The Island Capsule
Newsletter of the Prince Edward Island Pharmacy Board

November 2009

PRINCE EDWARD ISLAND PHARMACY BOARD

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MEMBERS

Jeff Jardine, Chair (Shoppers Drug Mart)
Iain Smith, Vice-Chair (QEH Pharmacy)
Ken Crawford (Shoppers Drug Mart)
Michelle Wyand (QEH Pharmacy)
Ryan Murphy (Murphy's Parkdale)
Bill Doucette (Murphy's Parkdale)
Jennifer Boswall (QEH Pharmacy)
Government Rep – Pat Crawford
Dennis Edgecomb – Lay Rep
Nancy Canham – Lay Rep

REGISTRATIONS

Pharmacists: 172
Permits: 42 + 7 hospitals + Provincial Phcy
Students: 25

APPOINTEES/COMMITTEES

Investigations/Complaints
David McLeod – November 2007 (CHAIR)
Greg Burton – January 2008
Rebecca Ellis – August 2007
Paul Gallant – January 2007
Nancy Canham (Lay Rep) 2008
Wally Kowalchuk 2008

CE/Competence Assessment
Michelle & Grant Wyand - Coordinator
Mary Ellen Rennie

Pharmacy Endowment Fund - Dalhousie
Ryan Murphy – November 2009
Lisa Kelly – August 2007

Practice Experience Committee - Dalhousie
Neila Auld

NAPRA Representation

NAPRA Voting Delegate
David McLeod

Council of Pharmacy Registrars of Canada (CPRC)
Neila Auld (Vice Chair)

PEI Health Sector Council
Bill Doucette

PhIP Advisory Committee (DIS)
Ken Crawford

Methadone Maintenance
Iain Smith – Chair
Bill Doucette
Linda Gordon-MacEachern
Amanda Burke
Paul Jenkins

Communication of Medication Prescriptions
Ryan Murphy – Chair
Pauline Tran-Roop

This newsletter is distributed to all licensed pharmacies in PEI, emailed 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

It is the responsibility of every pharmacist to ensure they are properly set up to receive information via the NAPRA E-Link System!

INCLUDED WITH THIS NEWSLETTER

- Revised "Guidelines for the Supply of Exempted Codeine Products
- Continuing Education recording forms
- Continued Care Prescriptions Legislation and Guidance document
- Revised "Model Standards of Practice for Canadian Pharmacists"

PHARMACISTS PRESCRIBING IN Prince Edward Island

"If Pharmaceuticals are a key cost driver in the system, isn't it simply common sense to make better use of those who are experts in pharmaceuticals? To tap their knowledge, use their skills and bring their expertise to bear in creating a more rational system of drug therapy? Leaving pharmacists on the sidelines is like having Wayne Gretzky on your team – and benching him. It makes no sense and it must change." – Roy Romanow

With an overburdened healthcare system, an aging population and a shortage of healthcare professionals; patients, healthcare workers and the government are positively supporting pharmacists as they move towards assuming a more prominent and active role on the health care team – now which fully utilizes their expertise in pharmacotherapy and medication management. Report after report, including the Romanow, Report have recognized the unique knowledge and skills of the pharmacist and have advocated for expanded roles for pharmacists within the primary health care system and for greated flexibility in who delivers health care services.

The Prince Edward Island Pharmacy Board also recognizes that the public of Prince Edward Island would benefit from pharmacists who are authorized to provide services consistent with their knowledge and skills. To that end, **the Board has developed amendments to the Pharmacy Regulations that will authorize pharmacists to provide enhanced care to their patients.** These amendments recognize pharmacists as experts in medications management.

It is the position of the Board that members of the pharmacy profession currently have the competencies to renew prescriptions and that the public, other health care workers and the government currently expect pharmacists to provide these services. The Board believes that these amendments, which will enable pharmacists to fully realize their role in the promotion of health and wellness and medication management, will also support the government's priorities to reduce wait times in emergency rooms and to increase public access to necessary health care services.

Over the course of the next few months, the Board will work on expanding regulatory amendments and will meet with stakeholders including the pharmacy profession through the Pharmacy Association, government officials, and the College of Physicians and Surgeons to address questions and any concerns with the proposed additional changes.

It is the goal of the Board to work closely with all stakeholders to ensure that everyone

benefits from these changes: pharmacists will be able to practice to their full scope, the health care system will be strengthened and, most of all, patients will experience improved access to care and better health outcomes.

Presently, pharmacists can renew prescriptions for continuity of care.

Proposed amendments to the Pharmacy Regulations hopes to see pharmacists authorized to:

***adapt prescriptions by altering the formulation, dose, duration or regimen to enhance patient outcomes**

***provide therapeutic alternatives to prescribed therapy**

***provide prescription drugs in emergency situations**

***prescribe Schedule II and III (non-prescription) drugs resulting in a valid prescription for patients**

***order, receive, and interpret lab tests for monitoring purposes**

***IF certified, to administer drugs, including vaccines, by injection**.

PROFESSIONAL MALPRACTICE INSURANCE EVIDENCE TO BE REQUIRED

The role of pharmacists in an evolving health care system brings about great opportunity and along with the opportunity, comes some risk. This risk, or exposures for health care deliverers, also translates into risk for the public.

Embedded in the new continued care prescription regulations is the requirement of at least **2 million dollars** of **personal** malpractice insurance in a *claims made* or *occurrence* – based format.

This means the policy must be issued in your name, and must be transportable and provide coverage regardless of where you practice pharmacy in Prince Edward Island.

The requirements are designed to protect the public and to ensure that there is a specified level of coverage behind each pharmacist that will become where a negligent act or omission by a pharmacist harms a patient. The Board has reaffirmed the requirement for **personal coverage** because:

- Employer policies are usually in the name of the employer and, depending on claims against any or all individuals addressed under the employer's plan, aggregate limits may not provide adequate coverage for individuals; and.
- Most employer plans are not transportable for the employee, i.e., they do not apply regardless of where the employees works. Given that the registration process authorizes practice any place in P.E.I, the registration requirement must similarly provide protection for practice any place in P.E.I., regardless of employer.
- It also ensures protection when a pharmacist offers professional advice outside the workplace. This is still considered practicing pharmacy.

While professional malpractice insurance was not a requirement for registration renewal at April 1, 2009, it will be a requirement for registration April 1, 2010.

What is the difference between claims-made insurance and occurrence-based insurance?

Claims-made insurance provides protection if the insurance policy is in force at the time a claim is made against a pharmacist. For example, if during the term of a claims-made insurance policy a malpractice claim is made, the policy would provide protection for the insured pharmacist. However, if an incident occurred during the term of the insurance, but the claim was not made until after the expiry or cancellation of the

insurance policy, the policy would not provide protection for the pharmacist. Although the legal requirement to maintain insurance is in force only while you are a registered pharmacist, prudence would suggest that if you subscribe a claims-made policy, you should maintain "tail coverage" after you cease to practice in the event you are sued after retirement. Consult your insurance broker about the availability of tail coverage.

Occurrence-based coverage provides protection if the insurance policy is in force at the time of the incident. This means that if an incident results in a claim, you will be protected by the policy, providing that the policy was in place at the time of the incident. However, if an incident occurs before the policy was in force, and the claim was made during the policy period, the policy would not provide protection for you. You can purchase "prior-events coverage" to accompany an occurrence-based policy to cover incidents that occurred before the insurance policy went into effect. The prior-events coverage is particularly important when you change from a claims-made to an occurrence-based policy.

The previous paragraphs offer basic definitions and explanations. Ask your broker about the differences. It is also important to know how changes in the type of policy you hold will affect the scope of your coverage. Again, your broker is the best person to explain the effect of changes from one type of policy to another.

Does PEIPB recommend one type of insurance over another?

No. Information received from legal counsel, insurance brokers and actuaries indicates that each type of insurance has its own merits.

Does PEIPB endorse any particular type of insurance or insurance provider?

No. The extent of PEIPB's direction to pharmacists about malpractice insurance requirements is limited to its policy statement. The Board does not endorse one insurance carrier or provider over another. PEIPB's sole interest is to facilitate reasonable access to malpractice insurance coverage that meets the requirements of its policy statement.

What should I ask about insurance and insurance policies when talking to a broker?

Here are some questions you might consider asking your broker.

- Will I receive a copy of the insurance policy? Will I receive a certificate in my name confirming my subscription to the policy?
- Is the coverage primary coverage, i.e., if a claim is made against me, will this policy apply immediately on my behalf, or is it secondary to another type of insurance.
- What are the limitations of the policy? Are there any incidents or situations that will not protect me against?
- Does this policy protect me for incidents that may have occurred, but which have not been reported or claimed, prior to me purchasing the policy? If so, what is the retroactive time-period? If not, can I purchase additional coverage to provide this protection?
- If I retire or cancel this policy, will it provide me protection for incidents that occurred during the term of the policy? If not, can I purchase additional coverage to provide this protection?
- Can I purchase coverage for more than one million dollars and, if so, what is the additional premium?
- Are there any limitations on the amount of coverage that will be provided for a single claim? Are there limitations on the coverage should I experience more than one claim during a given year, or during the term of the insurance policy?

- If an incident occurs that may result in a claim, what are my responsibilities in notifying the insurance company, and are there any time limitations for the reporting period?
- Does the coverage provide protection/reimbursement for legal costs incurred for criminal investigations or for professional investigations/disciplinary action taken by PEIPB? If so, will I have my choice of legal counsel?
- If I am acting as a preceptor and overseeing the practice of a pharmacy student or intern, will the policy cover any legal costs incurred by the intern or student if they are named in a claim?

Since it is your responsibility to adequately inform yourself before purchasing an insurance policy of your choice, you may have other questions you want to ask.

What is the term of the insurance I should purchase?

You need to ensure that you have insurance coverage for the entire period that you practice. At the time you renew your annual practice permit, the Board will ask you for evidence of insurance coverage. This process will begin with the 2010/2011 registration year.

How will PEIPB administer compliance with this registration requirement?

The Board will send to each practicing pharmacist a request for evidence that he/she has obtained an insurance policy that complies with the Board policy prior to re-licensure in March 2009. You will provide evidence of:

- Your name and registration number,
- The name, address, and telephone number of the insurance carrier,
- The insurance policy number,
- Confirmation of the amount and type of the insurance coverage,
- The term of the insurance (expiration date).
- An undertaking to notify PEIPB immediately should the insurance policy be cancelled terminated or expires.
- Consent to allow PEIPB to contact the carrier to confirm the stated coverage is in place, and
- Verification that the information provided is true and accurate.

PEIPB will randomly audit registrants for compliance, and may request that you submit a copy of the insurance certificate or may contact the carrier to ensure that the stated insurance coverage has been secured.

The Board will request this information annually, at the time of license renewal.

What options do I have regarding the source of the required insurance?

PEIPB does not have comprehensive information about the availability of the necessary malpractice insurance. The Board does not endorse one form of insurance over another, as long as the policy meets the requirements established by Council. Neither does PEIPB endorse one provider or carrier over another. The choice is entirely yours.

The malpractice insurance provided by the PEI Pharmacists Association and Canadian Society of Hospital Pharmacists is personal in scope.

DOCUMENT…DETAIL… DISCONTINUE…

Pharmacists must keep precise, up-to-date profiles on their patients. Not only are comprehensive and accurate files needed to serve patients effectively, pharmacists are increasingly being called upon by hospital and long term care facilities for medication history information. As they are and will

continue to be expected to provide enhanced patient care through more cognitively-focused interventions, it is imperative that the information they have on hand to guide their decision-making is correct.

As part of the Board routine inspection process, inspection officers will be monitoring the extent that pharmacies are establishing and maintaining complete and useful patient profiles.

A complete patient profile should include the following:
***Accurate list of all prescription medication patient is currently taking (discontinue inactive Rxs)**
***OTC (especially chronic medications)**
***Allergies (distinguish between true allergy and sensitivity). If no allergies, indicate NKA.**
***Medical conditions and pertinent medical history, including immunizations.**

WHOLESALING – THE FINE LINE…

Are you a member of a buying group where your pharmacy purchases drugs and then divides them up between members?

Do you routinely purchase pharmaceuticals and resell or distribute them to one or more pharmacies?

Please note that you could be in violation of the Food and Drug Regulations…..

"Wholesale" is defined in the *Food and Drug Regulations* as:
"…to sell any of the following drugs, other than at retail sale, where the seller's name does not appear on the label of the drugs:

(a) A drug listed in Schedule C, D, or G to the Act or in Schedule F to these *Regulations* or a controlled drug.. or
(b) A narcotic

According to the Food and Drug Regulations, a person is prohibited from wholesaling these drugs except in accordance with an Establishment License.

An Establishment License holder is subject to the Good Manufacturing Practices section of the Regulations as it applies to wholesalers. Requirements include, but are not limited to:
* Maintaining adequate distribution records to ensure a rapid and effective recall
* Storing drugs under acceptable conditions and maintain records to that effect
* Maintaining documentation to show that personnel are adequately qualified and trained
*Use and maintain standard operating procedures for their work

Pharmacies engaging in wholesaling activities need to apply for a Health Canada Establishment License. Wholesaling without an Establishment License would constitute a violation of the Food and Drug Act.

RX FILES SECRUITY

According to the Regulations, Pharmacists are required to keep all prescription records for a period of 2 years from the date of the last transaction (i.e. 3 years total for prescriptions with a year of refills). Revenue Canada requires the retention of records for 7 years. This means a lot of paper to store…somewhere. Often older Rx files will find themselves on a shelf in a storage closet or in a basement. Pharmacists are required by law to maintain the security of ALL personal information in their possession and access to Rx files must be restricted. Therefore, if files are being stored in an area outside the dispensary where people can access them, they are to be locked up.

ABSENCES FROM DISPENSARY

Sometimes you are required to briefly leave the dispensary. This can be unavoidable but is someone "manning the bridge" while you step away? Even though absences from the

dispensary are undoubtedly short, any absence from the dispensary presents an opportunity for someone to gain access. Remember to ensure that the dispensary is secure if you need to be away from it for even a minute.

ADVERSE REACTION REPORTING IS AS EASY AS 1-2-3

The Canada 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 provides a variety of tools for health professionals and consumers.

Suspected adverse reactions associated with the use of health products can be reported to the Canada Vigilance Program by one of the following 3 methods:

1. Report on-line via MedEffect™ Canada Web site: www.healthcanada.gc.ca/medeffect

2. Call toll free 1-866-678-6789

3. Complete a Canada Vigilance reporting form and fax or mail to Canada Vigilance Regional Office – Atlantic.

ADVERSE REACTION REPORTING – NEW GUIDELINES FOR AR REPORTING OF ANTIVIRAL DRUGS DURING INFLUENZA PANDEMIC FROM CANADA VIGILANCE

Health Canada would like to inform you that a new document entitled Guidelines for Reporting Suspected Adverse Reactions to Antiviral Drugs during an Influenza Pandemic is now available.

These new guidelines briefly define influenza pandemic, identify the role of antiviral drugs in the treatment or prevention of influenza, and highlight the importance of reporting adverse reactions to these products in the event of an influenza pandemic. The guidelines encourage the reporting of all serious adverse reactions, ie: adverse reactions which require in-patient hospitalization or prolongation of existing hospitalization, cause congenital malformation, result in persistent or significant disability or incapacity, are life-threatening or result in death. Information on how to report an adverse reaction is also provided in the guidelines.

At this point in time, serious adverse reactions to antiviral drugs have been very rare. However, during a pandemic it will be essential to look for and respond to any serious adverse reactions that may occur with widespread use of these drugs, as this information will help guide the safest and most effective use of these drugs.

The Guidelines for Reporting Suspected Adverse Reactions to Antiviral Drugs During and Influenza Pandemic are available on the Health Canada Web site at: http://www.hc-sc.gc.ca/dhpmps/pubs/medeff/_guide/2009-ar-ei_anti_guideldir/index-eng.php

Please visit the MedEffect™ Canada Website at or call 1-866-234-2345 for more information on reporting adverse reactions to antiviral drugs via the Canada Vigilance program during an influenza pandemic.

WHAT CAN YOU CLAIM AS ACCREDITED LEARNING?

PEI pharmacists may only claim as accredited learning those programs accredited by a **recognized pharmacy accrediting body.** Those are the Canadian Council on continuing Education in

Pharmacy (CCCEP), Accreditation Council on Pharmaceutical Education (ACPE), the Board and other provincial pharmacy accrediting/regulatory bodies and the College of Pharmacy.

You may have noticed that several CE providers are now offering continuing education courses for both pharmacists and technicians. In particular, in the US many providers are offering ACPE accredited programs for pharmacists and technicians. Please note that pharmacists may only claim courses that have been accredited for PHARMACISTS as accredited learning. Be sure to check the course description. If it says "Technician Education", has an ACPE file number in the format "XXX-000-08-XXX-H01-T" (the T denotes "technician"), or a CCCEP file number in the format "CCCEP#NA-TT00XX "or "CCCEP# 0001-1007 Tech" you may not claim it as accredited learning. It is also likely not appropriate to claim technician continuing education as non-accredited learning as it's probably not at a level appropriate for pharmacists.

Pharmacists are reminded that **20 CEUs** are required for the calendar year prior to renewal in April. Self-accredited/assessed learning can be no more than **7.5 CEUs** in the total. When claiming, be confident the program will pass the scrutiny of the CE committee at re-licensure time.

QUESTIONS AND ANSWERS

What is the difference between a controlled drug and a controlled substance?

These terms are defined and discussed in two different Acts.
A "controlled drug" is defined in the *Food and Drugs Regulation, Part G – Controlled Drugs* and is any drug (or preparation listed in Parts I, II and III of the Schedule to Part G.

A "controlled substance" is defined in the Controlled Drugs and Substance Act (CDSA) and refers to any substance listed in Schedule I, II, III, IV, and V of the CDSA. These Schedules include controlled drugs, narcotics, benzodiazepines and targeted substances.

The term "controlled substance" refers to all drugs and substances covered by the CDSA and encompass all activities related to the control of those drugs and substances. The definitions for "narcotic," "benzodiazepine and targeted substance" are found in their specific regulation to the CDSA.

We occasionally receive a notice that a physician is restricted from prescribing controlled drugs and narcotics. Does this include benzodiazepines and targeted substances?

No. "Controlled drug" and "narcotic" are defined terms. In such cases the physician is restricted from prescribing controlled drugs listed in Parts I, II, and III of the Food and *Drug regulation, Part G – Controlled Drugs* Or narcotics found in the Schedule to the Narcotic control Regulations. The physician is free to prescribe benzodiazepine and targeted substances. If the notice states the physician is restricted form prescribing controlled substances then the physician is not allowed to prescribe controlled drugs, narcotics, benzodiazepines or targeted substances.

Where can I get a new narcotic register to record my controlled drug and narcotic purchases?

Pharmacists can download new pages from the Board website at www.napra.ca – PE – Forms and References.