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## • EVOLVING PHARMACY LANDSCAPE SIGNALS MORE STRINGENT REGULATORY SCRUTINY OF “PATIENT STEERING” •

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The pharmacy landscape has evolved considerably over the past year, shining a spotlight on pharmacy “patient steering”, the practice of directing patients to certain preferred pharmacies. Though Quebec has long required that patients have “freedom of choice” to choose their pharmacy,<sup>1</sup> regulators in other jurisdictions have not imposed the same requirement, whether due to differences in specificity of the wording or differences in interpretation or enforcement.<sup>2</sup> Recent developments have now caused a range of stakeholders to consider the pharmacy landscape more closely, including whether an individual’s “freedom of choice” to choose their pharmacy should be mandated beyond Quebec. These developments have important implications for the relationships between pharmacies, pharmaceutical manufacturers, payers, pharmacy benefit managers (PBMs), and patient support program (PSP) service providers, among others.

Patient steering can occur in a variety of scenarios involving preferred provider networks (PPNs), PBMs, or PSPs.

- i. PPNs are contractual agreements between payers (e.g., insurance companies, employers that self-insure) and pharmacy operators, which set out the terms and conditions by which prescription drugs can be accessed. PPNs can be closed or open. The Ontario College of Pharmacists (OCP) defines closed PPNs as arrangements where the payer sets the terms and conditions with a limited group of pharmacies and the contractual agreements for such arrangements are not transparent. In contrast, OCP describes eligibility to join an open PPN as “broader”, where “conditions to join are transparent to pharmacies”. According to OCP, closed PPNs have the potential to cause greater harm as they limit pharmacy access and choice to a much larger degree than open PPNs.
- ii. PBMs are intermediaries in the drug supply chain between pharmacies, payers, pharmaceutical manufacturers, and wholesalers. The functions of a PBM can include claim adjudication, formulary design, and price negotiations with manufacturers.
- iii. A PSP is a set of services offered to support patients on a particular brand of medication. Due to the cost to provide PSP services, they are typically used only for higher cost medications associated with complex and/or rare diseases.

Below are some key developments on patient steering which have prompted scrutiny of the pharmacy landscape:

- *January 2024* – Manulife-Loblaw exclusive arrangement sparks backlash: When Manulife Financial Corp., a major insurance company, announced changes that would require patients to receive their specialty medications primarily through Shoppers Drug Mart and other Loblaw-owned pharmacies due to a PPN with Loblaw Cos. Ltd., media scrutiny and public backlash ensued, prompting the federal Minister of Innovation, Science and Industry to voice his concerns and also for the NDP to request the Competition Bureau conduct a formal investigation. Manulife reversed its decision soon after.
- *February 2024* – Canadian Pharmacists Association (CPhA) adopts position statement on payer-directed care: In addition to highlighting specific concerns with the practice of patient steering by payers and PBMs, CPhA has proposed that governments across Canada establish a regulatory framework to address payer-directed care, including specific elements such as transparent audit practices and restrictions on PPNs. Various provincial pharmacy associations have taken similar positions.  
CPhA has also (as part of its abuse of dominance complaint with the Competition Bureau against Express Scripts Canada, the largest PBM in Canada, regarding its new service fee to pharmacies for direct billing) called for the Competition Bureau to conduct “a thorough examination of the PBM industry as a whole”.
- *June 12, 2024* – L’Association québécoise des pharmaciens propriétaires (AQPP) seeks authorization to institute class action lawsuit against specialty pharmacies, PSP managers, and infusion clinics: The class action application asserts that AQPP members (*i.e.*, Quebec owner-pharmacists except for those listed among the defendants) are being denied substantial revenues

as a result of the defendants' anti-competitive practices, or their aiding and abetting of same, resulting in the concentration of specialty medication distribution in the hands of a few owner-pharmacists. In addition to compensatory damages, the AQPP seeks to nullify any agreements providing for preferential treatment of the defendants.

- *July 8, 2024* – OCP Board of Directors adopts position on closed PPNs: The position statement emphasizes OCP’s zero-tolerance approach to reimbursement models that compromise patient autonomy, interfere with a pharmacy professional’s duty to put patient interests first, or put patients at risk. It is one of a series of steps that OCP is taking towards addressing PPNs, and is linked to OCP’s broader efforts to address corporate influence over pharmacy professionals. OCP had previously taken the position that it had no jurisdiction over the practices of employers, insurance companies, or manufacturers, but given the lack of oversight over PPNs and recent developments on patient steering, OCP has now determined that a regulatory response by it is warranted.
- *July 9, 2024* – US Federal Trade Commission (FTC) releases an Interim Staff Report on PBMs entitled “Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies”: The Interim Report is part of an ongoing inquiry into the business practices of PBMs and their impact on the accessibility and affordability of prescription medications. While the study focuses on the relationship between PBMs and pharmacies, the FTC declares “PBMs and brand drug manufacturers negotiate prescription drug rebates some of which are expressly conditioned on limiting access to potentially lower-cost generic and biosimilar competitors”, and that there is “initial evidence about PBM and brand pharmaceutical rebating practices that urgently warrant further scrutiny and potential regulation”.

The Interim Report has spawned further activity, with Express Scripts (one of the largest PBMs in the US) suing the FTC on September 17, 2024 on various grounds, including defamation, and demanding withdrawal of the Interim Report. Days later, on September 20, 2024, FTC sued a trio of PBMs (including Express Scripts) for artificially inflating insulin drug prices, with the FTC Bureau of Competition Deputy Director warning, “Although not named in this case, all drug manufacturers should be on notice that their participation in the type of conduct challenged here can raise serious concerns, with a potential for significant consumer harm, and that the Bureau of Competition reserves the right to recommend naming drug manufacturers as defendants in any future enforcement actions over similar conduct.”

- *August 2024* – Ontario Teachers Insurance Plan (OTIP) member files professional-misconduct complaint against MemberRx: MemberRx is an in-house pharmacy established by the Ontario Teachers Insurance Plan. To be eligible for insurance coverage for specialty drugs, the plan members must receive the drug from the MemberRx pharmacy, and not any other pharmacy. The complaint filed with OCP highlights conflict of interest issues related to such exclusivity arrangement and concerns over the practice of patient steering.
- *August 23, 2024* - Ontario Ministry of Finance launches a 60-day public consultation on PPNs: The consultation is intended to gather stakeholder input on the role of PPNs in Ontario’s employer-sponsored drug insurance programs. While the Ontario government is not yet proposing specific legislative or regulatory changes, the public consultation signals increasing scrutiny of such relationships and potential regulation.

Given the public scrutiny and the range of regulators and other stakeholders interested in the issue of patient steering, it is important to ensure that PPN, PBM, and PSP practices and any other arrangement which may impact patient choice are considered carefully and structured appropriately. Actual practice should also reflect what is set out contractually. This is especially important since recent amendments to the *Competition Act* increase potential risk. For example, though historically the Competition Bureau had no power to compel a company to provide information for the purpose of market or industry studies, since the December 2023 amendments, the Bureau can now seek a court order compelling the production of documents for such studies.

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<sup>1</sup> Quebec, *Code of ethics of pharmacists*, CQLR c P-10, r 7, s 27; and Quebec, *Act respecting prescription drug insurance*, CQLR c A-29.01, s 42.2.1.

<sup>2</sup> Ontario, *Professional Misconduct and Conflict of Interest*, O Reg 130/17, s 2(1).