



Friday Five

June 15, 2018

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Important Update to the Food and Drug Regulations Regarding the Sale of Opioids

On April 23, 2018, the Government of Canada announced the Regulations Amending the Food and Drug Regulations (Opioids) that directly affect pharmacists dispensing opioids. **These changes will come into effect in October 2018.** Health Canada, as part of their strategy to reduce the consequences of opioid overuse, addiction and overdose deaths, will require patients to receive additional information about the safe use of opioids. These changes are intended to mitigate the current public health crisis by educating patients about the inherent risks associated with prescription opioids.

The amendments to the regulations involve altering the terms and conditions required for a pharmacist to sell an opioid. The following two requirements have been added to the *Food and Drug Regulations* for the sale of a Class A opioid (see attached table):

C.01.005.1 (1) No pharmacist or practitioner shall sell

Professional Development Opportunities

Manitoba Pharmacy Technician & Assistant Conference
(For Pharmacy Technicians only)

[June 21, 2018](#)

Opioid Replacement Therapy 101 Introduction to Clinical Practice

[September 13 & 14, 2018](#)
[November 22 & 23, 2018](#)

Health Sciences Centre Winnipeg Presents:

[The 22nd Annual Bug Day](#)

October 16, 2018

Online Programs:

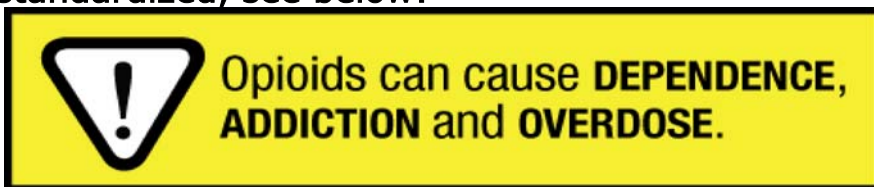
[Oral-Systemic Health Education for Non-Dental Healthcare Providers](#)

a Class A opioid — including one that is compounded by a pharmacist under a prescription or by a practitioner — unless

(a) the drug's package has applied to it a warning sticker that meets the specifications set out in the source document; and

(b) the drug is accompanied by a patient information handout that meets the specifications set out in the source document.

All dispensed medications (new or refills) listed in Part A **MUST** contain a Health Canada approved warning sticker affixed to the label. The warning sticker is standardized, see below:



In addition, all practitioners and/or pharmacists dispensing a Class A opioid **MUST** provide the following patient information handout to the patient, every time an opioid is sold:

<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/policies/warning-sticker-opioid-patient-information-handout/information-handout.html>

This warning sticker and patient information sheet can be found on the Health Canada website, entitled *Information for Patients Concerning Opioids*. This will allow Health Canada to update content as necessary.

An exception to this requirement is when an opioid is being administered directly to the patient under the supervision of a practitioner, or when an opioid product is sold from one pharmacist or practitioner to another. Please be reminded that pharmacy-to-pharmacy sales of opioids is only permitted in emergency situations.

[Table 1: Part A – Opioids subject to the prescription labelling provisions](#)

[Ordering Lab Tests for Manitoba Pharmacists](#)

Visit www.cphm.ca for more information on [Expanded Scope of Practice](#) training.

[Self-Limiting Conditions Independent Study Program](#)

Visit www.cphm.ca for more information on [Expanded Scope of Practice](#) training.

All PD opportunities are listed on the College website under

[Upcoming Professional Development Opportunities](#)

Quality Assurance Self-Assessment for Sterile Compounding

The final Quality Assurance Self-Assessment for Sterile Compounding has been posted to the website of the College of Pharmacists of Manitoba (College). The Quality Assurance Self-Assessment is recommended for use as a gap analysis tool for pharmacies in Manitoba as they work toward implementation of the NAPRA Model Standards regarding hazardous and non-hazardous sterile compounding.

The standards represent a significant change to sterile compounding practice, policies and physical facilities, and were approved by Council in February 2017, with phased-in implementation requirements.

The first implementation deadline for pharmacies engaged in sterile compounding is **January 1, 2019**. Following this initial phase, staff involved in sterile compounding are required to be educated and validated in accordance with Section 6.5 and 6.6 of the NAPRA Sterile Hazardous Model Standards by **June 1, 2019**.

Pharmacies engaged in sterile compounding are required to meet all NAPRA Model Standard Requirements by **January 1, 2021**.

More information regarding the implementation schedule for the Model Standards for Pharmacy Compounding of Sterile Preparations can be found [here](#) and [here](#).

Health Canada - Annual Community Pharmacy Inspection Report

Health Canada has released the [Community Pharmacy Inspection Program Annual Report for the 2015-2016 fiscal year](#). The annual report provides information on the objectives of the inspection program, the number of pharmacy inspections carried out for the year, as well as observations of non-compliance. The most common observations of non-compliance during that period were inventory reconciliation issues relating to

record keeping and security issues.

Record keeping issues occurred in approximately 64% of the inspections with inventory records found to be incomplete, inaccurate or corrected without an explanation for overage or shortages of controlled substances. Other inventory issues included purchase records that were incomplete or inaccurate, as well as narcotic prescriptions filed with regular prescriptions rather than in a special narcotic file.

During the 2015-16 Community Pharmacy Inspection Program, Health Canada inspectors observed security-related issues approximately 93% of the time. Inspectors checked security practices such as the sharing of keys and/or alarm codes with other pharmacy staff, the accessibility of the pharmacy after-hours, and the submission of loss and theft reports to Health Canada. Most observations were of a minor or non-critical nature, however, in some cases inspectors found that controlled substances were stored in unsecured locations such as unlocked safes, drawers, or open cabinets, creating a higher risk of loss or theft.

To ensure your pharmacy is in compliance of the Controlled Drugs and Substances Act, please review the following documents:

- [Community Pharmacy Inspection Program Annual Report](#)
- CPhM [Narcotic and Controlled Drug Accountability Guidelines](#)
- Health Canada Guidance Document – [Reporting of Loss or Theft of Controlled Substances and Precursors](#)
- Health Canada [Loss or Theft Report Form](#) for Controlled Substances and Precursors

Reminder: Notice to Voting Members of Amendment to the By-Laws

The College held its 2017 Annual General Meeting (AGM) on May 12, 2018. A total of 68 Voting Members were present at this meeting which represents 4.3% of the College's current membership. By-law 3.04

states that 5% of voting members constitutes the quorum for the transaction of business at any general meeting of the College. General Counsel to the College has advised that the business of the 2017 AGM may be concluded through an amendment to the College By-Laws to conduct an electronic vote of the membership on each motion made at the 2017 AGM.

Please be advised, therefore, that Council passed a motion on June 1, 2018, to make a by-law in accordance with section 75(1) of the *Pharmaceutical Act* that the business as set out in the agenda for the 2017 Annual General Meeting held on May 12, 2018, be completed by electronic ballot in which all voting members will vote separately on each motion made at the 2017 AGM.

This electronic vote is set to begin within the coming week and all voting members will receive instructions on the voting procedures in advance.

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The *Friday Five* e-bulletin is published by the **College of Pharmacists of Manitoba** and is forwarded to every licenced pharmacist and pharmacy owner in the Province of Manitoba. Decisions of the College of Pharmacists of Manitoba regarding all matters such as regulations, drug-related incidents, etc., are published in the *Friday Five*. The College of Pharmacists of Manitoba therefore assumes that all pharmacists and pharmacy owners are aware of these matters.

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