



POLICY NAME:	Practice Directive: Submission of Exempted Codeine Products provided to patients to the Drug information System (DIS) / Prescription Monitoring Program (PMP)
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PRACTICE DIRECTIVE: SUBMISSION OF EXEMPTED CODEINE PRODUCTS PROVIDED TO PATIENTS TO THE DRUG INFORMATION SYSTEM (DIS) / PRESCRIPTION MONITORING PROGRAM (PMP) *

Key Message: Pharmacy professionals must submit records to DIS/PMP of all exempted codeine products provided to patients.

Background: Codeine, in preparations exempted from the Regulations to the Controlled Drugs and Substances Act, Section 36(1) are currently listed in Schedule II of the National Association of Pharmacy Regulatory Authorities (NAPRA). These products have very little evidence to recommend their use beyond 3 to 7 days and indeed, pose health risks to consumers¹. Concerns include:

- Use beyond the acute phase of pain (3-7 days) may result in delay in seeking treatment of underlying causes of pain
- Potential addiction
- Off-label use to mitigate withdrawal from potent opioids may result in overdosing of other medicinal ingredients (particularly acetylsalicylic acid and acetaminophen)
- Variability in efficacy due to genomic mechanisms² can result in suboptimal conversion of codeine to its active form or conversely, result in high conversion rates and harmful effects^{3,4}
- Pediatric patients are at especially high risk of codeine overdose^{3,4} and the preparations should not be used in children under 12 years old for any indication^{5,6}
- Use as a cough suppressant in acute respiratory infections is not well-supported⁷

Purpose: The intent of mandatory submission of records of provision of exempted codeine products to the DIS is to facilitate a complete record of medication use within the electronic health record (EHR) upon which to base patient treatment plans. Exempted codeine product provision records will appear in the patient's EHR Medication Summary Profile and PMP Profile and will be accessible for all EHR users (e.g. physicians, dentists, nurse practitioners, etc.). This Practice Directive informs pharmacy professionals that the provision of Exempted Codeine Products must be submitted to the DIS (administered by eHealthNB) in accordance with the monitored drug list of the PMP[†].

*The New Brunswick College of Pharmacists (NBCP) and the New Brunswick Prescription Monitoring Program/Drug Information System (PMP/DIS) collaborated in producing this practice directive.

+Exempted codeine products are included on the monitored drug list as per the drug classes identified under the [regulations to the Prescription Monitoring Act](#).

Submission Process:

Information in the 'Prescriber' Field:

The name of the pharmacist providing the exempted codeine product should be entered in the prescriber field. Given the purpose (a complete medication record) of submitting this information, the pharmacist is not considered in this situation to have officially prescribed the exempted codeine product as per Regulation 21.8(2) of the *Pharmacy Act*.

Note: The terms 'prescribed', 'provided', 'sold', and 'recommended' all have different meanings. Importantly, in the New Brunswick Pharmacy Regulations Section XXI, 'prescribe' denotes taking a high level of responsibility for patient assessment, plan of care and follow-up as well as communications with other members of the patient care team. Pharmacists should employ 'prescribing' activities with all patients for whom use is deemed appropriate however, given the unique scheduling (Schedule 2 and a narcotic) [‡] and current pattern of usage of these products, pharmacists are considered to 'provide' or 'recommend' these medicines. When pharmacists 'provide' exempted codeine products, routine clinical documentation should ensue within the pharmacy's patient profile in addition to submitting the transaction record to the DIS.

Information in the 'Patient' Field:

Pharmacies should submit information to the DIS in a similar manner as a prescribed drug for the patient for whom the exempted codeine product is intended. In cases where the presenting individual indicates the intended patient is not physically present, the pharmacist will have to use professional judgement and determine the best course of action. Options could include:

1. The pharmacist can request the patient attend the pharmacy to confirm the documentation is attributed to the correct patient profile. This is the preferred action.
2. The pharmacist might be otherwise satisfied that the intended patient is indeed going to receive the medication and attribute the medicine to that profile. This would be a potential option where the pharmacist has an established relationship with the patient and their agent.
3. The presenting individual may have the medication recorded to their own profile. This would be a less-ideal scenario but one that may be appropriate in some circumstances.

In all cases where exempted codeine is provided, patient identification must be verified so the information is linked to the correct patient record within the EHR. Please note that if a practitioner has actually prescribed the preparation, it must continue to be recorded for the individual for whom the medication is prescribed. The patient (or recipient) should be informed that the exempted codeine product will appear in their EHR Medication and PMP Summaries.

Information in Other Fields:

The submission of exempted codeine products to the DIS should follow the regular requirements of the pharmacy software system for generating a record of dispensing within the DIS.

Future Developments: Health Canada is currently examining the scheduling of exempted codeine products. Given the lack of therapeutic evidence and the concerning safety profile of these

[‡] Although exempted codeine products are listed on schedule II of NAPRA's National Drug Schedules, the Narcotic Control Regulations 31(1) limits prescribing to 'practitioners'. The designation, according to Health Canada of 'practitioner' does not (at time of writing) extend to pharmacists. <http://laws-lois.justice.gc.ca/eng/regulations/SOR-2012-230/page-1.html> and http://laws-lois.justice.gc.ca/PDF/C.R.C.,_c._1041.pdf

medicines, the College and the PMP have determined to move forward with requiring submission of exempted codeine information while awaiting Health Canada's decision and action.

Monitoring: The College, through the PMP, will monitor outcomes related to this practice directive to evaluate achievement of intended impact on the establishment of complete patient profiles. While the rate of usage of exempted codeine products is of interest, it is not the primary reason for mandatory submission to the DIS/PMP. Any policy change can result in unintended consequences. This practice directive has a potential to cause opioid-addicted individuals who may use these preparations to mitigate withdrawal from opioids to seek out illicit sources of opioids. This is not the intent of this practice directive. The College and the PMP are interested in any evidence of this or other unforeseen impacts related to this practice directive.

Questions and Concerns: May be directed to: NBCP's Professional Practice Committee: info@nbpharmacists.ca or, for assistance with the PMP to: NBDIS@gnb.ca.

References:

1. Canadian Pharmacists Association. Choosing Wisely: Opioid Wisely: Pharmacist: Recommendation #2. Accessed April 2018. Available at: <https://choosingwiselycanada.org/campaign/opioid-wisely/>.
2. Goldman RD. Child Health Update: Codeine for acute cough in children. 2010;56:1293-1294. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3001921/pdf/0561293.pdf>.
3. Canada H. Health Canada's review recommends codeine only be used in patients aged 12 and over. 2013. <http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2013/33915a-eng.php>.
4. Canada H. Summary Safety Review - CODEINE PRESCRIPTION PRODUCTS Indicated for Cough - Further Assessing the Risk of Serious Breathing Problems in Children and Adolescents. 2015. <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/safety-reviews/summary-safety-review-codeine-prescription-products-indicated-cough-further-assessing-risk-serious-breathing-problems-children-adolescents-1.html> Accessed March 9, 2018.
5. Canada H. New safety measures for prescription codeine and hydrocodone to further restrict use in children and adolescents. 2016. <http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2016/59584a-eng.php> Accessed March 9, 2018.
6. Canada H. Summary Safety Review - Codeine-containing products - Further Assessing the Risk of Serious Breathing Problems in Children and Adolescents. 2016. <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/safety-reviews/summary-safety-review-codeine-prescription-products-cough-further-assessing-risk-serious.html>. Accessed March 9, 2018.
7. Bolser DC DP. Codeine and cough: an ineffective gold standard. *Curr Opin Allergy Clin Immunol*. 2010;7(1):32-36.

MONITORING FREQUENCY:

MONITORING METHOD:

REVIEW FREQUENCY:

RESPONSIBILITY: