

Ontario Public Drug Programs Division

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

June 1, 2016

On December 10, 2015, the *Safeguarding our Communities Act (Patch for Patch Return Policy), 2015* (the “Act”) received Royal Assent. The Act is based on the success of a community-led collaboration that requires used fentanyl patches to be returned to pharmacies prior to the dispensing of new patches (i.e. a patch-for-patch or “P4P” policy).

This P4P policy has been implemented in a number of Ontario communities supporting reductions in the deaths due to fentanyl misuse.

Expanding and mandating a P4P program through the Act will be a positive step towards addressing the abuse, misuse, and diversion of fentanyl patches in Ontario.

To implement the Act’s P4P requirements, the Ministry of Health and Long-Term Care (the “ministry”) is proposing a regulation under the Act.

The proposed regulation, if approved, would:

- Prescribe criteria that must be met in order for a drug product to be considered a “fentanyl patch” under the Act;
- Prescribe persons who dispense fentanyl patches outside of a pharmacy as “dispensers” under the Act (e.g., dispensing physicians);
- Prescribe additional requirements for prescribers of fentanyl patches;
- Prescribe additional requirements for pharmacy dispensers of fentanyl patches; and
- Prescribe different classes of prescribers and dispensers and establish rules for each class.

A copy of the proposed regulation and summary of the proposed regulation is available on the Regulatory Registry website at:

www.ontariocanada.com/registry/view.do?postingId=21762&language=en

The content of the final regulation is at the discretion of the Lieutenant Governor in Council (“LGIC”) who may make the regulation with any changes that the LGIC considers appropriate.

Interested parties are invited to provide written comments on the proposed regulation as part of the review. The ministry will consider comments received on or before **July 18, 2016 at midnight EST** (“comment period.”). Please be advised that submissions received after the comment period may not be considered.

Please submit your written comments to:

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Statement about Comments

Unless requested and otherwise agreed to by the ministry, all materials or comments received from organizations in response to the notice will be considered public information and may be used and disclosed by the ministry as part of its review. The ministry may disclose materials or comments, or summaries of them, to other interested parties during and after the comment period.

An individual who makes a submission and who indicates an affiliation with an organization in his or her submission will be considered to have made his or her submission on behalf of the affiliated organization. The ministry will not disclose any personal information contained in a submission of an individual who does not specify an organizational affiliation in his or her submission without the individual’s consent unless required by law. However, the ministry may use and disclose the content of the individual’s submission to assist the ministry in its review.

If you have any questions about the collection of this information, you can contact the ministry’s Freedom of Information and Privacy Coordinator at (416) 327-7040.