

Environmental Update: Policies & Regulations

**Daniel Weiss
John Greiss
Norton Rose Fulbright Canada LLP**

**PSP Essentials Workshop
December 4th, 2020**

The purpose of this communication is to provide general information of a legal nature. It does not contain a full analysis of the law nor does it constitute an opinion of any Norton Rose Fulbright entity on the points of law discussed. You must take specific legal advice on any particular matter which concerns you. If you require any advice or further information, please speak to your usual contact at Norton Rose Fulbright.

Norton Rose Fulbright Canada LLP



Agenda

Introduction

**IMC
Code of
Ethical
Practices**

**Quebec
Bill 92 /
PAAB**

**Assaraf
Decision**

The purpose of this communication is to provide general information of a legal nature. It does not contain a full analysis of the law nor does it constitute an opinion of any Norton Rose Fulbright entity on the points of law discussed. You must take specific legal advice on any particular matter which concerns you. If you require any advice or further information, please speak to your usual contact at Norton Rose Fulbright.

About Norton Rose Fulbright



Coverage



*associate office

**alliance

3***From second quarter 2017

About Norton Rose Fulbright



**Access to
key people**

- Elite global law practice
- 4000 lawyers, all continents (except Antarctica)



**Depth of
experience**

- Clients include multinational, start up and scaling innovative companies at every stage of the product life cycle



**Industry
knowledge**

- Award winning global practices
 - Life Sciences & Healthcare

Introduction



Daniel Weiss
Associate

Year of Call: 2019 (ON)

J.D., Western University, 2018

B.Sc. (Hons.), Biology, Queen's University, 2014



The purpose of this communication is to provide general information of a legal nature. It does not contain a full analysis of the law nor does it constitute an opinion of any Norton Rose Fulbright entity on the points of law discussed. You must take specific legal advice on any particular matter which concerns you. If you require any advice or further information, please speak to your usual contact at Norton Rose Fulbright.

Introduction



John Greiss
Associate

Year of Call: 2011 (AB), 2018 (ON)

LL.M., University of Toronto, 2016

J.D., University of Alberta, 2010

B.Sc. Pharm., University of Alberta, 2004



2020 Updates to IMC's Code of Ethical Practices

New 2020 Code of Ethical Practices

- Came into effect on January 1, 2020
- **Important changes related to PSP and Medical Practice Activities (MPAs) came into effect on June 1, 2020**

Changes to PSPs and MPAs Chapter

Conflict of Interest section was completely rewritten

Limits payments and benefits

- “Members must not provide any payment or other benefit for services rendered within the context of Patient Support Programs or Medical Practice Activities, either directly or indirectly” to:
 - Prescribing HC Professional of the patient being enrolled in the PSP
 - Any person who is not at arm’s length from the prescribing HC Professional (e.g. agent, staff member, medical practice controlled by the Professional or his family member)

Remote community exception

- “Members may pay or provide financial benefit to a concerned patient’s own prescribing HC [...] where the concerned patient resides in a remote community and would not otherwise be able to reasonably obtain the Patient Support Program services in question.”

Changes to PSPs and MPAs Chapter

Third party or Internal Staff services

- Members can still retain the services of a third party or engage their own qualified staff to provide PSPs
- These third parties are also prohibited from paying or providing a benefit to the Professional
- “Where a third party is retained to provide a Patient Support Program or a Medical Practice Activity, Members must ensure that the third party does not retain the services of the concerned patient’s prescribing Health Care Professional [...]. For greater clarity, a third party may be a Health Care Professional, however such Health Care Professional must not be the concerned patient’s prescribing Health Care Professional.”

Timing of PSP

- “Members may only initiate product-specific activities for a Patient Support Program after the prescribing Health Care Professional has made the treatment decision and/or prescribed the product.”

Changes to PSPs and MPAs Chapter

Focus is on prescribing HCPs

Benefit of the patient is the sole outcome sought

- *Before:* The programs must have a primary objective of bettering patient health outcomes.
- *Now:* PSPs must have the objective of benefitting patients

Restricting the intent behind the PSPs

- [...] these programs/services must not serve to ~~solely~~ cover day-to-day activities or resources considered part of the medical practice's operational expenses nor should they **duplicate**, replace or compete with services or resources provided and funded by the existing health care system.

Bill 92 in Quebec

PAAB and the use of RWE

Summary of Bill 92

Distribution model (s. 80.2(4))

- Restricts the ability of manufacturers and wholesalers to enter into exclusive or preferential distribution agreements
- A manufacturer may not “require that an owner pharmacist procure from the manufacturer, wholesaler or intermediary, on a preferential basis, medications or supplies entered on the list of medications, unless an agreement between them explicitly provides for the possibility of procuring medications or supplies otherwise when, in the pharmacist’s opinion, a person’s state or condition requires a medication or supply that is not available on a preferential basis”
- Very broad drafting
 - Would seem to prevent a manufacturer from electing to distribute a product through an exclusive wholesaler

Summary of Bill 92

Bill 92 amends, amongst other things, the *Act respecting prescription drug insurance*

- Adopted in 2016, entry into force in 2017

Prohibits manufacturers and wholesalers from reimbursing all or part of the price of a drug covered by the plan (s. 80.2(1))

- However this disposition will not come into force until regulations are drafted to define exceptions to the new prohibition
- Will probably take the form of a humanitarian exception

PAAB and the use of RWE

- PAAB distributed consultation draft on the use of RWE in advertising, including RWE obtained from PSP programs
- Current status: postponed until further direction on the use of decision-grade RWE for regulatory licensing purposes
 - PAAB is expected to follow Health Canada's lead once finalized
- For now, status quo: very limited use of PSP data in advertising claims
 - Adherence claims remain doubtful
 - Some ability to make experience claims (e.g., 90,000 doses dispensed; 50,000 patients prescribed product X)

Assaraf Decision

Pharmaciens (*Ordre professionnel des*) v. Assaraf (2020)

- Both the pharmaceutical industry and the practice of pharmacy are highly regulated industries
- Further complicated by federal laws + different provincial laws
- PSP design needs to consider a holistic view of all laws, regulations, industry codes, and professional standards of practice
 - All are constantly evolving
 - Multiple points of enforcement by different stakeholder
- Without proper preparation and tailoring of the PSP program, can end up facing regulatory enforcement issues

Pharmaciens (*Ordre professionnel des*) v. Assaraf (2020)

- Manufacturer entered into agreement for a PSP-type program with a wholesaler = a distribution program for certain injectable eye products
- Assaraf (pharmacist) had entered into an agreement with the wholesaler to dispense the drugs to the clinics
 - on the day of the injection, the patient signed enrollment form, which contained the prescription AND the pharmacy name; consented to Rx filled by pharmacist “unless patient chose otherwise”
 - Clinic would administer the injection from product in stock
 - Pharmacist received a copy of the form/prescription at a later time after the injection had been administered
 - Pharmacist would then dispense a new injection to replenish the clinic stock for the next injection
 - Pharmacist does not provide counseling to the patient or establish a relationship with the patient

Pharmaciens (*Ordre professionnel des*) v. Assaraf (2020)

PHARMACIST CODE OF ETHICS (QUEBEC)

- 27. Pharmacists must acknowledge the patient's right to choose his or her pharmacist; they must also respect the patient's right to consult another pharmacist, professional or other qualified person. They may not make any agreement which could affect those rights.
- 53. No pharmacist may make an agreement with a person authorized to write prescriptions if the agreement is likely to limit the professional independence of that person or interfere with the right of a patient to choose his or her pharmacist.

Pharmaciens (*Ordre professionnel des*) v. Assaraf (2020)

PHARMACIST CODE OF ETHICS (QUEBEC)

- 54. No pharmacist may give to a person authorized to write prescriptions any forms or prescription pads on which written or printed contact information identifies a pharmacist, a partnership or joint-stock company of pharmacists or a pharmacy; nor may a pharmacist allow a person authorized to write prescriptions to advertise the pharmacist, the partnership or joint-stock company of pharmacists or the pharmacy on either side of printed or handwritten paper used to write a medical prescription of any kind.
- 77(4) [Pharmacists may not obtain] clients through an intermediary or making an arrangement with an intermediary for that purpose;

Pharmaciens (*Ordre professionnel des*) v. Assaraf (2020)

Decision by the Disciplinary Board of the *Ordre des pharmaciens du Québec*

Several misconducts (between 2010 and 2019)

- Obtaining clients through an intermediary
- Storing drugs outside the pharmacy
- Prescription pads left at the clinic with the pharmacy name
- Several 'benefits' to clinics: injection kits, refrigerators to store the syringes, containers to dispose used syringes in
- Accepting the returns of unused medicine from the clinics and not destroying them
- No file was created for the patients, and no complete advice was given (but billing claims were sent to the RAMQ or the private insurer)

Pharmaciens (*Ordre professionnel des*) v. Assaraf (2020)

Penalties for the pharmacist

- 12 months suspension
- \$84 000 fine

No comments on the responsibility of the pharmaceutical company, BUT consider:

- 188.2.1. Every person who helps or, by encouragement, advice or consent, or by an authorization or order, otherwise than by soliciting or receiving professional services from a member of an order, leads a member of a professional order to contravene section 59.1, 59.1.1 or 59.2 or a provision of the code of ethics adopted under section 87 is guilty of an offence and is liable, for each day during which the contravention continues, to the fine prescribed in section 188.
- Fines prescribed for a violation of this prohibition are between \$5,000 and \$125,000 for corporations, double on second offences. In principle, these are continuing offences, meaning that the fines can apply every day the offence continues.

The purpose of this communication is to provide general information of a legal nature. It does not contain a full analysis of the law nor does it constitute an opinion of any Norton Rose Fulbright entity on the points of law discussed. You must take specific legal advice on any particular matter which concerns you. If you require any advice or further information, please speak to your usual contact at Norton Rose Fulbright.

Key Takeaways

- Ensure all aspects of the PSP are clearly thought through and designed with the relevant regulatory, ethical and professional practice standards in mind
- Seek advice early in the design process to help achieve the outcomes you want in a compliant fashion
- Disclaimers and consent forms are not always sufficient to avoid regulatory liability
- PSPs and industry involvement in providing healthcare-type services continue to be highly scrutinized by provincial regulatory bodies, so extra diligence is warranted



Questions

daniel.weiss@nortonrosefulbright.com

416.216.4771

john.greiss@nortonrosefulbright.com

416.203.4439



Law around the world

nortonrosefulbright.com

Norton Rose Fulbright US LLP, Norton Rose Fulbright LLP, Norton Rose Fulbright Australia, Norton Rose Fulbright Canada LLP and Norton Rose Fulbright South Africa Inc are separate legal entities and all of them are members of Norton Rose Fulbright Verein, a Swiss verein. Norton Rose Fulbright Verein helps coordinate the activities of the members but does not itself provide legal services to clients.

References to 'Norton Rose Fulbright', 'the law firm' and 'legal practice' are to one or more of the Norton Rose Fulbright members or to one of their respective affiliates (together 'Norton Rose Fulbright entity/entities'). No individual who is a member, partner, shareholder, director, employee or consultant of, in or to any Norton Rose Fulbright entity (whether or not such individual is described as a 'partner') accepts or assumes responsibility, or has any liability, to any person in respect of this communication. Any reference to a partner or director is to a member, employee or consultant with equivalent standing and qualifications of the relevant Norton Rose Fulbright entity.

The purpose of this communication is to provide general information of a legal nature. It does not contain a full analysis of the law nor does it constitute an opinion of any Norton Rose Fulbright entity on the points of law discussed. You must take specific legal advice on any particular matter which concerns you. If you require any advice or further information, please speak to your usual contact at Norton Rose Fulbright.