, or compensation tied to the audit outcomes, including the identification of overpayments, errors, or recoverable amounts. Compensation shall be structured in a way that prevents any potential bias or conflict of interest.
3. **Audit notification and scope:**
    - PBMs and insurers must provide pharmacies with a minimum of 10 business days' notice before an onsite audit, specifying the scope, time period, and records required.
    - The pharmacy must be allowed at least 10 business days from the date of the audit to produce documentation to address any discrepancies.
    - Audits must be limited to claims submitted within a two-year period from the date of the claim in question.
    - Audits must focus on actual claims, and extrapolation to other claims is prohibited.
4. **Limitations on Recoupment:**
    - Recoupment of funds by PBMs or insurers must be based solely on actual overpayments or fraudulent claims. Clerical or administrative errors, such as documentation or typographical mistakes, that do not result in financial harm shall not be grounds for recoupment.
5. **Appeal and Resolution Process:**
    - Pharmacies must be provided with a clear and transparent process to appeal audit findings. Any appeal must be resolved within 90 days of filing, and during this period, no recoupment actions shall be taken.
    - In the event of a dispute, PBMs or insurers must provide documentation supporting their findings and offer a resolution pathway for the pharmacy.

Prohibition on Recoupments Tied to Ratings

1. **No Retrospective Recoupments Based on Ratings:** A PBM or insurer shall not impose recoupments, chargebacks, or payment reductions on a pharmacy based on performance measurements, star ratings, adherence metrics, or any other performance-based criteria that were not explicitly tied to reimbursement at the time of claim adjudication.
2. **Transparency and Fair Compensation**: All reimbursement terms must be clearly defined in the contract between the PBM and the pharmacy before claims are submitted. A pharmacy must be able to determine its expected reimbursement at the time of claim adjudication, without risk of post-claim reductions.
3. **Prohibition of Unilateral Adjustments:** PBMs may not unilaterally withhold, deduct, or retroactively reduce payments to pharmacies based on subjective assessment or rating measures, patient adherence scores, or other non-claims-based evaluations that are beyond the direct control of the pharmacy.