The College of Licensed Practical Nurses of Alberta (CLPNA) supports its members in meeting the practice standards of the profession through a variety of educational resources that guide evidence-informed decision making and best practices.

The “In The Loop” Newsletter highlights a hand-picked selection of new and upcoming federal and provincial legislation and of court rulings (case law) that impact nursing practice. It is issued several times a year as necessary. Readers are advised that this newsletter does not include all legislative changes or case law judgments that may influence nursing practice.

This first issue highlights the following legal developments influencing nursing practice in Canada with implications for nurses in Alberta.

1 “Vanessa’s Law”

Canada’s existing Food and Drugs Act has ensured that drugs and medical devices are as safe as possible for healthcare consumers, prescribers and care providers before they enter the market¹. However, once products do reach the market, Health Canada’s ability to gather knowledge about them is limited, as is the ability to take action when problems arise¹.

The magnitude of this problem is significant according to a Canadian study on drug safety released in January, 2014². The research findings show that a total of 22 (4.2%) of the 528 new drugs approved by Health Canada in a 20-year period (from Jan. 1, 1990 to Dec. 31, 2009) were eventually withdrawn for safety reasons. They included drugs for cholesterol, blood pressure and weight loss, as well as anti-depressants and anti-inflammatory. They were removed from drugstore shelves primarily because of cardiovascular risks or liver toxicity. Of the 22 drugs withdrawn, 11 had received a serious safety warning, some of which were issued within 20 days of the drug being approved. The study found that the median time between drug approval and withdrawal from shelves for safety reasons was 1,271 days or almost three-and-a-half years.

As health professionals, nurses share the concerns expressed by the general public as to how well drugs are scrutinized before they are approved by Health Canada given that some are issued a safety warning 2 to 3 weeks after coming onto the market; and, why does it take over three years to remove an unsafe drug from Canadian drugstore shelves?

In response to drug safety concerns, in 2013, the Government of Canada introduced legislation known as the Protecting Canadians from Unsafe Drugs Act (Vanessa's Law): Amendments to the Food and Drugs Act (Bill C-17)³.

The new law is named after Vanessa Young, a 15-year-old Canadian, who tragically died of a heart attack while on a prescription drug that later was deemed unsafe and removed from the market³.
The law proposes changes to the existing *Food and Drugs Act* and will improve Health Canada’s ability to collect post-market safety information, and take appropriate action when a serious risk to health from food, medication, or medical device is identified\(^1\).

Under the new legislation, the federal government will have the power to\(^{1,3}\):

- Recall unsafe drugs and other therapeutic products;
- Establish stronger surveillance including mandatory adverse drug reaction reporting by healthcare institutions directly to Health Canada;
- Impose tough new penalties for unsafe products including jail time and new fines of up to $5 million per day instead of the current $5,000;
- Provide the courts with discretion to impose even stronger fines if violations were caused intentionally;
- Compel drug companies to revise labels to clearly reflect health risk information, including updates for health warnings for children; and
- Compel drug companies to do further testing on medications when they are shown to pose danger to consumers and especially with certain at-risk populations such as children.

*Vanessa’s Law* represents patient safety legislation that serves to protect Canadian families and children from unsafe medicine. Further, the new law will give care providers and hospitals better information upon which to make the best choices when prescribing medications\(^3\). The healthcare system in Canada will be better equipped to promote patient safety and reduce deaths and injuries caused by adverse drug reactions from prescription and over the counter drugs through mandatory reporting of such occurrences, so that drugs may be investigated and pulled from the shelves more expeditiously\(^2\). *Vanessa’s Law* will come into force once the supporting regulations are established.

**Implications for Nurses** One of the key strengths of the nursing profession in contributing to positive health outcomes is patient teaching. As part of standard practice, nurses provide health teaching to their patients to address knowledge needs, enable informed decision making, promote self-care management, and maintain patient safety.

Therefore, it is essential that nurses keep abreast of current findings in the research literature and of changes being made to government legislation that serves to improve the health and safety of Canadians. Through these actions, nurses can be confident in knowing the health information they impart to their patients is based on accurate and up-to-date facts. They are able to integrate new knowledge into their practice and translate research and legislative changes into information that is meaningful and understandable to the patient. Patients are then empowered to make informed decisions based on the best information possible arising from the nurse’s patient teaching.

Therefore, through a well-developed knowledge base of current research and legislation, nurses can apply both evidence and legislation into their practice. Regarding *Vanessa’s Law* and recent findings from the Canadian study on new drugs, nurses can empower patients to make informed choices about the benefits and risks of turning to the newest drugs available.

In addition to patient teaching, practising nurses may expect to see updated employer policies on adverse drug reaction reporting in response to the amended legislation when it comes into force. Nurses in education, research or administration may be engaged in the development, implementation and dissemination of enhanced policies, procedures and education materials on adverse drug reaction reporting. Further, nurses in self-employed practice will need to ensure they have polices and mechanisms in place for reporting critical drug incidents, should they occur during the course of the care encounter, as applicable.

For more information on the *Protecting Canadians from Unsafe Drugs Act (Vanessa’s Law) Amendments to the Food and Drugs Act* (Bill C-17), please visit the Health Canada information web page and questions and answers web page.
“Apology Legislation”

Most Canadian provinces and territories have enacted legislation protection for those who apologize for their actions. Some jurisdictions have enacted a statute called the Apology Act, whereas others like Alberta have amended existing legislation, e.g., the Alberta Evidence Act, to include protections for apology\(^4\). Under the amended act, an apology means an expression of sympathy or regret, whether or not the words admit or imply an admission of fault\(^5\).

**Implications for Nurses** For nurses and other healthcare professionals, apology legislation arises when a critical incident occurs\(^4\). When a patient is harmed by the provision of healthcare services, care providers and administrators must ensure patients are informed of what happened. A meaningful apology can assist patients, their families, and the healthcare professionals involved to heal after a critical event\(^6\)\(^7\).

Apology legislation encourages early resolution of the critical incident and is seen as an element of patient safety legislation\(^4\). The key provisions in the statute in Alberta to protect apology from liability include\(^5\):

- Saying sorry does not constitute admission of fault or liability;
- The apology is inadmissible in court proceeding as evidence of fault or liability;
- Professional insurance coverage for the person offering the apology is unaffected by the apology.

Nurses must be mindful that apology legislation does not disentitle a patient from launching a civil action or making a complaint to the regulatory body\(^4\).

**Best Practices for Nursing\(^4\):**

- Review the legislative requirements and your employer’s framework for critical incident investigations and disclosures;
- Nurses in self-employed practice must develop policies and procedures in conformity with apology legislation in Alberta as applicable;
- Express regret or sympathy to the patient, but refrain from accepting or assigning blame;
- Understand the possible implications prior to apologizing to a patient, if you are asked to do so.

To specifically view the section of the amended *Alberta Evidence Act* that introduces apology legislation, please visit: http://www.assembly.ab.ca/ISYS/LADDAR_files/docs/bills/bill/legislature_27/session_1/20080414_bill-030.pdf
“Case law: Nurse as an Advocate”

In nursing, advocacy is an expectation of practice established in the code of ethics and practice standards of the profession. Canadian court decisions have recognized the existence of a legal duty of nursing to obtain proper care for patients, even when this requires nurses to seek assistance outside the usual treatment team.

A few court rulings have held that there was a breach of the standard of nursing care when nurses did not immediately call for another healthcare provider to rescue a patient when it was obvious that:

- the charge nurse had not received a timely response to a call made to a physician, and
- the on-scene physician could not provide the care needed

Other cases, although not faced as of yet in a court of law by nurses, involve the legal duty to advocate in the face of scarce resources. In British Columbia, physicians defended their decision to not order a CT scan that may have diagnosed a ruptured aneurysm on the basis of budgetary constraints at the hospital. The court held that the physicians’ duty of care took precedent over any responsibility they had to the healthcare system overall.

**Implications for Nurses**

These cases indicate that nurses and other healthcare professionals can be required, in exceptional circumstances, to address problems by taking action beyond what is typically done in the normal course of treatment. This may include speaking to people outside the treatment team such as a physician other than the patient’s most responsible physician, risk managers, or regulatory bodies, all of who have a role to play in quality care. Advocating and reporting to those who have clinical, administrative or regulatory authority is not a breach of confidentiality, and in fact may be required by law.

Reaching the decision to report concern outside the treatment team requires careful deliberation. Improperly acting on a situation and calling another physician before allowing for response and treatment plan by the patient’s attending physician, as an example, can lead to unintended consequences such as disciplinary action, a complaint for breach of confidentiality or an action of defamation.

**Best Practices for Nursing**:

- Proceed through normal channels in accordance with employer policies
- Use professional language
- Report relevant facts as accurately as possible
- Explain the urgency and potential implications for the patient in the current situation
- Request action/feedback within a specific time, as warranted by the situation
- Where time permits, communicate concerns in writing in a professional manner
- Document measures taken to address the problem
- Follow-up if necessary, escalating through layers of the administration

Do not make assumptions; vent frustrations to patients, in the patient’s record or on social media; use inflammatory language, publicize concerns, or breach the duty of confidentiality. Do note, however, that proper reporting is an exception to the duty of confidentiality.
“Case Law: Mobile Devices in the Workplace”

Nurses are using smartphones and other mobile devices to communicate with colleagues and patients by phone, text message or email and even to photograph wounds or skin conditions. Mobile devices, such as smartphones, increase the risk of unauthorized disclosure of a patient’s personal health information (PHI). Mobile devices generally store and retain data on the device itself and are vulnerable to loss and theft because of their small size and portability.

**Implications for Nurses** Nurses have a professional and legal obligation to protect the privacy of patients’ PHI. Use of strong passwords and encryption can protect electronic PHI being communicated through mobile devices. Without encryption, any emails or text messages containing a patient’s PHI could be accessed if the mobile device is lost, stolen or inadvertently viewed by friends or family.

There have been several reported privacy breaches in Canada involving nurses and mobile technology in the healthcare sector:

- A nurse lost an unencrypted USB key that contained personal health information of approximately 83,500 patients. This incident resulted in an investigation by the privacy officer and a class action lawsuit.
- In another case, a nurse working in a hospital had her laptop stolen from her car. The laptop contained records of approximately 20,000 patients. It was not encrypted despite hospital policy.

Privacy breaches involving mobile devices have also occurred in Alberta:

- An unencrypted laptop was stolen from an information technology consultant that contained the names, birth dates, provincial health insurance numbers, billing codes, and diagnostic codes of 620,000 Albertans.
- Although not an electronic device per se but still worthy of note: a briefcase containing the personal information of approximately 40 people was stolen from a locked vehicle belonging to a hospital employee. The briefcase contained discharge summaries of patients including name, provincial health insurance number and diagnosis.

Use of mobile devices – personal or employer-owned – can increase risk of a privacy breach if they are not adequately equipped with encryption modalities. Privacy commissioners are requiring that health information be safeguarded at all times, specifically by ensuring that any personal health information stored on any mobile devices (e.g., laptops, memory sticks, PDAs) be strongly encrypted.

**Best Practices for Nurses**:

- Use employer-issued mobile devices, where available, instead of your own
- Ensure your device has features and software that comply with your employer’s information technology (IT) security policies
- Follow employer policies for taking photographs of patients with your mobile device for clinical purposes
- Have strong passwords and encryption capabilities on your mobile device
- Ensure WiFi or Bluetooth connections are secure and protected
- Transfer patient information from your mobile device to the patient’s record as soon as possible and permanently erase the information from your device
- Do not leave your device unattended or in any other way to allow others to access to it
- Confirm if the device has the capacity to remotely erase data stored on it, in the event that it is stolen.
Nurses in self-employed practice must be vigilant that they have appropriate practices in place to prevent a privacy breach and to protect health information records against loss, theft, unauthorized use or disclosure. Self-employed nurses must ensure that any personal health information stored on any mobile device is strongly encrypted.

RESOURCES


REFERENCES


4 Canadian Nurses Protective Society. (2013). Legal status of an apology. infoLAW, 21(3).


