Preferred Provider Network (PPN) Mandate: Expert Report, Ethics

UNIVERSITY OF TORONTO
LESLIE DAN FACULTY OF PHARMACY

Jamie Kellar, RPh, BScHK, BScPhm, PharmD, PhD
Associate Dean, Academic
April 22, 2024

Re: Preferred Provider Network (PPN) Mandate

OVERVIEW AND PROTOCOL

I have been retained by Ricketts Harris LLP to carry out an Expert Review and Analysis of the ethics of preferred provider networks (PPNs) as they relate to pharmacy practice in Ontario. Specifically, I have examined PPNs with respect to the core ethical principles codified in the Ontario College of Pharmacists (OCP) Code of Ethics (Code of Ethics); *beneficence, non-maleficence*, *respect for patients*, and *accountability*. In this report, I present my findings and opinions based entirely upon information derived from my review of published and publicly available information.

PROFESSIONAL BACKGROUND AND EXPERTISE

I am the Associate Dean Academic and an Associate Professor, Teaching, at the Leslie Dan Faculty of Pharmacy, University of Toronto. I am also a registered pharmacist in the province of Ontario. I have 20 years of pharmacy experience in various settings including hospital pharmacy (practice and administration), community pharmacy, and pharmacy education.

I received my Bachelor of Science in Human Kinetics (BScHK) from the University of Guelph in 2000, my Bachelor of Science in Pharmacy (BScPhm) from the University of Toronto in 2004, my Doctor of Pharmacy (PharmD) from the University of Toronto in 2011, and my PhD in Health Professions Education from Maastricht University, Netherlands in 2022.

Throughout my career, I have garnered recognition as an award-winning educator and an authority in several domains, including mental health, pharmacy education, education research, sociology of professions, professional identity formation, and ethics. My PhD training was grounded in the sociology of professions and health professions education, which fundamentally includes ethics and ethical practice.

The ethical obligations of health care providers are crucial elements to what differentiates professions and occupations, as well as what informs professional and ethical behaviours, values, and norms in education and practice settings. All pharmacy students and practicing pharmacists are socialized and re-socialized to professional and ethical obligations through their education, training, and daily work. My program of research uses a critical social theory lens to focus on professionalism and professional identity formation in pharmacy education and practice. This work inherently includes ethics, as it is a core component of professional identity. Specifically, I study how dominant societal discourses shape the way pharmacists can think, act, and feel and what professional roles, values, and functions they can embody in education and practice as a result of the powerful discourses at play. My research was recognized with the Rufus A. Lyman Award for the best paper published in the American Journal of Pharmaceutical Education in 2020, the highest indexed pharmacy education journal internationally. I am one of only two Canadian winners. For a more comprehensive overview of my background and expertise, please refer to my attached curriculum vitae.

MATERIALS REVIEWED

In preparation for the completion of this report, I consulted numerous documents including the Code of Ethics, The National Association of Pharmacy Regulatory Authorities (NAPRA) Model Standards of Practice for Pharmacists and Pharmacy Technicians in Canada, as well as several academic position and research papers on the topic of pharmacy benefit managers (PBMs), preferred provider networks (PPNs), and pharmacy and medical ethics. A full list of all materials referenced in this report is provided in the reference section.

BACKGROUND

Pharmacy Benefit Managers and Preferred Provider Networks: Negative Impacts on Patient Choice

In order to analyze the ethics of PPNs, one must understand the healthcare landscape that has given rise to PBMs and the subsequent designation of PPNs within the PBM system. In this background section, I review the rise of PBMs in Canada and internationally, and outline the current state of affairs.

In the absence of a comprehensive national pharmacare plan in Canada, the majority of Canadians rely on private drug insurance to help pay for prescription medications.[1, 2] Prescription drug spending in Canada and internationally is continuing to rise as our population ages and because of the increased costs of speciality drugs.[1, 3, 4]

Specific medications that are grouped together by insurers due to their costs are referred to as 'speciality drugs'. These drugs include chemotherapy for certain cancers, as well as drugs to treat complex chronic conditions like hepatitis and HIV.[2] Biopharmaceuticals (also called 'biologics'), a type of speciality drug, are complex medications that are derived from living cells or organisms.[5] They are used to treat autoimmune diseases like rheumatoid arthritis and multiple sclerosis, among an increasing number of others.[2, 5] Biopharmaceutical drug approvals have grown significantly in the last decade as technology has advanced and more disease targets have been identified.[5] These medications are highly effective and very versatile, hence they are valuable in several serious diseases and their use continues to rise.[5]

This rise of specialty drugs poses significant financial challenges for insurers. In addition to high research and development costs, specialty medications necessitate costly production technologies and strict temperature regulations for storage and distribution, adding to their overall expense.[5] Ultimately, the rapid proliferation and ongoing growth of speciality drugs has increased the pressure on insurers to find ways to manage costs. As such, PBMs and PPNs are becoming increasingly popular in Canada (and around the globe), to reduce prescription drug costs for employers who sponsor drug benefit plans through large insurance companies.[1, 4, 6, 7] However, while often marketed as saving money for patients and the health system, PPNs in fact offer savings to employers who provide insurance plans and insurers.[1]

PBMs are a growing aspect of PPNs that play a major role in the provision of pharmacy services by acting as an intermediary between plan sponsors/insurers and pharmacy providers.[8] They emerged in the late 1950s and have since expanded their influence in the pharmaceutical supply chain. PBMs now handle claims processing and adjudication, formularies, preferred pharmacy networks, mail order pharmacies, and contracting with wholesalers and manufacturers on behalf of insurers.[8]

PPNs are the result of contractual agreements negotiated between plan sponsors/insurers and PBMs with specific pharmacy operators.[1] In general, pharmacy operators that sponsors/insurers contract with as part of the PPNs provide prescriptions at lower costs for plan members, thus saving the plan sponsor money. In exchange, these pharmacies realize an increase in prescription volume, which benefits their pharmacy business financially. The terms of these agreements are often not transparent. Inclusion in a PPN is often limited to select corporate pharmacy operators or pharmacies owned and operated by the insurer that operates the PPN or a PBM. These practices create inherent conflicts of interest and often breach ethical obligations to patients, which will be discussed later in this report.

PPNs can be classified as mandatory or non-mandatory:

- In a non-mandatory PPN agreement patients can choose to have their prescriptions filled outside the network, with their provider of choice; however, if they elect to do so they will be required to pay a higher co-payment or deductible for their prescriptions.[1]
- In mandatory PPNs, patients are mandated to receive their prescription products only from designated network pharmacies, which are increasingly mail order pharmacies, or else they must pay the entire cost out-of-pocket.[1]

In addition, a PPN can be either open or closed, designated by the ability of providers to participate.

- In an open PPN, provider participation is allowed, as long as they are willing and able to meet the conditions of the PPN.
- In a closed PPN, provider participation is by invitation only and terms of the agreement are often confidential.

Historically, mandatory-closed PPNs have often been reserved for a small number of high-priced speciality drugs and biopharmaceuticals. Recently, they have expanded to include a significantly wider variety of drugs. Closed, mandatory PPNs create situations in which patients who elect to choose their own pharmacy encounter significant out-of-pocket costs for their medications. To avoid this expense, they are forced to use pharmacies in the PPN to access medications they need.

PPNs are on the rise in Canada and internationally.[1] It has been estimated that the growth of PPNs increased in Canada by 19% in 2015 compared to 2014.[9] Today, approximately 1 in 4 Canadian private insurers offer a PPN as part of their prescription medication plan.[10] The expansion of PPNs, particularly closed-mandatory PPNs, in Canada is concerning as they significantly impact patient choice and patient access to medications and pharmaceutical care services.[1]

In recent years, the relationship between PBMs, PPNs, and pharmacies has also changed. There is now considerable vertical integration between these entities with larger insurers/payors owning and operating their own licensed pharmacies, or national pharmacy chains acquiring PBMs to adjudicate insurance claims. Vertical integration increases the likelihood that patients will be mandated to use the pharmacies affiliated with the claims payor (i.e. the insurer) and/or PBM, thus restricting patient choice and access exclusively in the name of profit for the organizations managing the care/services.[8]

Such vertical integration is complicated further by the *Drug and Pharmacies Regulations Act* which require corporately owned pharmacies to ensure that the majority of the directors of the corporation are pharmacists.[11] In these situations, the same individual is sometimes both a Pharmacy Director of the

PPN and a Corporate Executive/Manager at the insurer or PBM, or a Corporate Executive/Manager overseeing the business of the insurer or PBM and the provision of pharmacy services and patient care.

The dual role of pharmacist and corporate insurance executive/director creates an inherent conflict of interest as it requires a single individual to be both a healthcare provider and a corporate executive, which is incompatible from an ethical point of view. Pharmacists have a fiduciary obligation to act in the best interest of the patient; this means that they are obligated to adhere to the Code of Ethics and must ensure that the needs of the patient, including autonomy and choice, are put first. This obligation is at direct odds with these individuals' corporate mandates, which are essentially to maximize profit (as fiduciaries or pseudo-fiduciaries of shareholders). The imperative to drive profits for an insurer or pharmacy corporation is fundamentally at odds with patient care and the fiduciary duty pharmacists owe to patients.

From an ethical perspective, the same individual, cannot in good faith, hold both a corporate position and be a registered pharmacist (i.e., comply with the Code of Ethics and related standards of practice) without compromising the Code of Ethics and the rights of patients.

Ethics and Pharmacy Practice

Pharmacists are regulated health professionals and as such have a duty to follow the Code of Ethics, of which dignity and welfare of patients is paramount.[12] In their role as healthcare providers, pharmacists enter into a covenantal relationship with society in which pharmacists work in service to the patient for their benefit.[13]

The OCP, the provincial regulatory body for pharmacists and pharmacies, has an obligation to develop and maintain standards of professional ethics for its members. The Code of Ethics, therefore, articulates the ethical principles and standards that guide the practice of pharmacists in fulfilling the College's mandate to serve and protect the public by putting patients first.[14] The Code of Ethics is applicable in all pharmacy practice, education, and research environments. All pharmacists are responsible for applying the Code of Ethics in their professional work environments. In fulfilling their professional role, pharmacists are guided by the following four core ethical principles:

- Beneficence (to benefit)
- Non-Maleficence (do no harm, prevent harm)
- Respect for Persons/justice (autonomy, justice)
- Accountability (Fidelity)

At a theoretical level, health professional socialization involves a pharmacist entering into an implicit social contract as they take on the obligations and responsibilities of a healthcare professional. This social contract distinguishes health professionals from other professionals. It requires that healthcare professionals are committed, first, foremost, and above all to the direct benefit of their patients and, only after their obligations to their patients are completely fulfilled, to monetary gain.[14] In return for this promise, society grants the profession the autonomy to self-govern with all the associated privileges and statuses.[14, 15]

This is a quasi-fiduciary relationship in which health professionals must safeguard a patient's interest above all; primarily his or her own self interest.[16] Pharmacists, regardless of setting, must always ensure

that their financial interests do not take precedence over doing what is best for patients. As fiduciaries, healthcare providers, including pharmacists, owe a duty of loyalty to their patients' interests that requires them to elevate their conduct above that of commercial actors.[16]

The nature and requirements of pharmacists' fiduciary duty is captured and embodied in a statement by Justice Cardozo, an associate justice of the US Supreme Court, speaking about physicians: "Many forms of conduct are permissible in a workday world for those acting at arm's length, are forbidden to those bound by fiduciary ties. A…[fiduciary] is held to something stricter than the morals of the marketplace. Not honesty alone, but the punctilio of an honor the most sensitive, is then the standard of behaviour."[16]

Based on this, pharmacists' dual corporate and pharmacist roles in the insurer, PBM, PPN web result in a conflict of interest that breaches the fiduciary obligations of the pharmacist role. As such, prohibiting pharmacists from functioning in such a dual capacity should be the norm, and should be the requirement for all pharmacists.

Ethical Principles and Application to Standards of Pharmacy Practice

Each ethical principle that pharmacists adhere to prioritizes the patient; hence, the principles are enacted through the standards of practice that pharmacists perform on a daily basis.[14, 17]

Non-Maleficence

Non-maleficence refers to the pharmacist's obligation to protect their patients and society from harm.[14] In practical terms, pharmacists must refrain from behaviours/attitudes which could potentially result in harm and utilize their professional judgment to make every reasonable and conscientious effort to prevent harm to patients and society.

Beneficence

The ethical principle of beneficence refers to the pharmacist's professional obligation to actively and positively serve and benefit the patient and society.[14, 18] In distinction to nonmaleficence, the language here is one of positive requirements. The principle calls for not just avoiding harm, but also to benefit patients and to promote their welfare. Pharmacists must ensure that their primary focus is always the well-being and best interest of the patient. Pharmacists use their knowledge, skills, and judgement to actively make decisions that provide patient-centered care and optimize health outcomes for patients.

Respect for Persons/Justice

Pharmacists have dual obligations to respect and honour the intrinsic worth and dignity of every patient as a human being (autonomy) and to treat all patients fairly and equitably (justice).

Autonomy

The philosophical underpinning for autonomy is that all persons have intrinsic and unconditional worth, and therefore, should have the power to make rational decisions and moral choices, and each should be allowed to exercise his or her capacity for self-determination.[18] Applying this principle to pharmacy practice, pharmacists must respect their patients as self-governing decision makers in their healthcare and will not unjustly restrain patients ability to choose

appropriate care or care providers without patients' free and informed consent. Therefore, pharmacists respect the patient's right to choose a pharmacy and/or pharmacist to provide services.[14, 17]

Justice

In pharmacy practice, pharmacists are obligated to provide fair and equitable access to pharmacy services and deliver consistent quality care to all patients, regardless of socio-economic status, culture, disease state, or any other related factor that may unfairly bias patient care.[14]

Accountability (Fidelity)

Pharmacists have a fiduciary duty to be a responsible and faithful custodian of the public trust. As such, pharmacists maintain trust in being required to always act in the best interest of their patients and society. To fulfill this obligation, pharmacists must practice in accordance with the code of ethics and standards of practice, refrain from participating in unethical business practices, and avoid conflict of interest.[14]

Trust

Trust is an important element in accountability. The patients' trust in pharmacists comes from a longstanding tradition of quality services and fair treatment that has been experienced in community pharmacies.[19]

ETHICAL ANALYSIS

The Conflict between Business Ethics and Medical Ethics

Currently, PBMs and PPNs are discussed frequently in literature and the media from an economic and legal perspective; however, they are rarely discussed from an ethical perspective.[3, 20]

As noted above, health care delivery and prescription medications are becoming increasingly expensive.[3, 6] In an attempt to manage the skyrocketing costs, various forms of managed care, like PBMs and PPNs, are becoming more popular in Canada.[6, 20] While implementing systems to maximize healthcare efficiency and contain costs are important, they must be balanced against the ethical principles that guide healthcare delivery.[3] The current nature of PBMs and PPNs places the 'good of the patient' into direct conflict with cost-savings and thus the 'good of the plan'.[6, 21]

PBMs and PPNs are corporate organizations created to achieve economic objectives that are generally fundamentally incompatible with traditional medical ethics.[20, 21] Managing prescription medication is a healthcare service and therefore inherently involves ethical considerations. This fact is often overlooked since the driving factors of these organizations is profit maximization.[4, 22] The rapid proliferation of PBMs and PPNs raises significant concerns that the fulfillment of pharmacists' ethical obligations to patients and society withing the PPN framework may be in conflict with the daily work requirements associated with PBM and PPN driven regulations.[3, 4]

This is a complex issue as PBMs and PPNs perform both medical and business functions. Ultimately, PBMs and PPNs are in the business of delivering health care, which is a necessity that allows one to fully

participate in society.[20] The paradigm and ethics relating to healthcare services is fundamentally at odds with the purpose and mandate of corporations which control PBMs and PPNs which inherently function to maximize revenues and reduce costs associated with consumers, to maximize profits for shareholders.

In contrast to the normative social understanding of corporations, the end users of PBMs and PPNs are patients, and not consumers; they are vulnerable people in need of medical care.[20] Patients are not just another 'stakeholder' of a corporation alongside many others, like shareholders (or the consumers in the normal corporate paradigm). Patients are necessarily the main and overriding stakeholder in any provision of health care goods and services.[20]

As such, PBMs and PPNs must be held to the strictest ethical standards and regulations. This requires that they design systems, policies, procedures, and codes of conduct that are in complete alignment with the ethical principles outlined in health codes of ethics to ensure patients are protected. Anything short of complete adherence to core ethical principles is unacceptable and breaches the social contract between healthcare providers and society. In most cases, this necessarily means increasing costs and/or reducing revenues; actions which are antithetical to their corporate imperatives.

Ethical Conflicts with Dual Roles: Senior Business Leader and Pharmacist

Many senior leaders and managers within insurance companies, PBMs and PPNs are pharmacists. These pharmacists may be the directors of community pharmacies owned by PPN insurers or PBMs. This is necessary because the *Drug and Pharmacies Regulation Act* mandates that the majority of Directors in any corporately owned or operated pharmacy must be pharmacists.[11] Therefore, the corporations involved in the managed care space hire executives who are also pharmacists so that they can be involved in the management of an in-house pharmacy and/or the operational decisions regarding PPNs. In other cases, PPNs and PBMs may offer care exclusively through corporate specialty pharmacies, with pharmacists being central to developing operational strategies and relationships between both corporations in order to maintain and sustain the PPN.

In these situations, pharmacist's main function as an executive or manager relates to setting corporate strategy aimed at maximizing profits; not prioritizing ethical patient care services. Maximizing profits involves increasing revenues and reducing costs, at both the insurer and the pharmacy levels. This often requires designating in-house pharmacies (i.e., PPN or PBM owned pharmacies) or specific corporate chain pharmacies as the mandatory PPN for the plan sponsor, setting restrictive formularies, and reducing clinical services to the bare minimum (e.g., in the case of mail order pharmacies). In promulgating these requirements, senior leaders/pharmacists are knowingly creating systems that breach their ethical obligations as pharmacists.

Where a pharmacist "wears two hats" – an entrepreneurial hat and a health care professional hat – he or she is inherently engaged in an ethical conflict.[23] In principle, it is the professional commitment that should prevail, as one's professional identity encompasses the importance of the ethical commitment made to patients. However, this is generally not the case.[23] Pharmacists in these circumstances prioritize optimization of corporate metrics, using their pharmacy background and knowledge to facilitate corporate advancement and profit. There is a clear conflict of interest in these dual roles.

PBMs, PPNs and Conflict of Interest

The relationships between plan sponsors (insurers), PBMs, and pharmacies have become increasingly blurred over the last several years. As managed care systems have evolved, there has been an increase in the vertical integration between insurers, PBMs, and pharmacies, and in the exclusive affiliation of PPNs/PBMs and insurers with specific, corporately owned pharmacies.

Essentially, PBMs establish their own preferred provider network of pharmacies, which may also happen to be vertically integrated and exclusive to the pharmacies they own.[3] For example, in the United States, CVS pharmacy owns the PBM Caremark. This integration allows CVS pharmacies to be designated as the PPNs for insurers managed by Caremark.[24]

In the Canadian context, Green Shield Canada, an insurer and a PBM, recently acquired the Health Depot, a digital pharmacy, which is a part of Greenshields's PPN for specialty medications. Another part of Green Shield's PPN is NKS Health Canada, a specialty pharmaceutical services company, through which Green Shield also exclusively provides coverage for various specialty medications. Canadian insurers and PBMs have also outsourced pharmacy services exclusively to large corporate chain store pharmacies, resulting in profits to both parties.

Within these vertically integrated systems there exists inherent conflict of interest between the parties (i.e. pharmacists, corporate executives), which can lead to fraud, deception, and anticompetitive conduct, which ultimately breaches ethical principles and impacts patient care by reducing patient choice (autonomy) and access to products and services.[3]

PPNs and Patient Choice

The economic objectives that PPNs were created to achieve are fundamentally incompatible with many of the ethical principles of respect for person (i.e. autonomy and justice) that are a cornerstone to pharmacy practice.[21] Patients have ethical rights to autonomy and choice, which include the right to choose one's care provider (pharmacist) and one's pharmacy, as noted earlier in this report.

PPNs breach this ethical principle by design. They force patients to a specific pharmacy, usually one which they own. Patient choice and autonomy are punished and rendered illusory: if patients choose another pharmacy, they incur exorbitant out-of-pocket costs*. Indeed, the main goal of PPNs is to achieve economic efficiency for plan sponsors and insurers, which comes with an ethical cost to patient autonomy and patient choice.[20]

---

* *Nancy is a 43-year-old woman from rural Ontario. She and her family are long time patients at your local pharmacy. Nancy has several medical conditions requiring medication. She has type 2 diabetes, rheumatoid arthritis (RA) and had a heart attack last year, which resulted in several new medications being added to her profile. She comes in often to discuss her health and she values the care and service provided by the pharmacy team. Recently Nancy's employer made a switch to the insurance company that provides her benefits. The new insurer has a different process, and will require Nancy to get her medications from a mail order pharmacy. Nancy does not want to switch pharmacies, however when she followed up, she was informed if she stays with her current pharmacy, she will have to cover the cost of her medications on her own. This is not feasible as one of Nancy's medications for her RA is a biologic medication (Inflectra®) which costs $15,000-30,000/year. She cannot afford these costs; hence she feels forced to change pharmacies if she is to maintain her health. This is one of many such examples of the negative impact of PPNs on patient care.*

PPN frameworks may also breach the ethical requirements to obtain free and informed consent from patients for pharmacy services or treatments. Free and informed consent requires a patient to have capacity and be fully informed of the service or treatment being offered. This means that the patient must understand, and have the ability to understand, the nature and effects of the service/treatment. Consent must also be voluntary; it cannot be coerced or provided under distress.

Most pharmacies in PPNs fail to adhere to the requirement of free and informed patient consent. PPN pharmacies assume or assert that consent to restrict patient choice, and to transfer patient prescriptions from their local community pharmacies, is either implied based on patients' enrolment in an insurance plan associated with the PPN, or actually given by the patient signing enrollment forms with the PPN noted in the "fine print." This is not accurate. Being enrolled in an insurance benefit program in and of itself does not constitute consent to restrict patient choice or transfer prescriptions between pharmacies.

Having a patient sign a form agreement does not meet the requirement for free and informed consent. Consent is not informed because at no point is the patient informed of the nature or implications of what they are consenting to (e.g., restriction of their choice to a PPN pharmacy). As well, because patients are not able to disagree to using a PPN provider – unless they are willing to pay impossible costs for out-of-pocket for medications – consent cannot be voluntary as it will always include an element of coercion, contravening the requirement for voluntary consent.

Based on this, prescription transfers from one pharmacy to another requires the informed consent of the patient, hence must involve a conversation with the patient. Most PPN arrangements breach this requirement and thus are breaching the ethical requirement to obtain informed consent from patients.

PPNs and Patient Access

Like autonomy, all patients have an ethical right to equitable and just access to health care.[20] PBMs and PPNs have the potential to significantly impact how patients access medications and pharmacy services within the healthcare system. Lack of access to medications ultimately impacts patient autonomy as the various mechanisms employed by insurers, PBMs and PPNs limit patients' autonomy and right to choose which medications are best for them, as well as which pharmacist and pharmacy is best suited to their individual health care needs.

PBMs control which medications are included on a given health plan's formulary and which are excluded. A formulary is a list of prescription medications that an insurance company agrees to cover the costs of, for its plan members. Medications that are not on the list are not covered, hence a patient either has to pay out-of-pocket for the medication, or has to change the medication to something similar that is on the approved list.

The process to set formulary lists is not solely based on medical evidence and pharmacoeconomics, but also involves negotiations with drug manufacturers to discount prices or pay rebates, to get their products placed favorably on formularies so usage will increase. Ultimately, the formulary determines which medications patients can access for their medical conditions. In some cases, a patient may need to try certain medications before others, even if their doctor believes it is not the best approach, as coverage is tiered and requires failure on certain drugs before access to others is granted. If a patient

wants the drug prescribed, they will need to pay out-of-pocket. Ultimately, this can result in patients receiving suboptimal, less effective or ineffective therapies.

In addition, formularies are insurer specific, not condition specific. Hence, a patient may be on a certain drug based on their plan. If the plan changes or the patient changes jobs, patients may no longer be able to access their medication. This could result in patients needing to change treatment frequently or be required to pay out-of-pocket to stay on a specific treatment that best meets their healthcare needs. This can result in negative health outcomes such as relapse of disease, increased side effect burdens, drug interactions, amongst others.

PBMs often require prior authorization for high-cost medications. This can result in lengthy delays for approval. Not surprisingly, these delays impact patients' timely access to medications. As such, patients will continue to suffer from symptoms, and might not receive therapy while they wait for approval.[7]

In a similar vein, many patients who are receiving biopharmaceuticals for chronic conditions are required to receive these medications some distance away from their normal community pharmacy, or from mail order pharmacies to minimize cost. Many of these medications require refrigeration to maintain strict temperature requirements for drug stability. As such, medications need to be properly transported and stored once they are dispensed from a PPN pharmacy. Unfortunately, with these mail order pharmacies, and even with PPN pharmacies which might be some distance from their homes, patients are given large delivery time windows, again inhibiting their autonomy to choose when to receive their medication. For mail order pharmacies, this often requires patients to stay home from work or other activities while waiting for the delivery. Patients have reported that deliveries have not arrived on time or on the correct day and patients have returned home to their medication sitting outside resulting in cold chain disruption. The same cold chain disruptions might occur with PPN community pharmacies which are long distances from a patient's home; this is especially problematic for vulnerable and marginalized populations due to limitations on transportation and storage. In these cases, patients may be at risk of using medication that is no longer stable and/or they will experience further delays awaiting new supply. The removal of patient autonomy in these situations inconveniences vulnerable patients, increases the risk of treatment delays and drug wastage.

Finally, PBMs and PPNs can restrict patients' access to their local community pharmacy, their pharmacist, and in some cases to in-person pharmacy services entirely. PBMs or PPNs may require patients to use pharmacies that are not located in their communities or that are online (i.e., mail order) only. These practices disadvantage those with physical incapacities and vulnerable patients, or patients from marginalized populations, who lack the financial means to travel to the location of the PPN. In addition, mail order pharmacies may disadvantage individuals who are less technologically savvy who may struggle with online services. Often elderly patients who are suffering the largest illness burden, and who are most in need of pharmacists' intervention (e.g., with respect to medication interactions) are the ones who are most negatively affected. It should also be noted that these practices may also disadvantage those who do not speak English as their first language, those with mental illness, or those with communication challenges.

Restricting access to local community pharmacies completely undermines a patient's right to choose their health care provider (i.e., pharmacist) and their health care setting (i.e., pharmacy) based on their individual needs and preferences.

Mandated PPN practices may inhibit patients from accessing crucial pharmacy services when they need them most. It also removes the significant benefits that come from the pharmacist-patient relationship. A recent systemic review of community pharmacists' interventions on adherence and quality use of medication concluded that the interaction of community pharmacists with patients in terms of medication adherence and quality use of medicines provided better health outcomes among patients and that community pharmacists influenced the decision/choice of patients in self-care and self-medications when involved in care.[25] Another study showed that patients willingness to accept pharmacist led health promotion and medication management services increased significantly as the level of the pharmacist-patient relationship grew.[26] Pharmacists in 'partnership' with patients had the most impact on health outcomes.[26] Pharmacists see patients more often than any other health care provider; hence they are often the first to assess if a patient's condition is getting worse, or if they have new symptoms that require care. Pharmacists are ideally placed to build relationships and proactively identify health issues in their patients and intervene as necessary.

The proactive care often provided by community pharmacists is not likely to occur with PPNs that are online or located outside a patient's community of residence. PPNs place the onus of seeking and initiating care on patients, and do not otherwise intervene in patient care. In addition, provision of pharmaceutical care through online services alone or in combination with multiple pharmacies may disrupt continuity of care, which is a core quality of primary care. Continuity of care has several domains, two of which (relational and informational) may be continually disrupted with PPNs to the ultimate detriment of the patient.[27]

Relational continuity can be described as an ongoing therapeutic relationship between a patient and their care givers. In the case of pharmacy, this domain may be negatively impacted by mandating patients to specific PPNs. In these arrangements, particularly with online pharmacies, patients may not consistently see and/or interact with the same pharmacist or pharmacy team members. This lack of interaction may inhibit the ability to build trusting relationships which may impact what information the patient shares and it may decrease the ability of the pharmacist to know the medical history of the patient, both of which may impact optimization of medication.

Informational continuity is the use of information to provide insights into previous care to make current care suitable for everyone.[27] Information continuity includes assessment of patients' needs, problems, and resources, and the patients' values and the context. Patients who are required to seek care from online pharmacies may be limited to interacting by audio means only which eliminates the visual and physical assessment of patients which is a fundamental component of health care.

Since the specialty and mail order pharmacies used by PPNs only support specific medications – and not all medications a patient might use - patients will often and necessarily be forced to seek care from multiple pharmacies and pharmacists, some of whom will not at all be familiar with their medication history or health status. This increases the risk of drug interactions and patient harm.

In these cases, patients must provide their medication list or will need to inform the pharmacist to contact other pharmacies to get the medication history in order to do a fulsome assessment for drug and disease interactions. In many cases, especially with respect to vulnerable (e.g., elderly) patients, this coordination of care and information continuity may not occur, putting patients at significant risk of harm due to drug interactions, duplicate therapy or a lack of effective therapy.

For example, a patient experiencing new signs and symptoms of illness and may walk into their local community pharmacy for an assessment instead of navigating the online services of the PPN, which may not even extend to assessment of such signs and symptoms. This patient may be diagnosed with a minor ailment and be prescribed medication by their community pharmacy. However, unless the patient specifically informs the PPN pharmacy of this interaction, the PPN pharmacy will have no record of the assessment or medication; increasing the risk of adverse events. Moreover, absent the patient actively taking steps to inform them, the local community pharmacy may have no medical information from the PPN regarding the patient, creating a significant potential for harm.

Ultimately, the restrictions to patient access and autonomy imposed by PPNs place patients at risk of undue harm. Therefore, these practices of PBMs and PPNs that restrict patient access breach the ethical principles of justice and non-maleficence. They are also not patient-centred, hence do not put patients first, a breach of the principle of beneficence. It should also be noted that the individuals who are both corporate executives and pharmacists have an inherent conflict of interest that prioritizes profit and the business outcomes of the organization over the needs of the patient which results in them breaching their ethical duty of beneficence.

At minimum, if patient autonomy or access is in any way restricted, it should occur on justifiable grounds that are patient-centered transparent, known to the patient, and understandable from their perspective.[20] Informed consent must be obtained from patients prior to transferring prescriptions or restricting access to patient choice in anyway. PBMs and PPNs have an obligation to be transparent about the allocation principles they apply so they can be held accountable for them if needed.

PPNs and Trust

Patient trust in their healthcare professionals is central to clinical practice and aligned with the ethical principle of fidelity (accountability).[14, 28]

Trust is fundamental for patient-centered, pharmaceutical care. Several studies have shown that trust in the patient-clinician relationship is associated with improved health outcomes.[28] [28]

Current PBM and PPN models erode relationships and trust between patients and pharmacists as staff pharmacists are first used by PPNs as the intermediaries of benefit adjudication, and only secondarily as healthcare providers. This role creates barriers to the therapeutic relationship required to maximize health outcomes. An example of a barrier created by the adjudication role is the power imbalance created when pharmacists are seen as the gatekeepers to medications.

When a pharmacist is unable to fill a prescription in a way that a patient expects (i.e., it is not covered thus has a cost, it requires prior authorization hence they have to wait, they have to switch brands etc.) the patient feels that the pharmacist is withholding care. This creates a tension that is incompatible with building a trusting relationship, which is essential to optimizing health outcomes. In addition, patients who are delegated to PPNs are not choosing their pharmacist and may be at odds with their pharmacist as a result of the restrictions placed on patient choice by PPNs.

Patient care may be compromised due to the inability to establish a therapeutic relationship, resulting such a lack of trust. In addition, patients may have selected their pharmacist based on language or

cultural backgrounds similar to their own to enable relationship building. This may not be possible within the mandated PPN which may also jeopardize patient health.

This lack of trust between patient and pharmacist can be inhibitory to building a therapeutic relationship which will negatively impact medication related outcomes. The current PBM and PPN structures therefore contravene the ethical principle of fidelity.

OPINION

It is my opinion that closed PBMs and PPNs violate the Code of Ethics and constitutes an unethical pharmacy practice.

The *Drug and Pharmacies Regulation Act* requires that any corporately owned or operated pharmacy must have the majority of its directors be pharmacists. This creates a conflict of interest as individuals are both corporate leaders and pharmacists. In these roles, individuals have an obligation to put patients ahead of profits, however their senior leadership role in the corporation pays them to maximize profits. Individuals working in these dual roles are breaching their ethical obligations as health care providers and must be held accountable. In the absence of regulatory sanction and accountability, these systems have the potential to erode patient trust in the pharmacy profession, which create reals risks to patient safety, and negatively impact patient outcomes, placing the public at risk.

Based on the rising costs of prescription drugs around the globe, the potential for evolution and growth of PBMs and PPNs with vertical integration is significant, especially if there is no accountability for those individuals who took an oath to put the wellbeing of patients ahead of profits. Payer-directed care is an important part of our health eco-system in Canada, and cost containment strategies are important, however these must not be subordinated to the ethical foundations on which healthcare is built and the patient must be at the centre of all work done.

CONCLUSIONS

Many PBM and PPN practices are unethical and contravene the Code of Ethics. I would support regulatory sanctions which would hold individuals and entities involved in PPNs and PBMs, and particularly pharmacist-leadership at those organizations, responsible for their ethical and professional breaches in order to ensure patients receive the care they deserve and that pharmacists are able to uphold their ethical obligations.

Sincerely,

Jamie Kellar, RPh, BScHK, BScPhm, PharmD, PhD

References

1. Greiss J, Tadrous M. Proceed with caution: The possible impact of preferred-provider networks. *Can Pharm J (Ott).* 2014;147:273-274.
2. Barlas S. Are specialty drug prices destroying insurers and hurting consumers?: a number of efforts are under way to reduce price pressure. *P t.* 2014;39:563-566.
3. Burton SL, Randel L, Titlow K, Emanuel EJ. The ethics of Pharmaceutical benefit management. *Health Aff (Millwood).* 2001;20:150-163.
4. Drettwan JJ, Kjos AL. An Ethical Analysis of Pharmacy Benefit Manager (PBM) Practices. *Pharmacy (Basel).* 2019;7.
5. Martins AC, Oshiro MY, Albericio F, de la Torre BG, Pereira GJV, Gonzaga RV. Trends and Perspectives of Biological Drug Approvals by the FDA: A Review from 2015 to 2021. *Biomedicines.* 2022;10.
6. Rimler GW, Morrison RD. The ethical impacts of managed care. *Journal of Business Ethics.* 1993;12:493-501.
7. Gale A. If Pharmacy Benefit Managers Raise Drug Prices, Then Why Are They Needed? *Mo Med.* Vol 120. United States2023:243-244.
8. Mattingly TJ, 2nd, Hyman DA, Bai G. Pharmacy Benefit Managers: History, Business Practices, Economics, and Policy. *JAMA Health Forum.* 2023;4:e233804.
9. Buckley J. How the trend factor affects your benefits costs: Benefits Canada; 2015.
10. Canada. S. The Sanofi Canada Healthcare Survey2015.
11. Ontario. Go. Drug and Pharmacies Regulation Act1990.
12. Chaar B, Brien J-A, Krass I. Professional ethics in pharmacy: the Australian experience. *International Journal of Pharmacy Practice.* 2010;13:195-204.
13. Lamsam GD. Human dignity and pharmaceutical care. *Am J Health Syst Pharm.* 1997;54:2733-2735.
14. Pharmacists OCo. Code of Ethics. In: Pharmacists OCo, ed2022.
15. Hepler CD. Pharmacy as a clinical profession. *Am J Hosp Pharm.* 1985;42:1298-1306.
16. Miller FH. Secondary Income From Recommended Treatment: Should Fiduciary Principles Constrain Physician Behaviour. *The New Health Care for Profit: Doctors and Hospitals in a Competitive Environment*. Washington, DC.: National Academies Press; 1983.
17. Authorities NAoPR. Model Standards of Practice for Pharmacists and Pharmacy Technicians in Canada. Ottawa2022.
18. Varkey B. Principles of Clinical Ethics and Their Application to Practice. *Med Princ Pract.* 2021;30:17-28.
19. Toma A, Crisan O. Ethics and business in community pharmacies - A framework for an ethical dialogue. *Farmacia.* 2022;70:985-990.
20. Raus K, Mortier E, Eeckloo K. The patient perspective in health care networks. *BMC Med Ethics.* 2018;19:52.
21. Mariner WK. Business vs. medical ethics: conflicting standards for managed care. *J Law Med Ethics.* 1995;23:236-246.
22. Glassman PA, Schneider PL, Good CB. An ethical framework for pharmacy management: balancing autonomy and other principles. *J Manag Care Spec Pharm.* 2014;20:334-338.
23. Schafer A. Canadian Internet Pharmacies: Some Ethical and Economic Issues. . *Canadian Pharmacists Journal.* 2008;141:191-197.

24. Balto D. Problems Arise When Pharmacy Chains Own Pharmacy Benefit Managers: Centre for American Progress Action Fund; 2010.

25. Rajiah K, Sivarasa S, Maharajan MK. Impact of Pharmacists' Interventions and Patients' Decision on Health Outcomes in Terms of Medication Adherence and Quality Use of Medicines among Patients Attending Community Pharmacies: A Systematic Review. *Int J Environ Res Public Health.* 2021;18.

26. Adekunle OA, Olson AW, Schommer JC, Brown LM. Influence of patient-pharmacist relationship on willingness to accept pharmacist-provided services. *Journal of the American Pharmacists Association.* 2023;63:760-768.e761.

27. Ljungholm L, Edin-Liljegren A, Ekstedt M, Klinga C. What is needed for continuity of care and how can we achieve it? – Perceptions among multiprofessionals on the chronic care trajectory. *BMC Health Services Research.* 2022;22.

28. Birkhäuer J, Gaab J, Kossowsky J, et al. Trust in the health care professional and health outcome: A meta-analysis. *PLoS One.* 2017;12:e0170988.