Opioid Warning Sticker and Patient Handout Requirements

New Health Canada Regulations

On April 23, 2018, Health Canada amended the *Food and Drug Regulations* to require pharmacists to comply with additional labelling and patient information handout requirements when dispensing certain opioids. These changes have been developed and implemented to reduce the risks associated with the post-market use of these products as well as increase patient awareness of the risks associated with these medications, and to encourage safer use.

How to Obtain the Opioid Warning Sticker and Patient Information Handout

Pharmacies will be responsible for obtaining the warning sticker and patient information handout and for ensuring that that they are not altered. Digital representation of the warning sticker and patient information handout can be found on the Government of Canada's website.

When are Stickers and Patient Handouts Required?

Pharmacists are required to apply the opioid warning sticker and provide the patient information handout for drugs listed in Part A - Opioids Subject to the Prescription Labelling Provisions for the first fill and all refills, with the following exceptions:

- Opioids authorized and used for the treatment of an opioid use disorder (e.g., witnessed doses or carries of methadone);
- Over-the-counter opioid preparations containing a low dose of codeine, in combination with two or more other medicinal ingredients, as detailed in s. 36(1) of the *Narcotic Control Regulations*;
- When the drug is to be administered under the supervision of a practitioner (e.g., a hospital ward, nursing homes, outpatient clinics, emergency departments and outpatient surgery settings);
- The sale of the drug is to a pharmacist or practitioner.

For more information on opioid labelling and handout requirements, see Health Canada's Questions and Answers: Prescription Opioids – Sticker and Handout Requirements for Pharmacists and Practitioners.