Fentanyl Patch 4 Patch (P4P) Return Program
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Fentanyl Patch 4 Patch (P4P) Return Program

BACKGROUND

The Fentanyl Patch 4 Patch Return Program was first implemented in the District of Nipissing on December 6, 2013. With the identification of the issue in our community by the North Bay City Police Crime Unit a partnership between the North Bay & Area Drug Strategy Committee, physicians and community pharmacists the program was developed, implemented and shared throughout the Province of Ontario.

Our first draft procedure was with a copy of a Fentanyl Patch return procedure that was developed by Mark Barnes, an Owner, Pharmacist with Pharmasave in Ottawa, who had been doing the P4P program in his store.

WHAT IS FENTANYL?

Fentanyl is a synthetic opioid analgesic that is used clinically for the management of chronic pain. It is available in its citrate form for oral transmucosal administration, as an injectable solution of fentanyl citrate, or in a transdermal delivery system (i.e. Duragesic). Aside from the drug’s therapeutic applications, fentanyl is a potent drug of abuse. Abuse of fentanyl has included the use of illicit preparations of the drugs as well as diversion of clinical preparations of fentanyl. In particular, the abuse of transdermal fentanyl patches has received increasing attention in recent years and is most commonly abused formed of fentanyl. The abuse of fentanyl patches is not restricted to transdermal application and includes intravenous injection of patch contents, inhalation of fentanyl patches and oral transmucosal abuse.

Fentanyl is approximately 100 times more potent than morphine and 40 times more potent than heroin.

There are several sources of illicit controlled prescription drugs: “double doctoring”, prescription forgeries, overprescribing, pharmacy robberies, Break and Entries and individual with legitimate prescriptions diverting them. The majority of fentanyl available on our streets is trafficked by criminal entrepreneurs – patients with legitimate prescriptions who sell part or all of the prescriptions to controlled prescriptions drug dealers or users. Organized crime involvement is growing.

PURPOSE OF P4P

This Fentanyl Patch 4 Patch Return Program has been established in many communities across the Province of Ontario as well as other provinces in Canada for the purpose of public education and awareness regarding the risks of fentanyl abuse and misuse. The policy is not meant to complicate the treatment of pain management but to guarantee the responsible provision of fentanyl and to reduce any possible criminal diversion of fentanyl. It is important to address the issue of proper fentanyl to disposal to avoid harm to members of the community.
WHAT IS THE FENTANYL PATCH 4 PATCH RETURN PROGRAM?

The fentanyl P4P return program is when a physician, pharmacist and patient work together to promote safe and responsible use of fentanyl patches. The program requires patients to return their used patches to their pharmacy before they can receive more.

The program is designed to reduce diversion by increasing fentanyl patch tracking by:
- Physicians prescribing and pharmacies dispensing no more than one-month supply of fentanyl patches at a time to patients with fentanyl prescriptions
- Ensuring that patients are provided education on the program
- Instructing each fentanyl patch patient to return their used patches, on the return prescription sheet, to the pharmacy the patches were dispensed from
- Documenting the date and the number of patches returned
- Dispensing one new patch for every used patch returned
- Reviewing the guidelines for “Returning Fentanyl Patches” and cautioning patients that they and/or person picking up their prescription are required to sign the Patch 4 Patch Disposal Sheet stating they understand the guidelines and agree to follow them.

If any patches are altered or found to be counterfeit, the client could be faced with criminal charges.

DISPOSAL OF USED PATCHES

- Fentanyl patches must be disposed at the pharmacy that dispensed them to the client (not at the physician office, or at the home). Patches are considered a hazardous waste. They need to be safely disposed of to prevent poisoning, injury, misuse and diversion while also protecting the environment. Pharmacy outlets have a system in place to carry out safe disposal.

STORAGE OF PATCHES

- Fentanyl patches (used and new) should be stored in a safe and secure place in the home. An example is a locked box for a cabinet.
- Keep them out of the reach of everyone, but especially children and pets.

GUIDELINES FOR PATIENTS: RETURNING PATCHES

- Stick each patch on the provided sheet in a numbered box. Place the patch flat, so it is totally visible.
- Tape the four corners of the patch with a small amount of tape so that the patch is totally visible to the pharmacy staff.
- You must return all patches (9 patches on the form and 1 in use = 10) in order to have your prescription refilled.
• You agree to waive any right of action of against any person or institution who provide information in compliance to this authorization.
• When you or family are picking up your prescription you are required to sign a consent form that states:  

  By signing this form, I am acknowledging that I understand the above guidelines, and agree to follow them. I am aware that if any of the attached Fentanyl Patches are found to be altered or to be counterfeit, I could face Criminal Charges.

PHYSICIAN RESPONSIBILITIES

PATIENT EDUCATION

• Accurate and thorough patient/family education is essential in promoting safe use of fentanyl patches.
• The physician will also caution the patient/family to store the patches in a secure place and to follow the procedure to keep track of the number of patches they have, to decrease the risk of accidental misuse by others.
• The physician is to review with the patient/family the “Pharmacy Fentanyl Parch 4 Patch Return Disposal Sheet” (Appendix A), explaining that if the steps are not followed as outlined, their prescription will not be refilled until the physician can be notified and the prescription approved.
• The physician is to explain to the patient/family that they shall not allow their patch(es) to be shared, sold or traded or exchanged for money, goods or services or otherwise permit others to have access to their medications. And if they alter their medications or counterfeit their Fentanyl patches in any way, they shall be charged with a criminal offense.
• The physician is to explain to the patient/family that if the patient alters or submits a counterfeit patch, that their personal identity and information will be shared with the pharmacy, physician, and legal authorities. The pharmacy and physician have the right to contact the legal authorities and/or regulatory agencies to provide information regarding the patient’s actions.
• The physician has the right to discontinue the medication or promptly terminate the patient’s care. Physicians are encouraged to have patients sign the “Consent for a Controlled Substance” (Appendix B).

PRESCRIPTIONS

• Physicians are cautioned not to prescribe large numbers of fentanyl patches for pharmacists to dispense.
• It is recommended that no more than **10 fentanyl patches** be dispensed at once (one patch every 72 hours x 10 = 30 days)

• Physicians in consultation with the patient will determine **which pharmacy and location** they utilize for medication management. The physician must write on the prescription the **actual pharmacy and location** in which the prescription will be dispensed (each time a prescription is filled). Whenever possible the prescription will be **faxed** to that pharmacy by the physician’s office.

**CONTINGENCY PLAN**

• If the patient/family returns only one patch or the quantity differs from the expected amount to be returned, the pharmacy will only dispense one fentanyl patch (1 patch = 3 days) and will immediately notify the physician either by phone or fax and document the incident on the patient’s record. The physician is responsible for contacting the pharmacy as soon as possible.

• Documentation should reflect the prescription issue and communication between the physician and pharmacist.

**PHARMACY RESPONSIBILITIES**

**PATIENT EDUCATION**

• The pharmacy will caution the patient/family to store the patches in a secure place, to keep track of the number of patches they have and to follow the return process to decrease the risk of misuse by others.

• The pharmacy will explain to the patient/family that patches are not to be disposed of in any other manner than by return to the pharmacy as outlined in this policy.

• If patients **do not** follow the guidelines as outlined on the Pharmacy Fentanyl Patch 4 Patch Return Disposal Sheet (e.g. the patch is taped completely over with masking tape, the patch is not visible, etc.) the pharmacist should not accept the patches and should notify the prescribing physician.

• If at any time the pharmacist is suspicious of the patches returned he/she is to call the police immediately and they will have the patches sent for verification. At this time, the patient’s physician shall be notified of the issue and the patient’s physician can direct the course action. If the physician is not immediately available, the pharmacist should provide the patient with only two (2) patches until the physician can be notified for decision-making. Communication and documentation in these situations is very important.
COUNSELING PATIENT/FAMILY ON FENTANYL

- Provide the “Pharmacy Fentanyl Patch 4 Patch Return Disposal Sheet” (Appendix A)
- Explain to the patient/family that they are required to tape each used patch flat on the return sheet on the four corners only so that the patch is completely visible.
- Explain that the person placing the patch on the sheet should date and initial it.
- Explain that the patient will not be able to receive more patches if the current patches are not returned to the pharmacy.
- Explain that the patch should be placed on a dry skin area and if the area is hairy that the area should be shaved so that the patch will adhere to the dry skin.
- Educate on the importance of the Fentanyl Return Policy and the need for such a policy.
- Explain that the pharmacy destroys the used patches in their environmental disposal bins.

RETURN POLICY

- Count the fentanyl patches returned and inspect them for any damages or tampering.
- Document the date and the number of patches returned in the patient’s file.
- Report all suspicious use or abuse to the prescribing physician and communicate this to the patient/family if applicable.
- At any point if the pharmacist believes that a criminal offence has occurred he/she shall report their concerns to the local police agency.
- Explain that the patient waives any right of action of against any person or institution who provide information in compliance to this authorization (Appendix A).

WHEN A PATIENT DOES NOT RETURN PATCHES

- The pharmacist will notify the physician immediately.
- The physician is responsible for acknowledging the pharmacy as soon as possible.
- Documentation should reflect the prescription issue and communication between the physician and pharmacist.
- When patches are not returned the pharmacist will dispense one patch (1 patch = 3 days) and notify the physician immediately by fax or phone.

DELIVERING MEDICATIONS AT HOME

- Place the used patches on the Pharmacy Fentanyl Patch 4 Patch Disposal Sheet in a paper bag for safe return to the pharmacy. In a similar way in which pharmacy delivery personnel collect money, drug cards, expired medications and other items such as signatures under the Narcotics Safety and Awareness Act 2010, they can also be entrusted to collect and return used patches to the pharmacy.
• As a best practice when delivering a patch prescription both the patient and delivery personnel may sign the Narcotics Safety and Awareness Act delivery record to indicate the used patches were picked up.

OTHER

ENTERING A GENERAL HOSPITAL WITH FENTANYL PATCHES

When patients are admitted to hospital (inpatients):
• Ask the family members to take the patient’s fentanyl patches as well as other medications home with them.
• The admitting nurse is to count how many patches are taken home.
• Document the information on the patient’s chart and give the patient’s family a note documenting how many fentanyl patches have been sent home, noting if one has been left on the patient. Document strength of patches along with the date and have the admitting nurse sign.
• Once the fentanyl patch has been removed by the hospital staff ensure that this is documented on the patient’s chart (date of removal)
• Upon discharge from hospital provide the patient with documentation from the hospital staff that the patient’s own fentanyl patch was removed. Provide the date and signature of the attending physician or nurse verifying this action.
• If the physician is providing the patient with a new prescription, have the prescription faxed only to the patient’s pharmacy as this will provide accountability around the number of fentanyl patches that the patient may already have in their care at home.

PATIENTS LEAVING THE COUNTRY
• The patient will require two (2) letters from their physician, one letter for their pharmacy, stating they are travelling out of country. Indicate the dates they will be away and the number of patches they require and that the patient must return used patches to their pharmacy upon return in order to have their prescription refilled. (Must follow the same procedure as monthly refill).
• Second letter from physician is for Customs/Border Security as to why they have Fentanyl Patches. Ensure that the letter and Fentanyl Patches are secure within the pharmacy labelled box with Prescription Return sheets.

PATIENTS THAT EXPIRE AT HOME
• When a patient expires at home under the care of Allied Home Care such as CCAC, the Home Care Staff are to return the fentanyl patches and all attached forms to the appropriate pharmacy that dispensed them and advise the physician.
• In other cases request that family members of the deceased return any unused/used fentanyl patches and other prescription medications to the pharmacy for proper disposal.
• In sudden death cases where Police attend the scene, medications will be secured and dealt with as per the police agency policy.

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