

Frequently Asked Questions: Implementation of the *Safeguarding our Communities Act (Patch for Patch Return Policy)*, 2015

Overview

As key stakeholders impacted by the implementation of the [Safeguarding our Communities Act \(Patch for Patch Return Policy\), 2015](#) (the “Act”), and its [regulation](#), prescribers and dispensers should be aware of how these requirements will affect their practices.

The regulation made under the Act has been approved by the Ontario Government, and the Act and regulation will come into force on October 1, 2016.

The Act and regulation set out rules for the prescribing and dispensing of fentanyl patches in Ontario. The Act places controls on the prescribing and dispensing of fentanyl patches, and requires patients to return used patches to their pharmacy before new patches can be dispensed.

The College of Physicians and Surgeons of Ontario (CPSO) and the Ontario College of Pharmacists (OCP), the “colleges”, strongly support this new legislation, as well as the government’s approach to delineate specific roles and responsibilities for physicians and pharmacists when prescribing and dispensing fentanyl. The colleges jointly developed a fact sheet for their members which is available on their respective websites:

- Ontario College of Pharmacists: www.ocpinfo.com
- College of Physicians and Surgeons of Ontario: www.cpsso.on.ca

1. What is the fentanyl Patch for Patch (P4P) return policy?

The P4P return policy for fentanyl patches requires patients to return used patches to their pharmacy before more can be dispensed.

This program involves the prescriber, dispenser (e.g., pharmacists) and the patient who is prescribed fentanyl patches.

2. Is the P4P program a government initiative?

The P4P program was originally a community-based initiative established in 2013 by the North Bay and Area Community Drug Strategy in consultation with local physicians and pharmacists, and the North Bay police service. As a result of its local success, the Ontario Association of Chiefs of Police (OACP) formed a working group and developed a guidance document for the implementation of this type of program in any Ontario community. The guidance document entitled "[Patch 4 Patch Initiative: Fentanyl Abuse Prevention – A Shared Responsibility](#)" (2014) was shared with police services throughout Ontario. As a result, the P4P program was implemented in a number of communities across the province on a voluntary basis.

Due to its success in communities across Ontario, on October 22, 2014, Bill 33 was introduced by the MPP from North Bay.

3. What is in the regulation made under the Act?

The regulation:

- Specifies the criteria that must be met in order for a drug product to be considered a "fentanyl patch" under the Act;
- Clarifies that persons who dispense fentanyl patches outside of a pharmacy are considered "dispensers" under the Act;
- Establishes additional requirements for prescribers of fentanyl patches;
- Establishes additional requirements for pharmacy dispensers of fentanyl patches; and
- Establishes different classes of prescribers and dispensers and establishes prescribing or dispensing rules for each class.

For the authoritative text of [the Act](#) and [regulation](#), please visit the e-Laws website at:

www.ontario.ca/laws

4. When do the P4P rules in the Act and regulation become mandatory?

The Act and regulation come into force on October 1, 2016.

5. How does the P4P return policy align with the ministry's strategic objectives?

The ministry takes the issue of the opioid abuse and misuse seriously. When Bill 33 was introduced in the Legislature by the MPP from North Bay, the Minister of Health and

Long-Term Care supported the Bill.

The government is currently developing a provincial framework for pain management and prescription opioid use disorder. The P4P Initiative is one component within this broad strategy framework and one way to address appropriate prescribing and distribution.

6. How will the public know about the P4P return policy?

In accordance with OCP and CPSO's fact sheet, it is responsibility of both prescribers and pharmacists to make sure they clearly communicate to patients what is required of them under this program.

Patient Eligibility

7. Are all Ontarians required to participate in the P4P return policy?

All patients who receive fentanyl patches dispensed in Ontario are required to return their used fentanyl patches to the pharmacy before more can be dispensed.

8. Is there a form that patients should use for the P4P return policy?

No, there is no specific form that patients are required to use. Patients are advised to attach their used fentanyl patches to a piece of paper or a P4P disposal form. The used patches must be returned to the pharmacy before new fentanyl patches may be dispensed.

A sample of a [P4P disposal form](#) can be found in the OACP's guidance document. Pharmacies may choose to use other versions.

Patients are encouraged to consult with their prescriber and/or pharmacists to access P4P disposal forms.

Ministry Payment

9. Does the ministry pay physicians or pharmacists to participate in the P4P program?

No, there is no reimbursement for physicians or pharmacists by the ministry. Participation is mandatory under the legislation.

Furthermore, prescribers, pharmacists and other dispensers cannot charge patients for the participation in the program. Prescribers, pharmacists and other dispensers should

familiarize themselves with the regulatory college's online fact sheet:

- Ontario College of Pharmacists's [fact sheet](#)
- College of Physicians and Surgeons of Ontario's [fact sheet](#)

10. Do pharmacists have to submit a claim for the P4P program?

No, there are not adjudication requirements for the P4P program – the P4P program is solely a practice change at the prescriber and pharmacy level.

11. Do pharmacists have to submit a claim to the Narcotics Monitoring System (NMS) for the P4P program?

No, there are no additional requirements for submissions to the NMS. Each prescription dispensed must be recorded in the NMS in the same manner as the current process.

Prescriber Participation

12. Will all Ontario prescribers be participating in the P4P program?

Yes, effective October 1, 2016, all Ontario prescribers are required to participate in the P4P program established under [the Act](#) and [regulation](#).

Prescribers should be familiar with the Act and its regulation, which include limited exemptions. Information is available on the [CPSO website](#) and [fact sheet](#).

13. What are prescribers expected to do when prescribing a fentanyl patch?

Under the P4P program, when a prescriber is writing a prescription to a patient, they must:

1. Record on every fentanyl prescription, the name and address of the pharmacy where the prescription will be filled.
2. Notify the pharmacy in advance that each prescription has been written, either by faxing a copy of the prescription to the pharmacy or by telephone.
3. In the case of a patient's first prescription for fentanyl patches, note "first prescription" on the prescription. A prescription is considered a "first prescription" when:
 - i. The prescriber has not previously prescribed a fentanyl patch for that patient; and

- ii. The prescriber is reasonably satisfied that the patient has not previously obtained a prescription for fentanyl from another prescriber.

The prescriber is also obligated to educate patients about the P4P program. A [fact sheet](#) on the P4P program is available on the [CPSO website](#).

14. I am a prescriber and have a patient who requires fentanyl patches. What should I do now prior to the October 1, 2016 implementation date?

In advance of the October 1, 2016 implementation of the P4P program, it is recommended that all prescribers of fentanyl patches inform their patients of the P4P program and its requirements.

To avoid scenarios where patients do not have used patches to return to their pharmacy on or after October 1, 2016, prescribers should inform their patients that the used fentanyl patches must be kept for the purposes of getting any new fentanyl patches.

You may wish to contact patients who have a current supply of patches to advise them of the change and encourage them to keep their used patches in preparation of getting new fentanyl patches on their next visit to the pharmacy.

Pharmacist Participation

15. Will all Ontario pharmacists be participating in the P4P return policy?

Yes, all Ontario pharmacists and other dispensers of fentanyl patches will be participating in the P4P program, starting on October 1, 2016.

Pharmacists should be familiar with the Act and its regulation, which include limited exemptions. A [fact sheet](#) that is available on the [OCP website](#).

16. Why are all dispensers of fentanyl included?

The requirements of the Act apply to any dispenser who dispenses fentanyl patches to help reduce the misuse, abuse and diversion of fentanyl patches in Ontario.

In this province, dispensers of fentanyl patches include:

- Pharmacists
- Physicians
- Dentists

- Veterinarians can also dispense fentanyl patches, but only for animals

17. What are pharmacists expected to do when a patient seeks to fill a prescription or repeat for fentanyl patches at the pharmacy?

Under the Act, regulation and OCP [Fact Sheet](#), dispensers must:

1. Confirm the name and location of the pharmacy is recorded on the prescription by the prescriber, and the pharmacy has been notified by the prescriber of the prescription before any patches are dispensed.
2. Unless a first time prescription, dispensers must only dispense fentanyl in exchange for used patches provided by the patient or his or her authorized representative.
3. Dispensers must examine and document returned patches, and store them in a secure location prior to proper destruction as outlined in the College's fact sheet entitled "[Destruction of Narcotics, Controlled Drugs, and Targeted Substances](#)".
4. Where a dispenser receives a prescription for fentanyl patches but does not collect all of the patient's used patches, or collects fewer patches than the quantity to be dispensed under the prescription, he or she must:
 - i. Use his or her professional judgment to dispense an appropriate number of patches based on an assessment of the patient, including an assessment of the patient's circumstances and the patient's medical condition; and
 - ii. Notify the prescribing physician of the number of used patches that were collected as well as the number of new patches that were dispensed, if any.
5. Dispensers apply exceptions in the following circumstances:
 - i. A prescription has been authorized by a prescriber from outside Ontario, and the prescription is verified by the dispenser by contacting the prescriber; or
 - ii. Another pharmacy is listed on the prescription, and the authenticity of the prescription is verified by contacting the prescriber, and no fentanyl patches were dispensed by the other pharmacy
6. Dispensers apply exceptions when dispensing to a resident of a long-term care home, a person who is confined in a prison/correctional facility, or a patient in a hospital, in the following circumstances:
 - i. The facility has a written policy establishing a medication management

- system for the collection and administration of fentanyl patches; and
- ii. The dispenser has a copy of the policy.

Dispensers should be familiar with the Act and its regulation, as well as the [fact sheet](#) that is available on the [OCP website](#).

18. I am a pharmacist and have a patient who requires new fentanyl patches. What should I do now prior to the October 1, 2016 implementation date?

In advance of the October 1, 2016 implementation of the P4P return policy, it is recommended that all pharmacists who dispense fentanyl patches should be informing the patients of the P4P program and its requirements.

To avoid scenarios where patients do not have used patches to return to their pharmacy on or after October 1, 2016, pharmacists should inform their patients that the used fentanyl patches must be kept for the purposes of getting new fentanyl patches.

You may wish to contact patients who have a current supply of patches to advise them of the change and encourage them to keep their used patches in preparation of getting new fentanyl patches on their next visit to the pharmacy.

19. I am a pharmacist and have a patient who requires new fentanyl patches. The patient does not have any patches to return. What should I do now prior to the October 1, 2016 implementation date?

See item #4 in question 17 above.

In addition, pharmacists should inform their patients of the P4P program and its requirements starting October 1, 2016, including the requirement that the used fentanyl patches must be kept for the purposes of getting new fentanyl patches.

Documentation and Record Keeping

20. What is the pharmacist required to document under the P4P program for eligible Ontarians?

Standard dispensing record keeping requirements under current standards of practice apply.

Pharmacists must keep records consistent with their obligations under the *Pharmacy Act, 1991*, the *Drug and Pharmacies Regulation Act* and any instructions provided by

the OCP or the ministry.

Please refer to the OCP for guidance relating to documentation within scope of practice at: www.ocpinfo.com/regulations-standards/policies-guidelines/documentation-guidelines.

21. For how long should the record be kept?

Please refer to section 21 of Ontario Regulation 264/16 made under the *Drug and Pharmacies Regulation Act* and associated OCP guidelines for record retention periods, which is the Record Retention, Disclosure, and Disposal Guideline that is available at www.ocpinfo.com/regulations-standards/policies-guidelines/records.

Additional Questions

22. How will the requirements of the P4P program be enforced?

The P4P program requires changes to the way both physicians and pharmacists practice. The requirements will be enforced by the colleges under their current health profession-specific statute, policies, protocols, guidelines, scope/standards of practice, and/or other directives, including the OCP and CPSO's fact sheet.

23. I have questions about the implementing the P4P program and/or the requirements at a practice level. Who should I contact?

If prescribers and/or pharmacies have any questions or concerns related to implementing the P4P program or requirements at a practice level, please refer to your professional college for guidance and/or resources relating to the P4P program.