

Exempted Codeine Preparations: Prescribing for Manitoba Pharmacists

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Disclosure

- Aside from the role of a Co-Chair of the Standards of Practice committee, I do not have any other financial interest or arrangements that could be perceived as a related or apparent conflict of interest in the context of the subject of this presentation
- I am a practicing pharmacist and pharmacy manager for the Red River Co-op Grant
- I sit on the Manitoba Monitored Drugs sub-committee



Acknowledgements

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- Other colleagues and co-workers



Learning Objectives

- Upon successful completion of this module, the pharmacist will be able to:
- Summarize prevention tactics for diversion of exempted codeine preparations in primary care
- Describe and apply the applicable sections of legislation, standards of practice, and practice directions related to prescribing exempted codeine preparations
- Complete the appropriate prescribing documentation for self-limiting conditions prescribing
- Implement the process of prescribing for exempted codeine preparations into your practice



Background

- Not a new thought...has been on the College's 'radar' for a while
- Needed some regulatory and practice directions in place first
- Concern from our profession
- Concern from other professions
- Manitoba Monitored Drugs Committee
 - Addiction specialists see usage with other narcotics and acetaminophen preps
- Not a direct response to negative publicity



WHY?

- Questionable effectiveness of the products
 - Minimum analgesic dose of codeine ~15mg
- Potential for abuse
 - Being used in excess, inappropriately and in dangerous combinations
- **PATIENT SAFETY**
 - Dangerous drug combinations
 - Overdose of acetaminophen



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WHAT?

36 (1) Subject to subsection (2), a pharmacist may, without a prescription, sell or provide a preparation containing not more than 8 mg or its equivalent of codeine phosphate per tablet or per unit in other solid form or not more than 20 mg or its equivalent of codeine phosphate per 30 mL in a liquid preparation if

(a) the preparation contains

- (i) two additional medicinal ingredients other than a narcotic in a quantity of not less than the regular minimum single dose for one such ingredient or one-half the regular minimum single dose for each such ingredient, or
- (ii) three additional medicinal ingredients other than a narcotic in a quantity of not less than the regular minimum single dose for one such ingredient or one-third the regular minimum single dose for each such ingredient

- Eg. Tylenol #1, 222's, Calmylin, Robax-8, Robaxasal-8



WHEN?

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What Are Other Provinces Doing?

- British Columbia – No Rx, behind the counter, no network
- Alberta – No Rx, but enter into AB Netcare
- Saskatchewan – No Rx, but entry into network
- Manitoba – Moving to Rx only, mandatory network entry
- Ontario – No Rx, behind the counter
- Quebec – No Rx, but entered into system
- Newfoundland – No Rx, but entered into system
- NS – No Rx, is ‘form’ & encouraged to enter to DIS for tracking
- PEI - No Rx, entered into DIS for tracking
- NB – No Rx, behind the counter, no network
- Yukon – No Rx, behind the counter, no network
- NWT – No Rx, logged internally, no network
- ⁹ Nunavut - ?



Can We Do This?

- Yes!
- Sections from federal & provincial legislation
 - ✓ *Controlled Drugs & Substances Act* and Regulation 36
 - ✓ *Pharmaceutical Act* of MB and Regulations 56(1)6, 118(1), 119 & 121(1)
- Notice of development & implementation of change was forwarded to Health Canada's Office of Controlled Substances, MB Health & provincial Minister of Health
- No opposition
- Support from other professions
- Provincial law can be more rigid than federal



Other Standards of Practice & Practice Directions that will interplay

- Patient profiles
- Prescribing
- Prescribing and dispensing drugs
- Ensuring patient safety
- Referring a patient
- Patient Counselling
- Records and information
- ExCP



Exempted Codeine Preparations Practice Direction

<http://mpa.in1touch.org/uploaded/web/Legislation/Exempted%20Codeine%20Products%20Council%20Approved%20%28002%29.pdf>



By Prescription Only...

- No pharmacist shall sell (distribute) or provide an Exempted Codeine Preparation (ExCP), including in hospital practice, unless it is pursuant to a **prescription**.
 - Prescription can be from a pharmacist, Nurse practitioner with CDSA prescribing authority, physician or dentist
 - All legal/jurisprudence requirements for Rx must be met
 - Practice Direction states mandatory DPIN entry
- NOT meant to be a barrier to care
 - ✓ Harm reduction
 - ✓ Augmentation of pharmacist delivered care
- Will need prescribing record consistent with the PD:
Prescribing & subject to record keeping regulations

Appropriateness & Assessment

- The pharmacist must determine the appropriateness of a patient's request to self-medicate for a recognized medical or dental reason, and then make the decision whether to prescribe an Exempted Codeine Preparation
- A licensed pharmacist shall only prescribe an Exempted Codeine Preparation for a patient they have **seen and assessed in person**
 - Cannot be a family member, neighbor, by phone, other technological means
 - Not necessary for the filling of a 'part fill'
 - Another person can pick-up the medication on behalf of someone already assessed if the patient has given permission
 - Required each and every time you are writing a Rx regardless of had before



Assessment Continued...

- The pharmacist's assessment of the patient shall include, but is not limited to the following:

- ✓ Signs and symptoms of the condition to be treated
- ✓ Length and severity of present symptoms
- ✓ Laboratory or other test results (if applicable)
- ✓ Medical History
- ✓ Allergies and /or sensitivities
- ✓ Current medications (**must include review of patient's DPIN**)
 - ? Other ExCP preps
 - Other acetaminophen containing preps?
 - Other conflicting or questionable medication therapy ?
 - Drug interactions
- ✓ Extent and results of previous treatment for the current condition
- ✓ Pregnancy and lactation status (if applicable)

Many of these are screening questions we already ask, we are formalizing the process



Risk vs. Benefit & Consider Alternatives

- Only prescribe an ExCP when in the patient's best interest, having considered risks and benefits to the patient and other relevant factors
- Issue a prescription only after advising the patient with therapeutic alternatives and providing adequate information so the patient can make an informed decision.
- Must comply with all rules, specifically the practice direction Prescribing and Dispensing



Patient Record

- For those patients not on file you will have to create a patient record
 - ‘Patient profile must be prepared and kept current for each patient for whom a Schedule I drug is dispensed and includes any other drug prescribed by the licensed pharmacist’ (Practice Direction: Patient Profiles)
- Profile must include:
 - Patient’s full name
 - Patient’s home address
 - Date of Birth
 - Telephone #, if available
 - PHIN if MB resident
 - Gender
 - Allergies, sensitivities, contraindications
 - Any other relevant medical history as required

Prescribing

- Issue a prescription for an ExCP must reduce the Rx to writing in a clear, concise format that includes all required information. The Rx must include the following legal requirements:
 - Name and address of the patient receiving the Rx
 - Name and address of the prescriber (i.e. pharmacist)
 - Name of the drug
 - Strength, quantity & dosage from of the drug
 - Manufacturer of the dispensed product
 - Part fill/interval (if applicable)
 - Directions for use
 - Signature of the prescribing pharmacist
 - Date Rx was written
 - Treatment goals, diagnosis or clinical indication

****Consider a Template****



Mandatory DPIN Entry

- All ExCP prescriptions must be entered into DPIN
 - For the safety of the patient
 - Patient may refuse to provide PHIN but per practice direction it is mandatory
 - Engage patient as to why and the rationale
- For out of province patients
 - Use the 'pseudo-PHIN' 8888888884
 - Send as 'Drug Utilization' only
- Should you refuse to prescribe and/or fill you may document in DPIN. Matter of professional judgement



Prescribed Quantity

- A Rx for ExCP written by a pharmacist should not exceed a quantity of 100 tablets or 250mL, depending on the dosage form, to be dispensed initially , if part fills are issued, the total quantity of the Rx should not exceed 200 tablets or 500mL, depending on the dosage form.
 - Quantities greater should only be prescribed under extenuating circumstances
 - Document professional judgement & rationale for decision
- Consistent with other provinces



Exempted Codeine Prescription by a Pharmacist

Patient's Name:

Date of Birth:

Address:

Gender:

Product prescribed:

Manufacturer:

Dosage form:

Total Quantity:

Strength:

Sig:

Interval for 'refill': N/A or _____

Name of Pharmacist:

Date:

Assessment:

Allergies:

Medical History:

Current Medications (Must include a review of patient's DPIN profile):

Consuming any other acetaminophen products or analgesics? Yes No

(APAP daily dose should not exceed 4000mg/day. FDA suggests <3200mg/day)

Other CNS active medications: Yes No

Alcohol Consumption: Yes No

Signs/Symptoms & Length/Severity:

Pain Intensity: +1 +2 +3 +4 +5 +6 +7 +8 +9 +10

Pain Relief Goals Achieved: Yes No Partially _____

Functional Status: Improved No Change Worsened _____

Adverse Effects: Nausea Constipation Drowsiness Vomiting Other

Previous Treatment(s):

Relevant Laboratory Data/Test results (if available):

Pregnant/Lactating: Yes No

Treatment Goals, diagnosis or clinical indication of prescription:

Rationale for the prescribing decision:

Follow-up Plan:

Other health Professionals notified: Yes No

Sections 118 – 121 of the Pharmaceutical regulations and the Practice Directions 'Prescribing' and 'Prescribing and Dispensing' enable pharmacists to prescribe for NAPRA schedule II and III drugs and devices approved by Health Canada. Pharmacists can additionally prescribe for minor ailments should they have certification to do so. This is to notify you, the patient's physician, that we have prescribed the above medication.

Patient Signature: _____

Date: _____



Prescribing...Key Points

- All components of the Standards of Practice #4: Prescribing and Dispensing & Practice Direction Prescribing need to be followed in addition to the ExCP practice direction
- You must provide enough information to the patient so they are able to make a decision about the prescribing & dispensing process & obtain informed consent to dispense the drug
- You must advise the patient they may fill the Rx elsewhere. The patient has the right to refuse to have the Rx filled by you or another licensed pharmacist at your site
 - You cannot refuse to prescribe for this reason
 - Potential safety issue: the second check of a prescriber's prescription by a pharmacist is absent when one pharmacist does both activities



Standard of Practice #1: Patient Counselling

- ‘Each time a drug is dispensed pursuant to a prescription, a member must provide the patient with sufficient information to enable the patient to safely and effectively manage his or her drug therapy’*
- The dispensing of ExCP must comply with the practice direction of patient counselling
- This is about patient safety...counselling is a critical part
 - Our professional duty
 - Safety & Effectiveness
 - Public scrutiny



Standard of Practice #1: Patient Counselling

- Ensure to review
 - ✓ Anticipated effectiveness
 - ✓ Proper usage
 - ✓ How to assess efficacy
 - ✓ Any potential drug-drug, drug-disease interactions
 - ✓ Possible adverse effects & how to manage them
 - ✓ Precautions
 - ✓ See PD – Patient Counselling
- Consider when the counselling should be done
 - Prior to or after dispensing?
- Documentation:
 - ✓ Patient counselling must be documented & the info contained in the recorded would be the judgement of the pharmacist
 - ✓ Refusal should be documented

Notification of other Health Care Professionals

- Not a requirement for prescribing for self-limiting conditions & for Exempted Codeine Preparations
- May be appropriate and can be determined on a case by case basis

Difficult Scenarios

- Aggression/refusal to participate in process
- Patient wants larger quantities than permitted
- Assessment questions or DPIN will reveal issues
 - ☒ Therapy may be inappropriate/unwarranted
 - ☒ Duplicate drug other pharmacy 'MY'
 - ☒ Duplicate therapy other pharmacy 'MZ'
- Suspected abuse/addiction
- Suspected diversion
- Suspect Rx is really not for themselves
- Refusal of payment
- Others

Documentation

- The licensed pharmacist must document & keep record of the consent to dispense including the name of the person consenting and the date the consent was obtained (PD Prescribing and Dispensing)
- ExCP Rx's are narcotics
 - Must keep separate Rx file
- 'Prescribing records are different from the prescription/dispensing record' *
 - Should be kept separately from regular Rx records

*College of Pharmacists of Manitoba Friday Five June 20-14



Documentation and Records

- All documentation shall be in a readily retrievable manner electronically or in written form.
- **79(1)** The records required by this Part may be recorded and retained either electronically or in written form, except that
 - (a) if a record requires a signature, it must be an original or electronic signature; and
 - (b) if a record requires initials, the initials must be original or electronic initials.
- **79(2)** A member or owner must retain the [following records] for at least five years.
- Review the Practice Direction for more information

See Practice Direction Documents & Records & *Pharmaceutical Regulations* Part 9



Referring A Patient: Standard #2

- A member must refer the patient to another appropriately qualified regulated health professional when
 - a) the care or treatment required by the patient is beyond the scope of the member's professional practice or competence;
 - b) the patient's condition cannot be effectively treated within the practice of pharmacy;
or
- Referral if the condition or symptom(s) are deemed to be serious in nature &/or the ExCP will likely inadequately treat
- Referral should also be done where continued use of ExCP is not in the best interest of the patient.
- Abuse or addiction issues



You Can Refuse

- You have the responsibility and duty to refuse to provide ExCP where there are reasonable grounds for believing the drug may be used by a person for a purpose other than recognized medical or dental reasons, or may result in harm to the patient
 - Inappropriate therapy
 - Drug interactions
 - Acetaminophen over dosage
 - Recreational use
 - Not for themselves
- Can follow PD for M3P Information Entered into DPIN section 2.3 for refusal to fill (use professional judgement)
- Can choose not to stock products
- Can refuse to prescribe, dispense or both

Authorization ≠ Obligation



Standard #3 Collaborative Care

- For difficult issues remember you are not alone...
- A member must work collaboratively with other health care professionals and others who provide care to the patient, as circumstances require, in order to provide integrated care and avoid duplication of services.
- When a member and one or more other persons are providing care to a patient, the member must
 - a) treat the other provider with respect;
 - b) recognize the skills, knowledge, competencies and roles of the other provider, and communicate effectively and appropriately with them; and
 - c) explain to the patient the member's role and responsibility.
- **Practice Direction will be created in the near future**



Integration into Practice: Communication is Key

1. To Patients:

- Have appropriate signage up
- See College website: <http://mpa.in1touch.org/site/legislation?nav=practice>
- Engage and educate patients to the change

2. To Staff:

- Make sure all staff are aware of change and can speak to it
- Consider staff note with clear directives as to expectations and how pharmacy will be handling ExCPs

3. To appropriate non-pharmacy personnel

- Eg. General store managers, shop owners



Integration into Practice: Workflow

- We all know this will be more time consuming
- Automate/standardize what you can in advance
 - Consider ExCP Rx template
- Direct patient to a private counseling area
 - ✓ Discuss reason for use - ? Legitimate
 - ✓ Perform your assessment, collect all relevant data
 - ✓ Consider Risks vs Benefits, therapeutic alternatives
 - ✓ Create patient profile (if you don't already have)
 - ✓ Review DPIN
 - ✓ Process and fill Rx if appropriate or discuss with patient when not
 - ✓ Counsel patient

Dealing With the Angry Patient



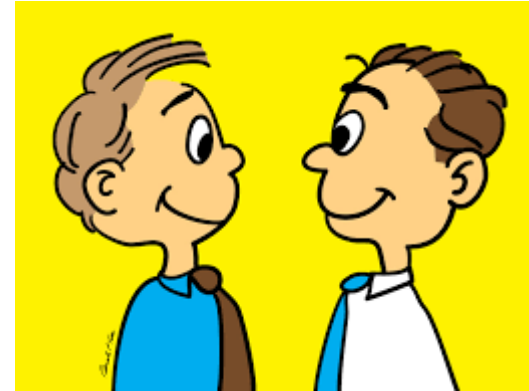
- There will be angry patients
- People don't like change
- May be viewed as more 'restrictive' or 'discriminatory' or 'punitive' to those using ExCPs properly
- ? Are we doing this in response to negative publicity
- Is it simply a means of charging more money?

Dealing With the Angry Patient...DON'Ts

- Have confrontation in front of others
- Belittle or discredit their feelings
- Become angry or aggressive
- Don't immediately interrupt
- Do not invade the persons personal space
- Try not to use 'defensive' types of responses
- Do not give in to demands that can't be met
- Don't take it personally
- Don't let it effect you professionally or impact the patients care



Dealing With the Angry Patient...DO's



*'People don't care how much you know...
until they know how much you care'*

Teddy Roosevelt

- Take the to a private area
- Listen to them & acknowledge their frustration
- Let them vent
- Maintain calm, professional demeanor and tone when speaking
- Empathize
- When appropriate attempt to explain rationale
- Point out this about safety and not meant for inconvenience
- Consider a cooling off period if appropriate



Diversion Prevention

1. Prior to arriving at the store:

- Check stock arrived vs. invoice

2. While at the store:

- Consider moving stock to same location as other narcotics (Eg. Tylenol #3, etc)
- Have inventory accurately entered into computer inventory
- Back count after filling Rx and reconcile with computer
- Regularly review order history
- Regularly perform physical inventory counts and reconcile with computer
- Regularly review narcotic or drug movement printouts

3. Prior/After being dispensed:

- ? Forgeries
- Look for erratic Rx filling
- Early releases/repeated requests for large quantities
- Other meds of abuse?
- Suspect Rxs not being fill for themselves ?

Remuneration

- The College recognizes the increase work involved but it is not their role to comment on or regulate fees
- Points to consider:
 - ExCPs are not a covered benefit
 - Nothing prevents pharmacists from charging a fee for service
 - In order to dispense an ExCP to a patient we must do an assessment in addition to our regular dispensing activities
 - Consider your usual dispensing fee
 - Consider monetary value of the assessment
- Be fair and professional to your patients



Key Points

- ✓ ExCPs only to be prescribed for recognized medical or dental reasons
- ✓ **ExCPs require a Rx**: pharmacist, physician, dentist or NP with CDSA prescribing authority
- ✓ For pharmacists to prescribe the patient must **be assessed in person**
- ✓ DPIN shall be reviewed to ensure appropriateness of therapy
- ✓ All ExCPs **must be entered into DPIN**
- ✓ All other pertinent Standards of Practice and Practice directions must be adhered to (Eg. Prescribing and Dispensing and Pt. Counselling)
- ✓ **This is about augmenting patient safety**
- ✓ **Authorization ≠ Obligation**



Some Other References

- <http://nationalpaincentre.mcmaster.ca/documents/practicetoolkit.pdf>. Accessed Jan 7th 2016.
- <http://mpa.in1touch.org/uploaded/web/New%20Pharmaceutical%20Act/July%203,%202013%20Pharmaceutical%20Regulations.pdf>. Accessed Jan 9th 2016.
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