

Context and Background on the Fentanyl Patch for Patch (P4P) Return Policy

A fentanyl P4P Program requires a patient to return all of their fentanyl patches to the pharmacy before the patient is able to have their next prescription filled.

The fentanyl P4P return policy was developed as a voluntary Fentanyl P4P Program that was started by several members of the local police force in a joint collaboration with their Drug Strategy Committee as well as physicians and pharmacists in the North Bay region. With reported success of this initiative, the Ontario Association of Chiefs of Police called together a working group and developed a guidance document for the implementation of this type of program, entitled "[Patch 4 Patch Initiative: Fentanyl Abuse Prevention – A Shared Responsibility](#)" (2014).

Bill 33 was introduced by the MPP from North Bay on October 22, 2014, and was passed in December 2015. The intent of the Bill is to implement a mandatory P4P Program in Ontario to address the ongoing issue of opioid-related deaths and serves as one tool to help reduce the abuse, misuse, and diversion of the fentanyl patches.

The *Safeguarding our Communities Act (Patch for Patch Return Policy), 2015* outlines specific P4P requirements for prescribers and pharmacy dispensers of fentanyl patches. A copy of the Act is accessible through <https://www.ontario.ca/laws>

Summary of Proposed Regulation under the *Safeguarding our Communities Act (Patch for Patch Return Policy), 2015*

Definitions

- The following criteria must be met in order for a fentanyl transdermal patch to be considered a "fentanyl patch" under the Act and regulation:
 - The patch must deliver its active ingredient across the skin for systemic distribution.
 - The patch must contain fentanyl, a fentanyl salt, a fentanyl derivative, a fentanyl analogue or a salt of a fentanyl derivative or fentanyl analogue as an active ingredient.
- Any person (other than a pharmacy dispenser) who is authorized to dispense fentanyl patches under the laws of Ontario is a "dispenser" for the purposes of the Act and regulation. (Note: the definition of "dispenser" in the Act already includes pharmacy dispensers. The purpose of this provision in the proposed regulation is to capture non-pharmacy dispensers).

Additional Requirements for Prescribers

- When prescribing fentanyl patches for a patient, the prescriber would also be required to indicate on the prescription that it is the patient's first prescription for fentanyl patches, if:
 - The prescriber has not previously prescribed fentanyl patches for the patient; and
 - The prescriber is reasonably satisfied that the patient has not previously obtained a prescription for fentanyl patches from another prescriber based on his or her discussions with the patient and any other information available to the prescriber.

Exceptions for Pharmacy Dispensers

- Allow pharmacy dispensers to dispense fentanyl patches pursuant to a prescription where they are not listed as the dispensing pharmacy on the prescription and where they did not receive prior telephone or fax notice from the prescriber about the prescription, in the following circumstances:
 - a. Where the prescription is from another province or territory in Canada, the dispenser can only dispense fentanyl patches after contacting the prescriber to verify the authenticity of the prescription.
 - b. Where the prescription lists another pharmacy, the dispenser can only dispense fentanyl patches after contacting the prescriber to verify the authenticity of the prescription and contacting the other pharmacy listed on the prescription to confirm that the other pharmacy did not dispense any fentanyl patches under the prescription.
 - Note: the requirement to contact the *other* pharmacy to confirm that the pharmacy did not dispense any patches under the prescription will not apply where the other pharmacy listed on the prescription is not in operation.

A dispenser who contacts a prescriber or pharmacy in the above scenarios must document the interaction in the dispenser's record of the patient.

Contingency Plans for Pharmacy Dispensers

- The following contingency plans would be prescribed for pharmacy dispensers:
 - a. Where no patches are returned to the pharmacy and the prescription indicates that it is the patient's first prescription for fentanyl patches, the dispenser must use his/her professional judgment in determining how many fentanyl patches to dispense under prescription.
 - b. Where a dispenser does not collect any used fentanyl patches or collects fewer used patches than the quantity of fentanyl patches to be dispensed under the prescription, the dispenser shall:
 - exercise his/her professional judgment in deciding how many fentanyl patches to dispense under prescription; and
 - notify the prescriber of the quantity of new patches that were dispensed and the fact that the patient returned zero/fewer used patches.
 - c. Where a dispenser has reason to believe that any of the used fentanyl patches are counterfeit or have been misused or tampered with:
 - The dispenser shall exercise his/her professional judgment in deciding how many fentanyl patches to dispense under prescription;
 - The dispenser shall notify the prescriber of:
 - the quantity of patches that were dispensed,
 - the dispenser's belief that the patient returned counterfeit/misused patches, and
 - whether the dispenser has contacted or intends to contact a law enforcement agency in Canada (see below)
 - Where the dispenser has reasonable grounds to believe that the counterfeit or misused patches relate to an offence under the laws of Ontario or Canada, the dispenser may contact a law enforcement agency in Canada (e.g. police) and disclose to the agency:

- the name of the patient, the name of the agent who attended the pharmacy on behalf of the patient (if applicable),
- the dispenser's belief that fentanyl patches returned to the pharmacy are counterfeit, have been misused or have been tampered with, and
- any other information that the dispenser reasonably believes may assist the law enforcement agency in an ongoing investigation or in determining whether to commence an investigation.

Any notifications to a prescriber in the above contingency plans must be documented in the dispenser's record of the patient.

Prescribe Different Classes of Prescribers and Establish Rules for Each Class

- The following classes of prescribers and rules for each class would be prescribed:
 - **Class #1:** Prescribers who authorize the dispensing of fentanyl patches by a community pharmacy dispenser.
 - **Rule for Class #1:** These prescribers are subject to the requirements set out in section 2 of the Act (including the additional requirement described above regarding first time prescriptions).
 - **Class #2:** Prescribers who authorize the dispensing of fentanyl patches and dispense the fentanyl patches themselves (e.g. dispensing physicians, dentists and veterinarians).
 - **Rule for Class #2:** These prescribers are not subject to the requirements set out in section 2 of the Act. Instead, paragraphs 3, 4 and 5 of subsection 3(1) apply to the prescriber's dispensing of patches as follows:
 - Prescriber is only permitted to dispense fentanyl patches if the patient or his or her authorized representative gives the prescriber a used fentanyl patch in exchange for every fentanyl patch dispensed (subject to exceptions below).
 - Prescriber must inspect every used fentanyl patch collected from the patient or his or her authorized representative.

- If prescriber collects zero/fewer used patches, then prescriber must exercise his/her professional judgment when dispensing and keep a record of the number of used patches returned and the number of new patches dispensed.
- If prescriber collects counterfeit or misused used patches, then prescriber must exercise his/her professional judgment when dispensing and keep a record of the incident and the number of new patches dispensed. If prescriber has reasonable grounds to believe that the counterfeit or misused patches relate to an offence, the prescriber may contact a law enforcement agency in Canada.
- **Class #3:** Prescribers in a public hospital or private hospital who prescribe fentanyl patches for patients of the hospital.
- **Rule for Class #3:** These prescribers are not subject to the requirements set out in section 2 of the Act.

Prescribe Different Classes of Dispensers and Establish Rules for Each Class

- The follow classes of dispensers and rules for each class would be prescribed:
 - **Class #1:** Pharmacy dispensers, other than the pharmacy dispensers mentioned in class #3 below.
 - **Class #2:** Dispensers operating in a public hospital or a private hospital who dispense fentanyl patches for a patient of the hospital.
 - **Class #3:** Dispensers at a pharmacy who dispense fentanyl patches for a resident of a long-term care home or a prisoner/inmate in a correctional facility.
 - **Rules for Class #1 Dispensers:** These dispensers are subject to the requirements set out in section 3 of the Act (including the contingency plans described above).
 - **Rules for Class #2 and Class #3 Dispensers:** These dispensers are not subject to the requirements set out in section 3 of the Act, provided that:
 - the hospital, long-term care home or correctional facility where the patient resides has a written policy establishing a medication management system for the collection and

administration of fentanyl patches used in the hospital, long-term care home or institution that safeguards the patches from misuse, abuse and diversion; and

- the dispenser has a copy of the written policy described above.

Commencement

It is proposed that the regulation, if approved, come into force on October 1, 2016.