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Narcotics crackdown

Act puts onus on Ōntario doctors to track patients

by Mark Cardwell

TORONTO | An Ontario physicians' group is warning that doctors are putting their licences at risk if they fail to heed new provincial prescribing rules for monitored drugs that were introduced with little fanfare this fall.

"We strongly advise doctors to read and understand the new rules and to comply with them to protect their careers," Dr. Doug Mark, president of the Coalition of Family Physicians and Specialists of Ontario, said in a statement.

He was referring to the new

rules and guidelines contained in Ontario's Narcotics Safety and Awareness Act, which came into effect on Nov. 1.

Passed last year to combat what the government said was a noticeable increase in narcotics-related deaths and a need for more effective addiction treatment services, the act permits officials to monitor and analyze data, including personal health information, in an effort to better control the prescription and dispensation of monitored drugs.

Specifically for physicians, the law carries new requirements for community-based prescribers and dispensers of any controlled substance under the federal Controlled Drugs and Substances Act.

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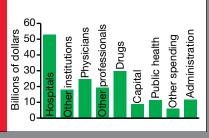
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The narcotics include opioid medications such as tramadol and tapentadol and "other controlled substances" such as marijuana derivatives, and methylphenidate and benzodiazepines.

In addition to the information they are normally required to collect and provide when prescribing opioids and other controlled substances, physicians (and dentists and pharmacists) must now ask for proof of identity from people who are being prescribed narcotics and controlled substance medications or from the people authorized to pick up those drugs on their behalf.

Prescribers and dispensers must also record the number on the identification used (either a health card or a driver's licence) and disclose it to either the health ministry or the executive officer of Ontario's public drug programs.

According to the College of Physicians and Surgeons of Ontario, the new legislation is an "important first step" in addressing the problem of illicit opioid use.

"The general intent is to consolidate information to help inform physicians and pharmacists and improve patient care," college senior communications' co-ordinator Kathryn Clarke told the *Medical Post*.

Clarke said the new rules are "broadly consistent" with what the college has recommended, in its "Avoiding Abuse, Achiev-

Narcotics "This single process only puts more onus on physicians and pharmacists while not addressing the problems in the system."

-Dr. Doug Mark

ing a Balance: Tackling the Opioid Public Health Crisis in Ontario," a report released in

She added, however, that the new measures fail to improve prescribing at the point of care—and/or help to curtail so-called "doctor shopping" for prescriptions—because the collected information about monitored drugs is not available to physicians in real time.

"Access to a patient's monitored drug history is needed before the prescription is written," said Clarke in an e-mail. "For this reason, the CPSO believes that eHealth Ontario and the provincial government should move quickly to develop and implement the planned Drug Information System, which is congruent with one of the key recommendations in our report."

Though agreeing with the aims of the new law, Dr. Mark said the government has missed the point. He said doctors are "fully aware of the responsibility we have to prescribe these powerful substances (and) that improper and illegal use can lead to devastating and even fatal outcomes in both patients and in society.

"However, this single process only puts more onus on physicians and pharmacists while not addressing the problems in the system."

The coalition, which is independent of the Ontario Medical Association (OMA), recommended the government implement a more comprehensive strategy based on success stories like Saskatchewan, where physicians are permitted to call up pharmacy records to assist in uncovering double-doctoring.

"We also strongly advise government to compensate physicians for the additional work that this legislation and future legislation entails," added Dr. Mark.

Dr. Steven Melemis, an addictions specialist in Toronto, said he agreed with the potential threat to physicians who fail to adhere to the new rules.

He said the changes would likely have little impact on the day-to-day activities of physicians who prescribe narcotics.

"There is potential to be audited by the college," said Dr. Melemis, who helped develop the substance abuse assessment guidelines the CPSO uses. "But I would think that virtually every doctor in Ontario already asks for a health card when prescribing," he noted. "I don't think (the new requirements) will be hard to follow in that regard."

In a statement to its members, the OMA said it "has expressed its concerns to the (ministry) regarding the short timelines for implementation and the challenges physicians will face implementing these changes."

OxyContin to be replaced

New OxyNEO is more tamper-resistant

by Lu-Ann Murdoch

TORONTO In early 2012, Purdue Pharma plans to introduce a new "tamper-resistant" controlled-release oxycodone tablet, called OxyNEO. The new product will be replacing OxyContin (oxycodone HCl controlled-release tablets) in an effort to curtail OxyContin tampering, misuse and abuse.

Oxycodone is rapidly released when OxyContin tablets are chewed, crushed and then inhaled, injected or swallowed. This results in a heroinlike euphoria, with potentially lethal consequences. OxyNEO tablets are physically much harder than OxyContin, making them more difficult to crush or break. When mixed with water, OxyNEO tablets form a highly viscous, gel-like matrix, which makes it difficult to extract oxycodone for injection purposes.

A September appraisal by the Canadian Agency for Drugs and Technologies in Health acknowledged that people can still take more of an opioid to experience euphoria, whether the dosage form is tamperresistant or not. It concluded that the benefits of tamperresistant products need to be determined in large, randomized controlled trials or epidemiological studies designed

to track abuse over time.

A recent newsletter from Cubic Health, a Toronto company that provides advice to drug plans, commented, "What's particularly interesting about the release of this new, 'safer' product is that Oxy-Contin is just about to come off patent, so the company is positioning itself to avoid having its product deemed interchangeable with lower cost alternatives that will be brought to market once OxyContin loses its exclusive patent."

Purdue has yet to release details of the transition from OxyContin to OxyNEO. The company is currently developing plans for an orderly introduction of OxyNEO and the withdrawal of Oxy-Contin, according to a letter Purdue sent to the College of Physicians and Surgeons of Newfoundland and Labrador. The letter advises physicians to "prescribe OxyContin only in conservative quantities to avoid a situation that could result in intentional stockpiling of supply." Purdue will issue a notice to physicians and pharmacists when further details are available on the transition program.

Bioavailability studies (under both fasting and fed conditions) show that OxyNEO is bioequivalent to OxyContin.



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See prescribing summary on page 102

Symbicort® is indicated for the treatment of asthma in natients 12 years and older with reversible obstructive airways disease.

Symbiocnt** should not be used in patients whose asthma can be managed by occasional use of a rapid onset, short duration, inhaled beta₂-agonist or in patients whose asthma can be managed by inhaled corticosteroids along with occasional use of a rapid onset, short duration, inhaled beta₂-agonist. Once asthma control has been achieved and maintained, assess the patient translations to the control of the c at regular intervals so that the dosage of Symbicort® they are receiving remains optimal, and do not use Symbicort® for patients whose asthma can be adequately controlled on low- to medium-dose inhaled corticosteroids.

In patients with asthma, there are two treatment approaches: Symbicort® Maintenance Therapy, where Symbicort® is taken as regular maintenance treatment with a separate rapid-acting bronchodilator as rescue, and Symbicort Maintenance and Reliever Therapy (SMART®), where Symbicort® is taken as regular maintenance treatment and as needed in response to symptoms

is also indicated for the maintenance treatment of moderate to severe COPD, including chronic bronchitis and emphysema in patients with persistent symptoms and a history of exacerbations, where the use of a combination product is considered appropriate. Symbicort® is not indicated for the relief of acute bronchospasm in COPD patients.

Adverse reactions that have been associated with budesonide or formoterol (1-10%) include palpitations, candida infections in the oropharynx, headache, tremor, mild irritation in the throat, coughing and hoarseness. In clinical trials the most commonly occurring side effect in COPD patients was nasopharyngitis (9%).

HPA-axis function status should be assessed periodically

WARNING

Asthma-Related Death: Long-acting beta, -agonists (LABA), such as formoterol, one of the active ingredients in Symbicort®, may increase the risk of asthma-related death. Data from a large placebo-controlled US study, which compared the safety of salmeterol, a LABA, with placebo when added to patients' usual asthma therapy showed an increase in asthma-related deaths in patients receiving salmeterol. This finding with salmeterol is considered a LABA class effect. Available data fro controlled clinical trials suggest that LABA may increase the risk of asthma-related hospitalization in pediatric and adolescent patients. Currently available data are inadequate to determine whether concurrent use of inhaled corticosteroids or other long-term asthma control drugs mitigates the increased risk of asthma-related death from LABA.

Therefore, when treating patients with asthma, Symbicort* should only be used for patients not adequately controlled on a long-term asthma control medication, such as an inhaled corticosteroid or whose disease severity clearly warrants the initiation of treatment with both an inhaled corticosteroid and LABA. Once asthma control is achieved and maintained, assess the patient at regular intervals, and do not use Symbicort® for patients whose asthma is adequately controlled on low- to medium-dose

†Comparative clinical significance has not been established.

Reference: 1. Symbicort® Turbuhaler® Product Monograph AstraZeneca Canada Inc. May 26, 2011.

