# alberta college of **pharmacists**



# acpnews

### In this issue...

#### **Notes from Council**

- Code of Ethics under review
- Council amends Standard 11.10

### Competence

- Learning Portfolio myths busted!
- 4 Audit do's and don'ts

#### **Registration & Licensure**

• Technician membership renewal

### **Partners in Practice**

- Technician regulation update
- From the faculty
  - It's Okay to Ask
  - In memory
- 7 Transition Times

### **Patient Safety**

**10** • Methadone labeling requirements

### **Quality Pharmacist Practice**

- **11** Compounding: are we in Agreement?
  - Are you "wholesaling"?
- **12** Drug schedule update
  - How to keep your cool in the pharmacy
- **15** ReSPOND to your patients
- 16 Call for APEX nominations

safe effective responsible pharmacist practice

# ACP/RxA public awareness campaign update

Albertans are receiving the messages, "You and your pharmacist... a healthy combination" and "Get to know your pharmacist - the more they know, the more they can help" from newsstands, airwaves, and computer monitors across the province.

The first wave of our campaign officially launched on Oct. 20 and will run until Nov. 13. The messages will be delivered via:

- 52 radio stations across the province
- Full page ads in the November issues of eight magazines
- PHSN TV (digital-TV network seen in health care waiting rooms)
- Online ads on a variety of websites

We've also presented the messages at the Speaking of Women's Health conference in Edmonton, through articles in other health publications, and at a variety of partner meetings.

# How can you get in on the action?

This is the first wave of a three-year campaign, so we need lots of feedback!

# Magazines featuring the campaign ads:

Canadian Living Chatelaine Apple Your Health Alberta Caregiver Today's Parent Homemakers Reader's Digest

- Tell us what you think of the ads.
- Pass along any feedback you get from customers.
- Got ideas for future ads? We'd love to hear them!
- Need materials to give out from your pharmacy? Let us know.
- Want support to help you with practice changes? Give us a call.
- Have questions about the campaign? Ask us.



### acpnews

is published six times per year by the Alberta College of Pharmacists. Send submissions for publication to:

Karen Mills, Communications Leader karen.mills@pharmacists.ab.ca

The deadline for submissions is Dec. 8, 2008 for the Jan. 2009 issue. Information about content and length of articles can be obtained from Karen.

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Pharmacy technician observers: Robin Burns Teresa Hennessey

Council members can be reached by email via our website at pharmacists.ab.ca under About ACP/Council, or by using the search feature to locate them by name.

### **Staff Directory**

All staff are available at 780-990-0321 or 1-877-227-3838 or by fax at 780-990-0328.

Their email addresses are available on our website at pharmacists.ab.ca under Contact Us.

Registrar: Greg Eberhart Deputy Registrar: Dale Cooney Competency Director: Roberta Stasyk Complaints Director: James Krempien Quality Pharmacy Operations Director: Jill Moore

Pharmacy Practice Consultants:

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alberta college of



Awareness campaign continued from page 1

### What are the campaign goals?

- 1. Instill in the public the value of the patient-pharmacist relationship.
- 2. Establish pharmacists as a key player in the patient's health team.
- 3. Increase public awareness of the range of services pharmacists offer.

### How were the ads created?

We researched similar campaigns by other health groups, studied demographic data, and found media ratings for health care decision makers. This helped us determine our target audience - females aged 35 to 54 - and our primary delivery channel - radio. We also looked to patient history data, Alberta health statistics and had conversations with many pharmacists to narrow down which disease states we include in the campaigns.

We then tested several ad concepts with four focus groups: two with females aged 35 to 54 and two with pharmacists from a variety of age groups and practice settings. The feedback from these groups confirmed our final choice of ads.

### Have lots of opinions, but little time?

If this describes you, then you're exactly who we need! We are creating a "go to" pharmacist group to bounce ideas off, check facts with, ask questions of, and make sure the campaign truly delivers the messages pharmacists want the public to hear. Interested? Contact Cynthia at RxA or Karen at ACP.

### **Campaign contacts**

Karen Mills **ACP Communications Leader** karen.mills@pharmacists.ab.ca

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# Council

Notes from

# ACP's Code of Ethics under review

ACP is reviewing its Code of Ethics to ensure that it is current and relevant to the emerging roles and responsibilities of pharmacists and pharmacy technicians.

The Code was first adopted in 1995. Regular reviews are appropriate, particularly in light of the many changes patients, pharmacists, and pharmacy technicians are experiencing in the health system.

In fulfilling its mandate, the review committee will:

- review changes in the practice and accountability framework for pharmacists and pharmacy technicians;
- consider ethical principals adopted by other regulated health professions;
- identify ethical dilemmas/questions that have arisen as a result of the new practice and accountability framework; and
- seek solutions either through amendment to the Code of Ethics, or through guidance to pharmacists and pharmacy technicians about how they may mitigate potential ethical dilemmas.

The committee will report its findings to council in December 2008. Following council's direction, any amendments to the Code will then be addressed in early 2009, including consultation with pharmacists and pharmacy technicians.

### Members of the Ethics Review Committee

- Dianne Donnan Chairperson, ACP past-president
- Donna Kowalishin community pharmacist, former APhA and CPhA president
- Nora MacLeod-Glover geriatrics pharmacist, Pharm D. candidate
- Kelly Olstad hospital pharmacist
- Ben Bhatti corporate pharmacy representative
- Bill Shores ACP legal counsel

- Joe Doolan public member, former ACP public member
- Tracey Bailey Executive Director, Health Law Institute
- Dr. Glenn Griener ethicist, University of Alberta
- Dr. Eric Wasylenko physician
- Greg Eberhart resource, registrar
- Darcey-Lynn Marc facilitator

# **RxCEL Learning** Portfolio myths – busted!

### **MYTH #1**

If I'm audited, I can substantiate nonaccredited learning programs by providing a certificate from the program.



All non-accredited BUSIED < learning activities must be supported by a

complete non-accredited learning record. Certificates may only be used to support accredited CE programs, i.e., programs accredited by ACP, CCCEP or ACPE.

### **MYTH #2**

The non-accredited learning record form is just a time-consuming paper exercise.



The non-accredited learning record form walks you through the

process of reflecting on the learning activity by considering what you wanted to learn, whether you learned it, and how you can implement this learning in your practice. This allows you to conduct your own mini-accreditation process for non-accredited learning activities.

In the RxCEL Continuing Professional Development Plan workshops, pharmacists reported the average time to complete a non-accredited learning record was 5 to 10 minutes.

### **MYTH #3**

CE programs accredited by ACPE are only worth 0.1 CEU per hour.



The ACPE system allows **BUSTED** < 0.1 CEU per hour of learning. However, in

Alberta the Competence Program Rules state that one hour of learning equals 1.0 CEU. If an ACPE-accredited program states it's worth 0.1 CEU you may claim 1.0 CEU.



## Council amends standard re: recording prescribing decisions on NETCARE

Council has amended Standard 11.10 in the Standards for Pharmacist Practice to read:

Effective upon a date to be determined by council, a pharmacist who prescribes must record all prescriptions they prescribe in the patient record on the Alberta Electronic Health Record (NETCARE).

The amendment defers implementation of the standard which was to come into effect Oct. 1, 2008. The change was made because the necessary technology and systems needed to comply with the standard are not available to the majority of pharmacists.

Council did not strike the standard because there remains support for the principle within it. Organized pharmacy has historically been amongst the leaders in supporting the importance of the Electronic Health Record to improve both the delivery and continuity of care. However, council recognizes that pharmacists require:

- technical solutions that are practical and that do not require duplicating processes within their practices; and
- access to the technologies and systems important to meeting the standard.

Council thanks the many pharmacists who took the time to provide written comments during the consultation period.

Council will monitor the evolution of the Electronic Health Record. When it is satisfied that pharmacists' needs have been reasonably addressed, council will consider a date for implementing the standard. The effective date will be communicated well in advance of implementation.



## Audit do's and don'ts

Audits of professional declarations commenced in September. The audit process should be very straightforward as it is merely confirming the declarations made at the time of registration renewal regarding professional liability insurance and learning activities. However, every

year we find that for various reasons many audits do not proceed as they should, take up valuable time for the pharmacist and ACP staff, and may impede or prevent registration renewal. The following steps can improve the process for everyone:



- only claim learning that you are able to substantiate with certificates or nonaccredited learning records;
- read the Guidelines for Audit of Professional Declarations carefully so you understand what you must submit to ACP (the Guidelines are included with the notice of audit);
- provide copies of course certificates for accredited programs;
- provide copies of non-accredited learning records for all non-accredited learning activities claimed on your CPD log;
- provide a copy of your professional liability insurance policy;
- fulfill all audit requirements within 30 days of notification;
- make sure you're sending documents for the correct registration year.



- send original documents;
- send copies of other supporting documentation such as exams, handouts, conference brochures, receipts;
- ask ACP to delete learning activities from your CPD log;
- alter course certificates in any way (e.g., strike out participant's name and write in another name);
- claim non-accredited learning activities that are not really "learning activities", such as golf tournaments, presentations to lay people, and precepting students;
- claim continuing medical education programs as accredited learning.

University of Alberta Practice Development/Continuing Pharmacy Education



## Winter Programs Announcement of Workshop Dates

The Faculty of Pharmacy and Pharmaceutical Sciences announces the following programs for Winter 2008:

## Women's Health - Menopause

### **Three-day Workshop Dates:**

Tuesday to Thursday, February 17 to 19, 2009

### Location:

**TELUS Centre for Professional Development** 111 Street and 87 Avenue, Room 217 - 219 Unversity of Alberta, Edmonton, Alberta

### Anticoagulation -On the Road to Practice Change

### **Two-day Workshop Dates:**

Saturday to Sunday, February 28 to March 1, 2009

### Location:

Stollery Executive Development Centre School of Business 5-22 Business Building, Room 5-40A Unversity of Alberta, Edmonton, Alberta



Programs involve pre-workshop assignments, participation at the workshop, three distance learning sessions, and a final assignment. Further details, including dates for distance learning sessions and registration fees will be available on our website at www.pharmacy.ualberta.ca/conted.



# Pharmacy licensees and technician membership renewal

Do you employ pharmacy technicians who are members of the Alberta College of Pharmacists? If so, you should be aware that all technician memberships will expire on December 31, 2008.

To continue to be a pharmacy technician member with ACP, technicians must renew their membership before Dec. 1, 2008. Renewal notices were mailed to all technician members in October. The pharmacy technician renewal fee is \$78.75. If your pharmacy technician member does not receive a renewal notice, they should go online to renew or contact the ACP Registration Department. One lucky technician who renews online will win the equivalent of her/his annual membership fee.

# Pharmacy technicians: moving from voluntary membership to regulated health professionals – an update

ACP currently enrolls pharmacy technicians as members through the authority of our by-laws. Membership indicates that a pharmacy technician has completed a training program that meets the criteria approved by ACP council and qualifies the technician to participate in activities in a pharmacy as outlined in the *Standards for Pharmacist Practice*. However, membership is not the same as being a regulated health professional under the *Health Professions Act*.

This fall the Alberta legislature will consider amendments to the Health Professions Act (HPA). Included is an amendment that will add pharmacy technicians to Schedule 19 of the Act. When this amendment is passed, pharmacy technicians will be defined in the Act and regulations can be revised to accommodate ACP in regulating pharmacy technicians in Alberta. Regulation will make pharmacy technician a protected title, meaning that only those who register as regulated technicians may call themselves a pharmacy technician. Regulation will also outline the restricted activities that can be performed by pharmacy technicians and will allow technicians to take responsibility for the work they do in the same way that other regulated health professionals do.

# Overview of qualifying exam process

ACP has set a goal to begin regulating pharmacy technicians in 2010. This date coincides with the expected offering of national qualifying exams administered by the Pharmacy Examining Board of Canada (PEBC). PEBC plans to pilot

these exams in 2009 and then administer them nationally in 2010. The exam process will be similar to the PEBC pharmacist exam process. The process includes three exams:

- 1. Evaluating Exam
  - To be completed by candidates who have not completed an accredited training program.
- Qualifying Exam Part I Multiple Choice Questions (MCQ)
- 3. Qualifying Exam Part II Objective Structured Practical Exam (OSPE)

A practical exam that simulates the work a technician would do in a community and/or institution pharmacy.

Accreditation of pharmacy technician training programs began in the spring of 2008. The accreditation is being completed by the Canadian Council for the Accreditation of Pharmacy Programs (CCAPP). This is the same body that accredits training programs for pharmacists in Canada. To date, one Alberta program has been accredited. Three additional Alberta programs will undergo evaluation this fall. Since accreditation is just beginning, no pharmacy technicians currently in the workplace will have completed an accredited training program. However, there have been many good training programs in place in Canada and there have been voluntary certification exams offered in Ontario and Alberta. For this reason, PEBC has stated that technicians who have completed the Alberta exam1 prior to December 2007 or the Ontario exam prior to December 2008 will not be

<sup>1</sup> The Alberta exam was offered by PTeB, the Pharmacy Technician Education Board, formerly PTCB-Ab, the Pharmacy Technician Certification Board of Alberta. The Ontario exam was offered by the Ontario College of Pharmacists.

Pharmacy technicians continued from page 5 required to complete the evaluating exam. They may proceed directly to the Qualifying Exam Part I.

# Bridging programs being developed

Other Canadian provinces are working toward technician regulation. The Ontario College of Pharmacists (OCP) has received approval to regulate pharmacy technicians in that province beginning in 2010. As part of their preparations, OCP is developing bridging education programs to help technicians make the transition to becoming regulated health professionals and to prepare for the national exams. ACP will be partnering with OCP to offer these bridging programs in Alberta. More information about these programs, including when and where they will be offered, will be communicated by ACP as soon as details are available.

# From the faculty...

Student admissions for Sept. 2008, the Class of 2012, received 578 applications. Of the 130 students accepted, 108 were Albertan, 16 non-Albertans and 7 were International. Female members total 88 and 43 are males.

The **Class of 1976** has fully endowed their bursary to be awarded to a student with satisfactory academic standing enrolled in the first, second or third year of an undergraduate degree program in the Faculty. Selection is based on financial need.

To celebrate their 35 Year Reunion, the Class of 1973 is establishing a Class gift and are over half way to their goal of \$12,500 for an endowed award. Homecoming, Sept 18 – 23, brought many alumni back to campus for the 100 Year celebrations, specifically the classes of 1958, 1973 and 1978.



# *It's Okay to Ask* – find out more

Fear, embarrassment and limited skills often keep patients with low health literacy from asking important questions of their health care providers. Research tells us that more than half of the Canadian population cannot understand or evaluate basic health information.

In early 2009, the Health Quality Council of Alberta (HQCA) will distribute *It's Okay to Ask*, a simple, newspaper-style report that encourages Albertans to work closely with their health care providers to give and get the information they need to play an active part in their own health, safety and well-being.

### **Preview for health care providers**

Before Albertans receive *It's Okay to Ask*, the HQCA invites you to preview a one-page briefing (included with this mailing) which outlines the publication's contents and offers suggestions for steps you can take to help foster better understanding. To receive electronic or hard copies of this briefing please contact us:

Health Quality Council of Alberta Email: info@hqca.ca Tel: 403.297.8162 www.hqca.ca

The Council recognizes the vital role health care providers play helping patients understand what they need to do to get better and stay healthy. *It's Okay to Ask* was developed to support your efforts. We welcome and encourage your feedback. Copies will be delivered to you once the report is released in early 2009



Robert James (Bob) Edgar passed away at the U of A Hospital on Aug. 29, 2008, after a lengthy illness. Bob was born in Innisfail and obtained his BSc Pharm from the U of A in 1955. While operating a pharmacy in Westlock, he was President of the Chamber of Commerce and the Kinsmen Club as well as President of the Alberta Pharmaceutical Association in 1965/66.

In 1973, Bob and his wife, Eleanor moved to Edmonton where Bob began a long and successful career with the Alberta Department of Consumer and Corporate Affairs. Bob was always very involved with his community and will be missed by his family and friends, and everyone whose life he touched.



# "First fifteen" profiles

This month, we introduce three more of the first 15 pharmacists to earn additional prescribing authorization.

### Kim Mettimano, BSc. Pharm

Certified Diabetes Educator, Insulin Pump Trainer

Signature Medicine Centre Pharmacy, Calgary

Establishing solid relationships with patients and other health care providers is a priority to pharmacist Kim Mettimano, owner of the Signature Medicine Centre Pharmacy in southwest Calgary. So it's not much of a surprise to find that, as a result of her positive relationships, she often has patients come in from Manitoba to see her if they have an appointment with one of the local specialists she works with on a daily basis.

Kim has owned her pharmacy for the past two years and worked for another independent pharmacy prior to taking on Signature Medicine Centre Pharmacy. She says that obtaining her additional prescribing authorization was a "natural fit" with her practice.

"I work with diabetes specialists, endocrinologists, and some internal medicine specialists," says Kim. "With my additional authorization I am able to provide education, switch products, make product recommendations, and do follow-up dosages with less hassle and less time spent waiting to get approval for certain things."

When the additional prescribing authorization pilot came out, Kim thought, "Finally! Pharmacists are on the road to providing the care they are truly capable of." And with the additional authorization under her belt, Kim is ready to forge ahead.

"My practice is a little unique. I work in my pharmacy but I also provide diabetes care and education within the pharmacy. The local specialists and physicians often send their patients to me specifically. I don't do a lot of initial prescribing for diabetes, but I do assist in follow up and titration of doses."

"In terms of general practice, I feel that pharmacists can continue to play a larger role and being able to provide generalized care will move the pharmacy profession forward. I believe what the government and public are looking for from this initiative is better access—pharmacists can make a difference for the system and for patients."

It was in trying to show the balance between her diabetes care and general practice that Kim found her challenge with the application process. "The most challenging aspect of the application for me was that I really tried to look at the application from two sides: using an area of expertise such as diabetes or anticoagulation and the more generalized prescribing - providing topical creams or antiviral drugs. I knew there was a balance and I wanted to address that in my application. I had plenty of care plans, so that was quite straightforward, but I felt that the application could be filled out differently whether a pharmacist was coming from community, hospital site, or a specialized practice.

"My recommendations to other pharmacists would be to think about what you want to do with this opportunity. Look at your practice and your patients. Don't hesitate to go after it even if you're not working in a specialized area. In general, maintain positive relationships with the physicians and health care professionals around you.

"In several situations, this additional prescribing authority was definitely



helpful. As an example, I had a patient come into the pharmacy late on a Friday night, who was in clear need of an antiviral for a cold sore. The patient informed me that an antiviral had been prescribed in the past for the same ailment. I assessed the patient and was able to prescribe a treatment. In situations like these, being able to offer quick and effective treatment makes things easier for patients."

The response from Kim's patients so far has been very positive. "I haven't advertised the service that I provide, although there is a sign up in the pharmacy that informs people of my authorization. I have a lot of loyal patients who I know very well and fewer new patients."

With regards to a response from other health professionals, Kim says, "To date, I haven't had any negative responses from other health professionals and I continue to be very respectful of the physicians, their skills, and expertise. For example, a mother and daughter came

Kim Mettimano continued from page 5

into my pharmacy and wanted to initiate birth control. Because I wouldn't be doing any of the follow up, I felt that I could recommend some products but that ultimately, they should see their family physician for a prescription."

"We need to participate in successful health care partnerships in order to move forward and although sometimes it may be a challenging transition, building these close personal and professional relationships with physicians within the prescribing scope will be a tremendous asset.

"It is important to do this as a pharmacist. It's not about our patients coming to use solely for drugs—but about pharmacists providing important health education services."

### Rami Chowaniec, BSc. Pharm

Certified Diabetes Educator Canada Safeway, Edmonton and WestView PCN (Spruce Grove, Stony Plain and Wabamun)

Having too much spare time isn't a problem for Rami Chowaniec. Rami keeps very busy putting her knowledge as a pharmacist and diabetes educator to use in a variety of settings. She divides her work week into one day at the Southgate Safeway, two days in community settings for Safeway, and two days with the WestView PCN. "I have a bit of all worlds," Rami observes. "I'm still in retail and do the dispensing and see a variety of patients; then my work at the PCN means I get a different kind of collaboration with other health professionals. I'm really lucky that way."

Rami chose pharmacy to combine two of her greatest interests: science and helping people. Early on, she knew she had a scientific bent. She always loved chemistry and biology. She also had good communication skills and a desire to connect with those around her.



Her efforts were encouraged by her supportive mother, as well as an early mentor and role model, Gladys Whyte. Rami worked with Gladys as part of a high school work experience project. That experience set the direction for Rami's career.

Rami's interest in diabetes education stems from family: both her grandmother and uncle have diabetes. Having worked both at Food For Less Southside and Southgate Safeway Pharmacy, containing the Diabetes Care Centre for Safeway in Edmonton, opened her eyes to the need for more diabetes education by pharmacists. She quickly discovered how hungry patients newly diagnosed with diabetes were for information and support. She also learned how even those patients who had lived with diabetes for decades often needed medication adjustments and ongoing education. She had found her role, one she has worked on expanding throughout her career.

One of Rami's most recent "career expansions" was her successful completion of the additional prescribing authorization pilot. Why did she put her name forward for the project? "I thought prescribing was something pharmacists

should have been doing a long time ago. When the opportunity finally came, I knew we had to step up and really prove we could do it. I really felt compelled to support the initiative because I thought that was the way pharmacy should be going.

"I had good, established relationships with my patients and other health care professionals. I also knew how much my patients could benefit.

"There have been many times when a patient is sent to me specifically to start insulin or a dosage should be altered but the doctor is not in. Now, I can make that change and get the patient started with what they need right away. I've also been able to get the ball rolling faster with Pneumovax vaccinations. Having the additional prescribing authorization just makes the initiation of changes so much simpler. I can ensure continuity of care and also remove one more step or hurdle for my patients. It just streamlines the process."

Rami's new authorization has drawn nothing but praise from her patients and her colleagues. "Most of them say, 'You should have been doing this before!"

As for the application process itself, while it took time it was not too daunting. "The process is good because it ensures that those who are authorized are the ones who are competent to prescribe. My biggest area of uncertainty was charting. I wasn't sure if I had all the documentation I needed. However, once I got started, I realized I was doing OK. It was a nice affirmation of my practice habits

"For anyone thinking about applying, I would say the first step is to ensure you're already meeting the requirements sets out in the Standards of Practice. You also need to be clear about your basis for prescribing in each case. If you expect others to accept your recommendations, you have to have something to prove your knowledge. You need to help them see your reasoning and become comfortable with your decision. "

### Christine Hughes, BSc. Pharm, PharmD, ACPR, FCSHP

Associate Professor
U of A Faculty of Pharmacy and
Pharmaceutical Sciences
Clinical Pharmacist, HIV
Northern Alberta HIV Program

Dr. Christine Hughes graduated from the U of A in 1994 and went on to complete her PharmD at the University of British Columbia in 1997. For the past 11 years, she has been working in an interdisciplinary HIV outpatient clinic at the U of A Hospital. The clinic is part of the Northern Alberta HIV program which cares for HIV-infected patients in the northern half of the province. In addition to her work at the hospital, Christine is a faculty member with the Faculty of Pharmacy and Pharmaceutical Sciences at the U of A.

What motivated this busy pharmacist to take part in the additional prescribing authorization pilot? "I thought this was an exciting opportunity for the profession and I wanted to be a part of it," says Christine. "I have been working in a collaborative practice environment for many years and have been highly involved in drug therapy decision making and monitoring. It seemed like a natural progression to apply for additional prescribing authorization for both legal reasons as well as to improve efficiencies in practice."

Christine says that she has always been a strong proponent of documentation, but that the application process reinforced the importance of ensuring thorough documentation of the care that she provides throughout the treatment process to ensure transparency and continuity of care. The most challenging aspect of the application process was, "selecting cases to put forward that highlight the level of care that I provide," she says.



With the additional prescribing authorization included in her arsenal of tools, Christine plans to use her prescribing authority to manage select concomitant conditions in her patient population, as well as to help manage adverse effects of antiretroviral drug therapy. Citing an example, Christine says, "Reducing cardiovascular risk is important in HIV-infected patients. Therefore, smoking cessation and managing hyperlipidemia are areas where I plan to use my prescribing authority.

"The antiretroviral drugs have common side effects such as nausea and diarrhea; therefore, antinauseants and antidiarrheals are other areas in which I plan to prescribe. Although I would prescribe antiretroviral drugs in certain circumstances, I think it is important that refill requests go to the Infectious Disease physician who is looking after the patient as I only work part-time with the clinic and they have support staff as well as coverage from other physicians to handle requests."

Christine believes that this new tool will benefit her patients in a number of

instances. "Managing HIV disease and related conditions is very complex and requires an interdisciplinary team approach," she says. "I think this new tool provides the opportunity for the pharmacist to manage and take responsibility for certain aspects of the patient's care. This will lead to decreased waiting time for the patient (e.g., not having to wait to get a prescription authorized by the physician). It may also lead to improved outcomes as we could more proactively manage and titrate medication doses and follow-up with blood work. More importantly, I think it will reduce some of the workload on the healthcare team—the physician dealing with non-infectious disease related areas and some routine prescriptions, as well as the pharmacist/nurse having to track down the physician for certain prescriptions."

Because pharmacists have always been highly involved where Christine practices, she isn't sure that patients have noticed a huge difference. The health professionals she works with, who have become more and more aware of her increased authorizations, have noticed a difference and are very supportive of her, other pharmacists, and changes to the scope of practice.

Considering beginning your application for additional prescribing authorization? Here are some words of advice from Christine. "Don't be overwhelmed by the documentation required. This is a great opportunity for pharmacists and the profession and we really need to embrace it in order to move forward with changes to pharmacy practice in the future."

# Labeling requirements for the storage and dispensing of methadone solutions

ACP Pharmacy Practice Consultants have observed that a number of pharmacies involved in providing methadone are not properly labeling stock solutions and prescription containers.

# Packaging requirements and labeling

Methadone stock solutions prepared in advance of dispensing to patients must be handled in the following manner:

- The aqueous stock solution must be prominently labeled and stored in a container that is distinct and not easily confused with other stock solution containers (such as water bottles).
- The label on the stock solution must list the strength of the methadone solution, date of preparation, the

- individual(s) involved in the preparation and the beyond use date.
- 3. A written record must be maintained in the pharmacy as to the preparation of the methadone stock solutions. This information should include the initials of the individuals involved in preparation, the lot number and expiry date of the methadone powder, and beyond use date.
- 4. The stock solution container must have an appropriate warning label indicating the medication may cause harm or toxicity if consumed by other than for whom it was prescribed.
- 5. When "carry" doses are dispensed, in addition to the information on the label as prescribed in the standards, the following warning label must be affixed to the container:

Methadone may cause serious harm to someone other than the intended person. Not to be used by anyone other than the patient for whom it was intended.

Pharmacists providing methadone prescriptions are encouraged to review *Methadone Treatment in Alberta: Guidelines for Dispensing Pharmacists*, available under Pharmacist Resources/ACP practice guidelines on the ACP website (https://pharmacists.ab.ca/nPharmacist Resources/ACPPracticeGuidelines.aspx? id=6049).





# Call I fill a prescription for methadone from a physician outside of Alberta?

Health Canada has indicated that a physician licensed in one province cannot legally prescribe methadone in another province. However, Health Canada recognizes that it may be necessary for the physician in the patient's home province to continue managing their care for a short period to allow transition to an Alberta physician.

If you are filling a methadone prescription, you must ensure that:

 the prescription is current, authentic, complete and appropriate (Standard 5 of Standards for Pharmacist Practice).  the prescriber has the required exemption. Methadone may only be prescribed by a physician with an exemption under section 56 of the Controlled Drugs and Substances Act. You may check with Health Canada's Methadone Program (toll free 1-866-358-0453) if the physician holds an exemption and if so, for which indication (treatment of opiate dependence and/or analgesia).

Note: Many provinces in Canada do not have a triplicate prescription program. Although methadone is on the triplicate list in Alberta, you cannot ask a physician from another province to comply with Alberta's triplicate prescription program.

# Compounding for other pharmacies: are we in Agreement?

Are you a pharmacy that prepares compounded prescription products for your patients and has special equipment, training or interest in compounds? Remember that if you prepare compounded preparations for sale to other pharmacies, your pharmacy must meet two criteria:

- 1. You must have a Compounding and Repackaging license for your pharmacy; and
- 2. You must have a signed written contract or agreement with each pharmacy that you prepare compounds for.

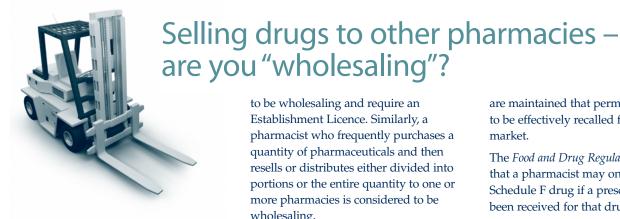
In addition to a Community Pharmacy license, a pharmacy that prepares compounds or pre-packaged drugs for another pharmacy must have a Compounding and Repackaging license. This additional license is for pharmacies that provide these services for patients of other pharmacies, not their own patients. If you prepare compounded products and compliance packages only for your patients, you do not need a Compounding and Repackaging license.

Pharmacies that prepare compounds and sell them to other pharmacies must have an agreement in place with each



pharmacy they sell to, otherwise they may be deemed to be manufacturing under the terms of the Food and Drug Regulations. An agreement with the content and form approved by Council and the Registrar is available on the college's website (https://pharmacists. ab.ca/Content\_Files/Files/CandR Agreement.PDF).

More information on the agreement may be found in the Sept/Oct 2007 issue of acpnews. The requirement for compounding and repackaging agreements comes from Section 19 of the Pharmacy and Drug Regulation.



According to the Food and Drug Regulations, wholesaling is the activity of selling any prescription drug other than at retail (prescription) sale, where the seller's name does not appear on the label of the drug.

C.01A.004. (1) Subject to subsection (2), no person shall, except in accordance with an establishment licence,

(a) fabricate, package/label, distribute as set out in section C.01A.003, import or wholesale a drug.

Buying groups, where one pharmacy purchases drugs in bulk on behalf of a number of pharmacies, are considered

to be wholesaling and require an Establishment Licence. Similarly, a pharmacist who frequently purchases a quantity of pharmaceuticals and then resells or distributes either divided into portions or the entire quantity to one or more pharmacies is considered to be wholesaling.

Pharmacies engaging in the practice of the wholesale of Schedule F drugs require an Establishment Licence. An Establishment Licence is required by any site involved in manufacturing, importing, wholesaling, distributing, packaging/labeling or testing of drug products. It is issued after a firm has been inspected by Health Canada and the firm has demonstrated that it has fulfilled the applicable requirements of the Food and Drug Regulations. An Establishment Licence is necessary to ensure that products entering the drug distribution chain are adequately stored, transported and that records

are maintained that permit products to be effectively recalled from the market.

The Food and Drug Regulations also say that a pharmacist may only sell a Schedule F drug if a prescription has been received for that drug.

C.01.041. (1.1) Subject to sections C.01.043 and C.01.046, no person shall sell a substance containing a Schedule F Drug unless:

(a) the sale is made pursuant to a verbal or written prescription received by the seller: and

(b) where the prescription has been transferred to the seller under section C.01.041.1, the requirements of section C.01.041.2 have been complied with.

In the past, Health Canada has not enforced these regulations when a pharmacist supplies another pharmacy with a small quantity of a drug in an

"Wholesaling" continued from page 11

exceptional or urgent circumstance if the amount of drug exchanged between pharmacies is sold in a quantity sufficient only to fill the prescription at hand. Health Canada has identified some pharmacies engaged in significant wholesaling of prescription drugs and has issued regulatory letters.

Pharmacies wishing to obtain an Establishment Licence should contact the Health Products and Food Branch Inspectorate Establishment Licensing Unit at (613) 954-6790 or visit the website at: www.hc-sc.gc.ca/dhp-mps/compliconform/licences/index-eng.php for information regarding obtaining the required site licence.

### **References:**

Lambert, J. (2004, November 16). Obligations of Pharmacists under the *Food and Drugs Act* and *Food and Drug Regulations*. Retrieved from Health Canada website:

www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/\_2004/distrib\_distanc\_dispens\_ltp-lp-eng.php)

Drug Compliance Verification & Investigation Unit (2004, November 16). Frequently Asked Questions - Compliance Inspections. Retrieved from Health Canada website: www.hc-sc.gc.ca/dhp-mps/compliconform/info-prod/drugs-drogues/internet\_faqs\_tc-tm-eng.php

# Drug schedule updates: topical diclofenac and niacin

Since Novartis Consumer Health introduced a new product, Voltaren Emulgel (diclofenac diethylamine 1.16 % w/w), pharmacists have been asking if this is a Schedule I or Schedule III product. Based on the information contained in the product monograph, Voltaren Emulgel contains 1% diclofenac-Na equivalent and is a Schedule III product.

Diclofenac diethylamine preparations for topical use on the skin in concentrations of not more than the equivalent of 1% diclofenac were removed from Schedule F in April, 2008 and placed in Schedule III.

Higher strengths of niacin (nicotinic acid, Vitamin B3) used as antilipidemics were placed in Schedule F1 of the *Food and Drug Regulations* in June, 2008 by Health Canada making them prescription-only products.

Nicotinic acid (niacin), when sold in a modified-release oral dosage form that provides 500 mg or more per dosage unit or per daily dose; or in an immediate-release oral dosage form that provides

more than 500 mg per dosage unit or per daily dose, now requires a prescription for human and veterinary use.

Slow release niacin in strengths below 500 mg remains in Schedule II and immediate release niacin in tablet strengths of 500 mg or less remain unscheduled.

# Not sure where to put the products in the pharmacy?

Newer packaging of slow release niacin, such as Niaspan®, now comes with a Pr symbol on the bottle. Most immediate release niacin vitamin products in strengths of 500 mg or less are intended for once a day dosing and may be placed outside the pharmacy with the other vitamins. Check the dosing instructions on the package to be sure. Slow release lower strength products should be kept behind the counter in Schedule II. When counseling patients on niacin and other vitamins. Health Canada has a useful resource for vitamin reference values: www.hc-sc.gc.ca/fnan/nutrition/ reference/table/ref\_vitam\_tbl-eng.php.

# How to keep your cool in the pharmacy

# Understanding the Cold Chain

### Introduction

Temperature is key to vaccine integrity. Most vaccines must be kept between 2 to 8°C since vaccines undergo a natural degradation through protein denaturation and other mechanisms. While warm temperatures accelerate degradation, the process is relatively slow. However, the vaccine integrity is severely affected when vaccines are exposed to temperatures below 2°C. In fact, freezing changes the molecular shape of the product and renders it ineffective almost instantly.

According to the Public Health Agency of Canada document *National Vaccine Storage and Handling Guidelines for Immunization Providers* (2007):

An estimated 17% to 37% of healthcare providers expose vaccines to improper storage temperatures. Refrigerator temperatures are more commonly kept too cold rather than too warm. One study involving site visits showed that 15% of refrigeration units had temperatures of +1°C or lower.

Health Canada audits and enforces Good Manufacturing Practices (GMP) to ensure that products are held within the proper temperature range from the manufacturer through to the final distributor. The processes involved in keeping a vaccine between 2 to 8°C from the manufacturer to client is often called the Cold Chain. The Cold Chain is a global process. In the private system, it includes manufacturing and cold storage, distribution channels, pharmacies and clinics. The temperatures and storage conditions of the vaccine are tracked and documented until received by the pharmacy or clinic.

Once the product is released by the final distributor, and accepted by the clinician or pharmacy, jurisdiction for this control rests with the provincial regulatory body (e.g., Alberta College of Pharmacists). Pharmacists routinely store and dispense vaccines, especially for travelers, as these products are not covered under public health programs. Furthermore, pharmacists now have the ability to administer vaccines. Thus we have a key responsibility to ensure that the Cold Chain is maintained during this "last mile of distribution" to the client.

This responsibility is codified under Standard 47 of the *Standards for Operating Licensed Pharmacies* which states that the licensee of a pharmacy must ensure that drugs are stored in the licensed pharmacy at:

- a) appropriate temperatures,
- b) under appropriate conditions, and
- c) in accordance with any manufacturer's requirements to ensure stability.

There are two key roles a pharmacist plays in ensuring the vaccine will be safe and effective.

- 1. The first is to ensure that the vaccine has been stored appropriately. This involves ensuring refrigeration equipment is adequate and that the storage temperatures are tracked and documented. Once it is understood how a refrigerator works it becomes alarmingly evident just how easy it would be to unknowingly allow a vaccine to go below 2°C.
- The second pharmacist role is to ensure the client is also taking precautions to safeguard the product from the time it is picked up at the pharmacy to the time it is injected by the immunizer.

### How a fridge works

There is marked difference between the temperature control afforded by a fridge designed for vaccines compared to a fridge designed for household use.

A fridge functions around its *set point* (i.e., the temperature the user has set the fridge to maintain.) This is the initial challenge a household fridge has compared to a vaccine fridge. On a vaccine fridge, one can simply set it at 5°C for example. However, in many household fridges one must select a number between 1 and 9 and then confirm the temperature through monitoring.

Once a set point is assigned, the fridge will then start to cool when it reaches the trigger point (i.e., a temperature above the set point). It will then continue to cool until it reaches its cut-off point (i.e., a temperature below the set point.). The temperature difference between the trigger point and the cut-off point is called the *operating range*. The critical difference between a vaccine fridge and a household fridge is that this operating range is much greater in a household fridge. A vaccine fridge cycles tightly around its set point and is almost constantly operating a fan to keep the temperature even.

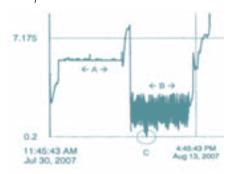
# Risks involved with using household fridges

The following graph illustrates a shipment monitored over time. In Section A. the vaccine is being held in a vaccine fridge. Note that it has a tight operating range of about 0.1°C and that it is being held at about 5°C. The shipment is then packed out for transport and placed into a household fridge in a different location shown in section B. Note the comparatively extreme operating range of about 3°C. Also note that this fridge breaches the manufacturer's recommendation by reaching a minimum temperature of 0.2°C at the point circled C.

The following example shows how easy it would be to put vaccines at risk if monitoring is not occurring. If a pharmacy had a fridge set at 2°C, the *cut-off point* of the cycle could reach -1°C or even less if the *set point* is not really known. This would inactivate certain vaccines in that refrigerator. Thus there is

a potential for inactive vaccine to then be dispensed or injected by the pharmacist or other clinician resulting in poor or no protection for the client.

### Example:



Ideally if a pharmacy has a strong interest in an effective vaccine practice they should be investing in a fridge especially designed to store biological products.

A domestic style fridge is acceptable as long as the freezer and fridge compartments are separate. If this style of fridge is used, it is recommended to remove the crisper drawers to avoid the temptation of storing vaccines there. Further the floor and door of the fridge should never be used to store vaccines.

Smaller household "bar" style fridges where the freezer and fridge are within the same compartment are difficult to control and are strongly discouraged. If space is an issue there are smaller fridges available which are designed for vaccine storage.

Regardless of the type of fridge used, it is important that the following procedures are adhered to:

- 1. Ensure the fridge is equipped with a digital min/max thermometer (Fig. 1).
  - a. The thermometer should have a probe which is set in liquid so it is not prone to false alarms due to rapidly changing air temperature (when a door is opened, for example).
  - b. It should have alarms set to activate if the temperature goes below 3°C or above 8°C.



Figure 1: Min/Max Thermometer example. Note liquid filled probe.

Keep your cool continued from page 13

- The thermometer should be read every day upon opening and closing of the pharmacy and the following should be documented:
  - Minimum temperature
  - Maximum temperature
  - Actual temperature
- After reading the above temperatures, the memory needs to be cleared so fresh values can be read for the next logging period. A periodic review of the actual temperatures should occur at least monthly in case minor adjustments are necessary for a 5°C average.
- 3. In the event that readings deviate from 2°C to 8°C, the above information is invaluable to the manufacturer to assist the pharmacist in determining the next steps to take with the product.
- 4. The set point of the fridge should be 5°C. This will provide the widest safety margin to both 2°C and 8°C. Try to break the myth that you need to stay close to 2°C to protect vaccines. As explained, this practice is very risky.
- 5. Fill any extra spaces with water bottles. (1 liter water for irrigation works nicely.) This is a great way to fill the space where crisper drawers may have been removed to avoid the temptation of using the floor of the fridge for storage. In the event of a power failure, the water will assist in

- holding the temperature longer than if there was only empty air within the refrigerator.
- 6. Do not use the door shelves of the fridge: this would be a good place to line with water bottles as well.
- 7. Never store lunches, drinks, etc. in the fridge. This leads to opening the door more often than necessary and also creates the risk of spills and contamination. The goal is to minimize the number of times the door is opened.
- 8. If using a domestic fridge, be especially careful of product placement. The centre is safest. The position next to the fan is the least safe and could expose vaccines to subzero degree air circulated from the freezer. This is usually the back top position but may be different in different models.

# Counseling the client upon dispensing the vaccine

Pharmacists dispensing product for injection by other health care professionals have added challenges. You can perform your due diligence to ensure the cold chain has been maintained to the client. But, how do you help the client maintain the cold chain until administration? This is an area which has not been given due attention and as such there is little information available regarding best practices.

The most ideal situation for a client obtaining vaccine at a pharmacy would be for the pharmacist (or practitioner in a location adjacent to the pharmacy) to inject the vaccine. This option poses virtually no risk to the cold chain. The next ideal option would be for the client to obtain the vaccine from the pharmacy but then head directly to the practitioner for administration. This avoids the risk of freezing the product in a household fridge.

It is not an ideal situation to dispense a vaccine to a client for storage at home and injection on a different day. Thus, this practice needs to be avoided.

The minimum counseling a pharmacist needs to provide to the client is as follows:

- 1. Ascertain if the client is heading directly (within 15 to 30 minutes) to the practitioner. Offer to hold the vaccine until the appointment day and actively discourage storage in a home refrigerator.
- Explain that the vaccine should be transported in the temperature controlled cabin of their car and not the glove box or trunk, away from heater, air conditioner vents and out of direct sunlight.
- 3, Bust the myth of "colder is better" and deter the client from taking extraordinary measures to keep the vaccine really cold. Thus do not allow the vaccine to be transported in a cooler bag filled with ice, for example. The best way to transport a vaccine a short distance is to use a cooler filled with refrigerated gel packs (not frozen ice packs). Of course this may not be practical and thus heading straight to the immunizer with the vaccine unprotected is better than on ice.

Under Health Canada regulations, manufacturers have tracked the integrity of the product over air, oceans, rail and road until the final distributor. The above steps would help to ensure pharmacists maintain this cold chain right until the client's arm.

Some excellent references surrounding cold chain as it pertains to pharmacists are:

- National Vaccine Storage and Handling Guidelines for Immunization Providers (2007): www.phac-aspc.gc.ca/ publicat/2007/nvshglp-ldemv/indexeng.php, Public Health Agency of Canada.
- Vaccine Storage and Handling Guidelines. Pharmacist's Letter, May 2008

# Helping you ReLATE and ReSPOND to your patients

This is the second of a two-part series in acp*news* based on a program developed by Capital Health and the Health Quality Council of Alberta (HQCA) in 2001. Capital Health designed the tools in response to the 2001 provincial mandate to develop a concerns management process, and the HQCA, working with Capital Health, adapted their successful R.E.L.A.T.E.-R.E.S.P.O.N.D® 2001 program for use across the province in 2007.

If a concern or complaint is received, effective complaint handling using ReSPOND techniques can prevent escalation and further enhance patient-provider relations.

**ReSPOND** is an acronym for some basic steps to take when you first receive a concern:



Everybody deals with situations differently. Acknowledge what the person is experiencing and his/her reaction to it.

# E Establish a rapport with the complainant

Listen and show that his/her concern matters to you.

Paraphrase what the person is saying to be sure that you understand what he/she meant.

## Single out the complainant's real issues

Ask questions to identify the specific things that the person is concerned about.

Check to see what he/she would like to see done to improve his/her situation.

Provide information to the complainant about action to be taken

If the solutions to the concern are within your area of responsibility, explain what steps you will take to resolve it. If the concern deals with issues outside of your area of responsibility, explain to whom you will refer the concern. Be as specific as possible.

# Operationalize the indicated plan of action

Follow through on any action that falls within your area of responsibility.

Notify the complainant of the action you have taken

Report back to the complainant – update them on your progress and keep them in the loop.

Discuss the concern with your manager if indicated

Clarify specific details as necessary.

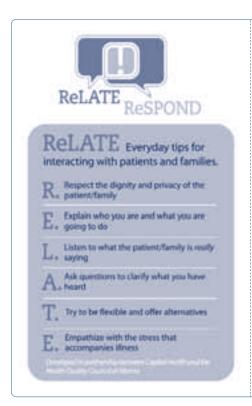
Work with your supervisor/manager to plan the response to the complainant, and

to determine who is most appropriate to deliver the response to the complainant.

# Why do you need to ReSPOND to your patients?

Handling confrontations is the professional's reality. You are often busy providing care to many patients, focused on other priorities and unable to predict when a confrontation may occur.

If a situation occurs where you are required to ReSPOND to a patient or their family, these tips will help you navigate through the situation calmly and effectively and in the end, will likely enhance your relationships with current patients and help build positive relationships with new patients.





You can cut out the above card and carry with you as a reminder of techniques to help you ReSPOND to your patients and their families. This, along with the ReLATE information from the Sept/Oct 2008 issue of acpnews, is a practical tool to assist you in interacting safely and respectfully with your patients and their families.



Brought to you by the Alberta College of Pharmacists and the Alberta Pharmacists' Association

## **Call for Nominations**

The APEX Awards recognize the achievements of colleagues, friends and supporters who have demonstrated leadership and excellence within the profession and the community at large.

**December 12, 2008 is your deadline to submit a nomination.** Are you or someone you know reaching new heights?

Nominating is simple! Visit https://pharmacists.ab.ca/nAboutACP/ APEXAwards.aspx for details.

The award winners will shine in front of their peers, and also in front of respected health care providers from other disciplines, at the tri-profession conference in Banff this May. It's an excellent opportunity to showcase the great work of the profession.

**APEX Award Categories** 

M.J. Huston Pharmacist of the Year honours a pharmacist who has demonstrated outstanding professional excellence in the practice of pharmacy.

- W.L. Boddy Pharmacy of the Year recognizes a pharmacy licensed in Alberta, whose health professionals, by virtue of their practice, have positively impacted the health of their community.
- Award of Excellence pays tribute to an Alberta pharmacist for individual outstanding achievement in the field of pharmacy. This award is granted for a single unique accomplishment or contribution thus differing in this way from the Pharmacist of the Year Award.
- Future of Pharmacy provides funding for up to three new pharmacists to attend their first ACP/RxA conference. This award is presented to pharmacists who exude enthusiasm and passion for the future of pharmacy, are visionary, and offer extraordinary promise to the profession.
- Partners in Practice awards a multidisciplinary team which has

- demonstrated collaboration between a pharmacist/pharmacists and one or more other health professionals to optimize patient care and/or safety.
- Friend of Pharmacy is presented to a non-pharmacist who has contributed to the success of the profession of pharmacy.
- Wyeth Consumer Healthcare Bowl of Hygeia celebrates a pharmacist who has compiled an outstanding record of community service which, apart from his/her specific identification as a pharmacist, reflects well on the profession.



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16



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