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Member Organization of the National Association of Pharmacy Regulatory Authorities (NAPRA)

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*This newsletter is distributed to all licensed pharmacists in PEI and posted on our website. Decisions regarding all matters such as regulations, drug related incidents, etc. are published in it. The PEI Pharmacy Board therefore assumes that all pharmacists are aware of these matters.*

## **Chair's Message**

Spring is the season of renewal, transformation, and growth and these days, PEI Pharmacists can relate. The PEI Pharmacy Board has undergone a bit of a transformation, with the introduction of a new logo and website in February. The new logo is a red crescent shielding a silhouette of a person's body. As the crescent is a symbol of protection, the image illustrates the PEI Pharmacy Board protecting the public. The red and green colours were selected to be representative of PEI's red soil and green grass. In addition to the logo, a new website ([www.pepharmacists.ca](http://www.pepharmacists.ca)) has been developed. The website is user-friendly, easy to navigate, and is aesthetically pleasing with more online capabilities than its predecessor. We have successfully processed the yearly license renewals online with only a few minor glitches. This was the first test for the new website, and it passed! I would like to ask for your patience as we continue to update website content.

As PEI Pharmacists, we can all see the growth and transformation of our profession as the scope of practice and role of the pharmacist across the country continues to evolve. This past summer/fall, the PEI Pharmacy Board worked with a consultant to revise the current PEI Pharmacy Act and Regulations to include the Regulated Pharmacy Technician Regulations and Pharmacist Prescribing Regulations. The Act and Regulations are currently in draft format and will require approval by government. The Board is also developing the Standards of Practice that will accompany the revised Act and Regulations and will include a section on administering injections. Representatives from the PEI Pharmacy Board have met with government, the College of Physicians and Surgeons of

PEI, and the Association of Registered Nurses of PEI to discuss the proposed changes to the Pharmacy Act and Regulations. Appointments to meet with the PEI Association of Optometrists, PEI Dental Association, and the PEI Veterinary Medical Association are in the works. If any PEI Pharmacist would like to contribute to the development of the Standards of Practice, please contact myself, or any other Board member.

In the last couple of months, the PEI Pharmacy Board has been updating the membership and terms of reference of several committees of the PEI Pharmacy Board. In February, an e-mail went out to PEI Pharmacists seeking volunteers for a number of these committees. I would like to take this opportunity to thank everyone who volunteered to represent PEI Pharmacists in these important initiatives.

With kindest regards,  
Jennifer Boswell, Chair

### **Scheduling Change for Large Package Sizes of Ibuprofen**

Effective February 17, 2012, ibuprofen and its salts containing 400mg or less per oral dosage unit when sold in package sizes exceeding 18,000mg will move from Unscheduled status to Schedule III.

The scheduling change follows a review by the National Drug Scheduling Advisory Committee of non-prescription non-steroidal anti-inflammatory drugs (NSAIDs) available on the Canadian market (excluding ASA and acetaminophen).

Some individuals, particularly the elderly and those who have co-morbid diseases or those with cardiovascular and gastrointestinal risk factors may be at particular risk of adverse events from inappropriate use of oral NSAIDs. These individuals could benefit from pharmacist advice and clarification on appropriate selection and use of NSAIDs.

#### Summary of NSAID Scheduling

<u>MEDICATION</u>	<u>PKG SIZE/CONC</u>	<u>SCHEDULE</u>
Ibuprofen and its salts containing 400mg or less per oral dosage unit	Up to 18,000 mg	Unscheduled (no change)
Ibuprofen and its salts containing 400mg or less per oral dosage unit	Exceeding 18,000 mg	Schedule III (from Unscheduled)
Naproxen sodium 220mg per oral dosage unit, in products labeled with a recommended max daily dose of 440mg	Up to 6,600 mg	Unscheduled (no change)
Naproxen sodium 220mg per oral dosage unit, in products labeled with a recommended max daily dose of 440mg	Exceeding 6,600 mg	Schedule III (no change)
Diclofenac diethylamine in preparations for topical use on the skin	Not more than the equivalent of 1% diclofenac	Unscheduled (no change)

## Included in Newsletter

- New Advertising Regulations and Policy on “Loyalty Programs” and Inducements
- Pharmacies Readiness to Receive Email Messages from PEIPB
- New Computer Guidelines



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## New Professional Practice Guideline

Included with this newsletter are new and/or revised Board policies. Pharmacists should become familiar with them. The **Computer Guidelines** have been revised to make them more in-line with current pharmacy practice.

The Board will be implementing **mandatory email/Internet access** at the pharmacy level. This is to ensure pharmacies and pharmacists have timely access to Board messages, notifications, license renewals, etc. Pharmacies are also reminded that the recently updated **Library Requirements** also requires Internet access for access to current professional practice resources and information. This policy will take effect **July 1, 2012**.

The **Advertising Regulations** have been amended to eliminate the ability to provide loyalty incentives with **any** professional pharmacy service. Upon reviewing policies and precedents in other jurisdictions, the Board agreed that it will no longer permit these incentives. Such practice is inconsistent with being health care professionals. If we are truly going to try and move pharmacists forward in an expanded role we are going to have to be seen as health care professionals first and retailers second. It is also felt that such practices have the public making pharmacy choices using more than the professional service as an incentive in their choice of where to obtain pharmacy services, and when to change them. A policy was also developed to clarify what is considered “loyalty programs” that will no longer be permitted to be associated with professional and prescription services. The changes to these regulations will take effect **July 1, 2012**. Any violation to the advertising regulations will be addressed through “professional misconduct”.

## Inspector’s Corner

The Prince Edward Island Pharmacy Board, under the authority of the PEI Pharmacy Act, regularly performs inspections to ensure pharmacies’ and pharmacists’ compliance with the Regulations, Standards of Practice and Board Policies. The inspection process also provides an opportunity for pharmacists to ask questions about pharmacy practice.

The Professional Practice Audit is a type of practice review that focuses on the operational standards in the pharmacy. Many of the areas that are reviewed are derived from the *Model Standards of Practice for Canadian Pharmacists (MSOP)*, which is the Standards of Practice document the PEI Pharmacy Board uses for measuring Pharmacists' performance. Pharmacists should become familiar with this document as it details the minimum standards of practice for pharmacists. Although pharmacists may not perform all roles outlined in the *MSOP*, they are expected to perform those that they do at a level specified in the Standards.

## Areas for Improvement Identified During Inspections

### Patient Counseling

**MSOP 1.17. Pharmacists when providing patient care as part of the care provided when dispensing medications or medication therapies: educate patients to whom they dispense medications or medication therapies to enable the patients to receive the intended benefit of the medication or therapies.**

Initiating dialogue with patients concerning their medications, especially upon the initial prescription, is necessary to ensure safe and effective use of medications and provides an opportunity to establish a relationship with the patient. The pharmacist can often make assessments of the patient's therapy during conversations when patients return for refills. It is therefore necessary for the pharmacist to counsel patients on all prescriptions even if the patient has had a medication in the past. The pharmacy technician should not be asking patients if they want to be counseled by the pharmacist.

Delivery of prescriptions does not preclude a pharmacist from counselling a patient. All efforts need to be made to follow up with the patient at a later time.

### Documentation

**MSOP 1.60. Pharmacists when providing patient care: document their decisions/actions, supporting patient and related information, and their interpretation of this information, including.....**

Pharmacists should document any decision or intervention related to a patient's care. This may include patient counselling, best possible medication histories, allergies and reactions, discussion with physicians, patient assessments, blood pressures and lab values. Many pharmacy software systems include areas for electronic documentation and provide an accessible area for maintaining patient information.

## **Do You Compound and Repackage?**

Pharmacies that compound or repackage drugs to be dispensed through other community pharmacies require an agreement in the form approved by the Board with each community pharmacy to which they provide services. This can be found on the website at:

[https://pei.in1touch.org/uploaded/68/web/pdf/Centralized\\_Prescription\\_Filling\\_Process\\_Dec2007.pdf](https://pei.in1touch.org/uploaded/68/web/pdf/Centralized_Prescription_Filling_Process_Dec2007.pdf) .

Products prepared at compounding and repackaging pharmacies cannot be further compounded or manipulated at a community pharmacy. This agreement authorizes you to compound a drug for or on behalf of the community pharmacy **only** if the community pharmacy holds a valid prescription for that drug or has a reasonable expectation of receiving a valid prescription for a patient for that drug in the immediate future.

This does **not** include bulk compounds that are diluted or further compounded at the community pharmacy before dispensing (e.g., diluting 10% diclofenac gel to 5%). Preparation of products for which there is no prescription or no reasonable expectation of a prescription is considered manufacturing.

## **Narcotic Reconciliation in Community Pharmacies**

Last year the Board approved a policy on proper narcotic reconciliation procedures in community pharmacies. A presentation was made, and an implementation date of January 2012 set. Information regarding this process and the appropriate forms can be found at <https://pei.in1touch.org/uploaded/68/web/pdf/NarcoticRecPolicyWithForms2010.pdf>

These forms do not need to be used exactly as depicted, but the “process” must be adhered to. Records must be accessible and made available during the pharmacy inspection process.

Pharmacists are also reminded to include returned narcotics and controlled drugs in the accountability and destruction process. When a patient returns a narcotic or controlled drug to the pharmacy (directly hand to hand to the pharmacist), the pharmacist also accepts the legal responsibility of the drug and must therefore request a destruction authorization, clearly distinguishing the substances from those in his/her own inventory, before proceeding with the destruction of the controlled substances. The pharmacist must record the amount of narcotic/controlled drug to be destroyed, ensure the drugs are rendered unusable and have the destruction witnessed.

This differs slightly in the case of a deceased patient. In this case, the Estate Administrator becomes the legal guardian of the controlled substances. The drugs can be destroyed in the presence of the Estate Executor and a health professional. A complete and detailed list of the controlled substances to be destroyed must be prepared and the Estate Executor and the health professional must date and sign as witnesses, confirming the destruction took place. Prior authorization from the Office of Controlled Substances in this case is not required. **Form HPB 3631** can be used to this effect.

Please note that prior authorization for the destruction of targeted substances and benzodiazepines is not required.

## **Reminder of Responsibility When Reporting Narcotic and Controlled Drug Loss/Shortages**

When a pharmacist-in charge determines that there is a quantity of narcotic or controlled drug that is missing from their inventory (e.g. subsequent to conducting a monthly narcotic reconciliation, after a known theft, etc.) they are required to report this loss or theft to the Office of Controlled Substances within 10 days (form can be accessed on the PEIPB website). In addition, the PEIPB Narcotic Reconciliation Policy requires that this completed form be faxed to the PEIPB (Fax: 902-658-2528).

## **IMPORTANT NOTICE REGARDING HEALTH CANADA ADVISORIES**

Due to declining usage and need, the National Association of Pharmacy Regulatory Authorities (NAPRA) will terminate the E-link mailboxes.

The E-link system was developed to allow E-mail accounts to be created for pharmacists. The PEIPB, along with other provincial regulatory authorities, elected to use the system to communicate with their registrants. The system also had the capacity for NAPRA to provide the means to communicate MedEffect e-notices (issued by Health Canada) to all users. The PEIPB will be switching from E-Link to regular email from its new database. **Please ensure your email address is kept current on your electronic file.**

Pharmacists are encouraged to subscribe directly to MedEffect e-Notice to receive the latest advisories, warning and recalls and the Canadian Adverse Reaction Newsletter (CARN) as they are issued by Health Canada. These alerts are an important source

of information regarding the post-market safety and effectiveness of health and drug products and pharmacists are reminded of their responsibility to be aware of this vital information.

For your information, the following are the steps on how to register for the MedEffect notices:

Go to <http://www.hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>

On the MedEffect Canada webpage, select from the left side in the grey area under “Stay Informed MedEffect Canada”. Once on this particular page, a person can choose “Subscribe to MedEffect e-Notice”. It is important to then follow the instructions provided.

Once the subscription is completed and confirmed, you will automatically receive all notices via the E-Mail address given. If you have requested the subscription using the English website, you will only receive the notices in English.

### **Q: Can a pharmacy compound ibuprofen topical without a prescription?**

A: No. Ibuprofen topical is a prescription item, only the oral form of the medication is classified as OTC in the Federal Regulations. The Schedule F entry states: Ibuprofen and its salts except when sold for oral administration in a concentration of 400mg or less per dosage unit.

### **Q: Can a pharmacist continue a prescription under Continued Care Prescribing if the physician is no longer practicing?**

A: No. A pharmacist cannot “continue” a prescription if the physician is no longer practicing as there is no method of informing him/her and ensure the record is documented.

### **Q: Does the prescriber have to be the one who authorizes a Part-fill for a narcotic or controlled drug?**

A: No. “Part-fill” is defined as the dispensing of a quantity of medication which is less than the total amount of the drug specified by the practitioner when the prescription was written or issued. Part-fills are allowed if the quantity dispensed does not exceed the quantity originally authorized. The doctor has to authorize either in writing or verbally the total quantity involved as a single figure, and not as a smaller figure multiplied by the number of times the medication is to be dispensed, so that it does not appear the practitioner is prescribing a repeat prescription. Such a repeat is not permitted under the *Narcotic Control Regulations* (NCR). The practitioner should also include specific directions for how the part-fill is to be dispensed (e.g., 5 tablets per week). For narcotic and controlled drugs, part-fills are also permitted when requested by the patient or when a pharmacy is dealing with an inventory shortage. The nature of the part-fill becomes a matter for discussion between the patient and the pharmacist. Health Canada also recommends that when part-fills that are not requested by the practitioner are issued, the reason for the part-fill should be documented.

**Q: What’s the latest on Cold Chain?**

A: According to the Public Health Agency’s *Vaccine Storage and Handling Guidelines for Immunization Providers*, Cold Chain refers to the process used to maintain optimal conditions during the transport, storage, and handling of vaccines, starting at the manufacturer and ending with the administration to the client. Pharmacists handling vaccines should familiarize themselves with the Public Health Agency of Canada’s *National Vaccine Storage and Handling Guidelines for Immunization Providers (2007)*. This valuable resource provides support regarding storage and handling protocols, equipment, temperature management and shipping and information on storage troubleshooting. Pharmacies that handle vaccines should use these Guidelines to support them in the safe and appropriate handling of vaccines and other biological.

**CACDS/CPhA (Blueprint) *Canadian Pharmacy Services Framework***

Registrars have reviewed the document and were unable to extend support for it. The CPSF appears to fall short of fully demonstrating how it reconciles the Framework’s goals with pharmacists’ obligations to comply with the standards of practice. While the CPSF maps certain elements of the Standards of Practice, pharmacists have to take into consideration numerous elements of the Standards of Practice that directly or indirectly affect their activities when they perform pharmacy services. It was felt the Framework does not accurately reflect the comprehensiveness of the standards. It is recognized that a tool is needed to educate some stakeholders with respect to the funding of pharmacy services as well as to assist pharmacy owners transitioning from the current business model to a new one. However in its goal to educate others, the CPSF should not create confusion in the minds of pharmacists when it comes to their practice obligations. Pharmacists must comply with the standards of practice – first and foremost.

**Respect and Privacy for All**

Pharmacies that provide methadone to patients with substance dependence must ensure that the pharmacy provides patients with a respectful environment in which to receive these pharmacy services. This includes setting aside a private area for observing the ingestion of methadone

While some patients may be comfortable taking their dose at the pharmacy counter in full view of other customers, some may prefer more privacy. Giving patients additional privacy to ensure their ingestion of methadone is not witnessed by other customers may help protect them from stigmatization.

Pharmacists can determine the patient's privacy preference during the initial conversation when the patient is enrolling in the program at the pharmacy. It is important to respect the patient's wishes and to note their stated preference in their chart.

As a patient's treatment progresses, their preference with respect to privacy of witnessed ingestion may change. Pharmacies should consider confirming the patient's preference at set times, such as the start of each new year, or when the patient progresses in their recovery so that they are authorized to receive the maximum carries (i.e. six per week).

It is important to remember that the interactions a patient has with their health care providers have a significant impact on their success in recovery.

The Board has a Committee reviewing our Methadone Maintenance Policy/Guidelines. It is anticipated that within a year there will be a new set of guidelines and criteria for the dispensing of methadone.



### **New IWK Regional Poison Centre Website**

In the treatment of real or potential exposures to toxic substances, timely access to up-to-date information is very important. The IWK Regional Poison Centre (RPC) provides 24-hour telephone consultation to the public as well as health care professionals. The IWK RPC is pleased to announce that they also have enabled access to poison-related information on-line to both the public as well as health professionals via the centre website: <http://www.iwkpoisoncentre.ca>

### **Drug Diversion Considerations with Dilaudid® and Generic Equivalents**

In an attempt to increase health professionals' awareness regarding drug diversion, we would like to remind pharmacists of the possible implications of choosing trade name Dilaudid® over generic hydromorphone when dispensing. It appears that many health professionals are aware of the fact that Dilaudid® is sought out by substance abusers much more so than its generic alternatives as it is purported to require very little "cooking down" in order to render it safe for injection. Dilaudid® is highly soluble in water and minimal, if any, filtering before injection. The generics are said to require a much more involved process (often 2-3 steps of "cooking down") before they are injection-ready. Pharmacists should consider the possible risks to themselves, their patients, and their communities when choosing which formulation of hydromorphone they will dispense.

## Adverse Reaction Reporting Made Easy for You



The Canadian Vigilance Program is Health Canada's post-market surveillance program that collects and assesses reports of suspected adverse reactions to health products marketed in Canada. Adverse reaction reports are submitted by health professionals and consumers on a voluntary basis.

To encourage active and ongoing reporting, The Canada Vigilance Program provided a variety of tools for health professionals and consumers.

You can report any suspected adverse reactions associated with the use of health products to the Canadian Vigilance Program by any of the following three methods:

1. Call toll free
2. Complete a Canada Vigilance reporting Form and fax or mail to Canada Vigilance Regional Office-Atlantic
3. Report on-line via MedEffect™ Canada Web site [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the web site. The Canada Vigilance Reporting Form is also found in the back of the CPS.

**You do not have to be certain that a health product caused the reaction in order to report it.** Adverse reaction reports are, for the most part, only suspected associations. Health Canada **wants to know about all suspected adverse reactions**, but especially if they are:

- **Unexpected** (not consistent with product information or labeling), *regardless of their severity*
- **Serious**, whether expected or not
- Related to a health product that has **been on the market less than five years**.

## Alternate Prescribers and Labeling

Pharmacists and Pharmacy Assistants need to be cautious when filling prescriptions ordered by alternate prescribers (e.g. nurse practitioners, pharmacists) and how their designation comes out on the prescription labels. Most software systems “default” to “Dr.” and the Board office has been receiving complaints from physicians regarding this error. Please ensure the nurse practitioner reads “NP” and the pharmacist reads “PhC”. This will become more and more important as other prescribers are authorized and/or as pharmacist expanded scope evolves.