

CADTH ENVIRONMENTAL SCAN

Prescribing and Dispensing Policies to Address Harms Associated With Prescription Drug Abuse

Product Line: Environmental Scan
Version: 1.0
Issue Number: 52
Publication Date: October 2015
Report Length: 103 Pages

Table of Contents

| | |
|--|-----------|
| SECTION 1: Mandatory Education for Prescribing and Dispensing Opioids, Stimulants, and Benzodiazepines | 11 |
| 1.1 Mandatory Education Requirements for Prescribing and Dispensing Opioids, Stimulants, and Benzodiazepines | 11 |
| 1.1.1 Mandatory Education on Prescribing Opioids, Stimulants, and Benzodiazepines for Practising Health Care Professionals | 11 |
| 1.1.2 Extension of Prescribing Authority | 14 |
| 1.2 Mandatory Education Requirements for Prescribing and Dispensing Opioid Substitution Therapy | 15 |
| 1.3 Mandatory Education Requirements for Prescribers and Dispensers in Cases of Inappropriate Prescribing and Dispensing | 17 |
| 1.4 Mandatory Education Requirements for Prescribers and Dispensers to Practice at Specialized Clinics and Pharmacy Settings (e.g., Pain Management Clinics) | 17 |
| 1.5 Clinical Practice Guidelines | 18 |
| SECTION 2: Formulary and Reimbursement Strategies, Policies, and Measures | 21 |
| 2.1 Scheduling of Opioids, Stimulants, and Benzodiazepines | 21 |
| 2.2 Formulary Listing and Reimbursement Conditions and Requirements for Opioids, Stimulants, and Benzodiazepines | 23 |
| 2.3 Payer Incentives for Pharmacist Interventions | 26 |
| 2.4 Designated Prescriber or Pharmacy Programs | 27 |
| 2.5 Reimbursement Conditions for Tamper-Resistant Products | 27 |
| 2.6 Delisting of Opioids, Benzodiazepines, or Stimulants (Individual Drug or Drug Class) From Formularies | 28 |
| 2.7 Access and Reimbursement Conditions for Naloxone | 28 |
| SECTION 3: Prescription-Writing and Prescription-Dispensing Strategies, Policies, and Measures | 32 |
| 3.1 Prescription Requirements | 32 |
| 3.1.1 Refills | 32 |
| 3.1.2 Personal Identification | 32 |
| 3.1.3 Prescription Validity Periods | 33 |
| 3.2 Tamper-Resistant Prescription Drug Pad Programs | 33 |
| SECTION 4: Prescription Drug Monitoring Programs | 36 |
| 4.1 Prescription Drug Monitoring Programs Models and Features | 36 |
| 4.2 Prescription Drug Monitoring Program Coverage, Requirements for Prescribers and Dispensers, and Access | 43 |
| 4.3 Assessments of Prescription Drug Monitoring Program Effectiveness | 43 |
| SECTION 5: Other Regulatory and Oversight Activities | 46 |
| 5.1 Measures to Incentivize the Innovation or Approval of Tamper-Resistant Opioids, Benzodiazepines, and Stimulants | 46 |
| REFERENCES | 49 |
| APPENDIX 1: Survey Findings | 58 |
| APPENDIX 2: Survey Findings: Criteria and Approval Processes for Opioids, Stimulants, Benzodiazepines, and Opioid Substitution Therapies | 88 |
| APPENDIX 3: Survey Questionnaire – 2015 CADTH Survey of Public Drug Plans | 96 |

List of Tables

| | |
|---|----|
| Table 1: New England State Medicaid Agency Coverage Policies for Medications Used in Opioid Dependence Treatment | 24 |
| Table 2: New England Private Coverage Policies for Medications Used in Opioid Dependence Treatment | 25 |
| Table 3: Features of Prescription Drug Monitoring Program in Canadian Provinces and Territories – Program, Implementation Date, and Monitored Drugs | 37 |
| Table 4: Features of Prescription Drug Monitoring Program in Canadian Provinces and Territories – Questionable Activity Criteria and Interventions | 38 |
| Table 5: Access to Prescription Drug Monitoring Program (PDMP) Data Across Four Provincial PDMP Systems | 42 |
| Table 6: Opioid Substitution Therapies and Naloxone Included on Public Drug Plan Formularies | 58 |
| Table 7: Established Reimbursement Criteria | 59 |
| Table 8: Reimbursed with Limits | 60 |
| Table 9: Supply Limits or Annual Quantity Limits | 61 |
| Table 10: Dosage Restrictions | 63 |
| Table 11: Listing and Reimbursement Restrictions for High-Dose Opioids | 66 |
| Table 12: Filling and Refill Restrictions as Determined by the Drug Benefit Plan | 67 |
| Table 13: Specific Refill Restrictions as Determined by the Drug Benefit Plan | 68 |
| Table 14: Delisting of Opioids, Stimulants, or Benzodiazepines | 70 |
| Table 15: Incentives for Pharmacists | 71 |
| Table 16: Single-Pharmacy Designation | 72 |
| Table 17: Single Prescriber Designation | 73 |
| Table 18: Details of Single Prescriber or Pharmacy Designation Program | 74 |
| Table 19: Reimbursement of Tamper-Resistant Products | 76 |
| Table 20: Listing and Reimbursement Actions for OxyNEO by Public Drug Plans in Canada | 77 |
| Table 21: Requirement to Show Identification to Prescriber or Pharmacist, and/or Requirement for Pharmacist to Keep a Record of Patient’s Identification When Dispensing | 78 |
| Table 23: Paper-Based (Tamper-Resistant Prescription Drug Pad Program) or Electronic (Prescription Drug Monitoring Program) Program to Monitor the Use of Opioids, Stimulants, and/or Benzodiazepines | 81 |
| Table 24: System in Place for Reporting Forged or Illegal Prescriptions | 86 |
| Table 25: Reimbursement Criteria for Opioids, Stimulants, Benzodiazepines, and Opioid Substitution Therapies | 88 |
| Table 26: Approval Process (Manual Prior Approval, Use of Prescription Codes or Electronic) for Drugs Listed With Criteria | 95 |

List of Figures

| | |
|---|----|
| Figure 1: Interstate Sharing of Prescription Monitoring Program Data Pursuant to Statute, Regulation, and/or Statutory Interpretation | 41 |
| Figure 2: Prevalence of Potentially Inappropriate Prescriptions in Ontario, by Monitored Drug, Before and After Introduction of Safety Legislation and a Monitoring Program, January 2007 to May 2013 | 45 |
| Figure 3: Prevalence of Opioid, Benzodiazepine, and Stimulant Prescriptions Triggering Drug Utilization Review Warnings of Both Double-Doctoring and Polypharmacy in Ontario Before and After Introduction of Safety Legislation and a Monitoring Program, January 2007 to May 2013 | 45 |

Abbreviations

| | |
|------------------|--|
| AC | Accreditation Canada |
| ACMD | Advisory Council on the Misuse of Drugs (United Kingdom) |
| ACP | Alberta College of Pharmacists |
| ACT | Australian Capital Territory |
| ANCD | Australian National Council on Drugs |
| CADTH | Canadian Agency for Drugs and Technologies in Health |
| CARF | Commission on Accreditation of Rehabilitation Facilities |
| CD | controlled drugs |
| CDAO | controlled drugs accountable officers (United Kingdom) |
| CDC | Centers for Disease Control and Prevention (United States) |
| CE | continuing education |
| CED | Committee to Evaluate Drugs (Ontario) |
| CPBC | College of Pharmacists of British Columbia |
| CPG | clinical practice guideline |
| CPSA | College of Physicians and Surgeons of Alberta |
| CPSO | College of Physicians and Surgeons of Ontario |
| DATA 2000 | Drug Addiction Treatment Act of 2000 (United States) |
| DEA | Drug Enforcement Administration (United States) |
| EDS | exception drug status |
| ER | extended-release |
| ERRCD | Electronic Recording and Reporting of Controlled Drugs (Australia) |
| FDA | Food and Drug Administration (United States) |
| HHS | Department of Health and Human Services (United States) |
| LA | long-acting |
| MCPP | Multiple Copy Prescription Program |
| MH | Ministry of Health |
| NABP | National Association of Boards of Pharmacy (United States) |
| NAMSDL | National Alliance for Model State Drug Laws (United States) |
| NASPER | <i>National All Schedules Prescription Electronic Reporting Act</i> |
| NHS | National Health Service (United Kingdom) |
| NHSBSA | National Health Service Business Services Authority (United Kingdom) |
| NHSPS | National Health Service Prescription Services (United Kingdom) |

| | |
|---------------|--|
| NICE | National Institute for Health and Care Excellence (United Kingdom) |
| NIHB | Non-insured Health Benefits Program (Health Canada) |
| NOUGG | National Opioid Use Guideline Group |
| NSPMP | Nova Scotia Prescription Monitoring Program |
| NSW | New South Wales (Australia) |
| OPQ | Ordre des pharmaciens du Québec |
| OTP | outpatient methadone maintenance treatment programs |
| PDMP | prescription drug–monitoring program |
| PDP | provincial drug program |
| PMP | prescription monitoring program |
| PRR | Patient Review and Restriction |
| QAA | quality assessment and assurance |
| REMS | Risk Evaluation and Mitigation Strategies |
| SAMHSA | <i>Substance Abuse and Mental Health Services Administration (United States)</i> |
| TRI | Treatment Research Institute (United States) |

Executive Summary

Background

Prescription opioids, benzodiazepines, and stimulants are primarily used in the management of pain, insomnia and anxiety, and attention-deficit/hyperactivity disorder, respectively. Certain opioids are also used to treat opioid dependence (e.g., methadone). While these drugs are important therapeutic options in clinical practice, they also have the potential for misuse, abuse, and diversion for non-medical use due to their psychoactive properties. Over the past decade, the harms associated with prescription drug abuse are increasingly becoming a public health and safety concern in Canada. There has been a significant increase in the number of people seeking treatment for addiction to prescription drugs; an increase in the number of youth who report having used prescription opioids for non-medical use; and an increase in the number of overdose deaths associated with prescription opioids.¹

Purpose

This Environmental Scan explores existing policies and strategies that aim to reduce harms from prescription opioids, stimulants, and benzodiazepines in the following five areas:

- Additional education for practising health care professionals
- Formulary and reimbursement policies
- Prescription writing and dispensing requirements
- Prescription drug–monitoring programs (PDMPs)
- Regulatory measures and oversight activities.

The Scan provides an overview of such policies in Canada and four reference countries (the United States, the United Kingdom, Australia, and New Zealand). It does not provide a comprehensive review or appraise the effectiveness of these policies, nor does it recommend one policy option over another. The Environmental Scan serves to illustrate the range of possible policy options and potentially inform future direction to achieve safe and effective use of opioids, stimulants, and benzodiazepines.

Sources of information

This Environmental Scan synthesizes information gathered from four different sources:

1. Limited literature search and targeted Web-based research
2. Information gathered from Health Canada’s consultations with regulatory colleges of physician and surgeons, dentists, and nurses from various Canadian provinces
3. Information reported in CADTH’s Environmental Scan *Narcotics, Benzodiazepines, Stimulants, and Gabapentin: Policies, Initiatives, and Practices Across Canada (2014)*²
4. CADTH survey of federal, provincial, and territorial public drug benefit plans conducted in May 2015 (hereafter, 2015 CADTH survey of public drug plans).

Of note: most of the information identified through these sources focused on opioids compared with benzodiazepines and stimulants.

Education for Health Care Professionals

Generally, additional education for practising health care professionals in Canada for the appropriate prescribing of opioids, stimulants, and benzodiazepines is not part of standards of practice and related clinical practice guidelines. Regulatory bodies may include additional education requirements in quality assurance processes, opioid substitution therapy regulation, misconduct procedures, or for those new to prescribing opioids (e.g., nurse practitioners).

In the US, pain facilities include mandatory education requirements for prescribing opioids.

In May 2015, new federal funding was announced in Canada to improve prescribing practices for prescription drugs that have a high risk of abuse or addiction. Projects will aim to support the development of new guidelines and training and tools for health care practitioners.³

Formulary and Reimbursement Policies

Public drug plans in Canada currently list opioids, stimulants, benzodiazepines, and opioid substitute therapies, although some have quantity and refill restrictions. Some drugs, like methadone, oxycodone (OxyNEO), fentanyl, and methylphenidate, require prior approval in some jurisdictions.

Only Health Canada's Non-insured Health Benefits Program and Newfoundland and Labrador have requirements for a rationale or special authorization for higher doses of opioids. In almost all jurisdictions where public drug plans have listed OxyNEO (a tamper-resistant formulation), they have done so under the Exceptional Drug Status program or special authorization.

Excepting the Department of National Defence Canadian Armed Forces drug plan, public drug plans that participated in the 2015 CADTH survey do not reimburse naloxone. Naloxone, however, is available in some Canadian cities (e.g., Edmonton) and provinces (e.g., Ontario and British Columbia) through public health harm reduction programs.^{4,5} In July 2015, Health Canada announced its intention to review the prescription-only status of Naloxone. Naloxone is reimbursed under public health drug plans in Australia, while reimbursement in the US is unclear.

Prescription-Writing and -Dispensing Policies

To a varying degree, most Canadian jurisdictions have requirements such as refill restrictions, patient identification and records, limits on prescription-validity period, and use of paper-based tamper-resistant prescription pads or electronic PDMPs.

Some Canadian, US, and New Zealand jurisdictions have payer incentives for pharmacist activities that address suspected misuse and abuse, such as refusing to fill a prescription. Some jurisdictions also restrict patients to a limited number of pharmacies or prescribers for accessing opioids, stimulants, and benzodiazepines.

Prescription Drug–Monitoring Programs

Most Canadian jurisdictions have some form of PDMP, or have programs in development.¹ Monitoring of the precise range of specific opioids, stimulants, or benzodiazepines varies across Canada, but most of the PDMPs monitor at least one of these drugs. In 2014, Federal, Provincial and Territorial (FPT) Health Ministers, with the exception of Quebec, agreed to establish an FPT Prescription Monitoring Program Network with a mandate

to focus on access and privacy related to prescription monitoring data. National utilization information is not presently tracked. In May 2015, Health Canada announced funding for the Canadian Institute for Health Information to develop a coordinated national approach for the monitoring and surveillance of prescription drug abuse in Canada.⁶

In the US, the majority of states have PDMP legislation.⁷ Entities responsible for administering the PDMP vary greatly by state, and a range of PDMP access restrictions and requirements exist.⁸ Interoperability between the various state systems is also a challenge due to a series of legal and technical issues.⁷

Other Regulatory Measures and Oversight Activities

Tamper-resistant formulation grants and changes in drug approval regulations, including abuse deterrent labelling, have been promoted by the US government.⁹⁻¹² Similarly, Health Canada is currently consulting with Canadians on its draft *Proposed Tamper-Resistant Properties of Drugs Regulations*.¹³

Of the jurisdictions covered by this Scan, the US appears to have made the most investment in programs and policies to address prescription drug harms. Many state and local strategies exist to expand upon the US federal government's National Drug Control Strategy.¹⁴ The US Department of Health and Human Services will use new funding to focus on educational resources, increasing the use of naloxone, and expanding the use of medication-assisted treatment for opioid addiction.¹⁵

Conclusion

The issue of prescription drug abuse is common to all the jurisdictions studied in this Scan. Policies and strategies to reduce prescription drug harms are developed and executed by various authorities and differing combinations are applied in each jurisdiction.

Some of the emerging trends identified by this Scan include the development of educational tools to change prescriber behaviour; investment in improving access, scope, and functionality of PDMPs; reconsidering access requirements for naloxone; and regulatory agencies' exploration of tamper-resistant formulations of opioids.

Introduction

Prescription opioids (*hereafter* opioids^a), benzodiazepines, and stimulants are primarily used in the management of pain, of insomnia and anxiety, and of attention-deficit/hyperactivity disorder, respectively. Certain opioids are also used to manage opioid dependence; e.g., methadone. These drugs are important therapeutic options in clinical practice, with the potential to improve the quality of life of patients. However, they also have the potential to be misused, abused, and diverted for non-medical use due to their psychoactive properties, potentially leading to serious harms like addiction, overdose, and death.

In March 2013, a multi-stakeholder group led by the Canadian Centre on Substance Abuse (CCSA) released its report titled *First Do No Harm: Responding to Canada's Prescription Drug Crisis*. The report makes many recommendations to address the harms associated with prescription drugs, including promoting appropriate prescribing and dispensing practices; increasing timely, equitable access to a range of effective treatment options for pain and addiction; developing a standardized pan-Canadian surveillance system; establishing prescription monitoring programs; and engaging industry, governments, regulatory bodies, and others to commit to and collaborate in addressing the issue.^{16,17} This Environmental Scan aims to present the current landscape of such strategies and policies adopted by Canadian and international jurisdictions.

Objective

The objective of this Environmental Scan is to identify and synthesize information on prescribing and dispensing strategies, policies, and measures used in Canada and four reference countries (the United States [US], the United Kingdom [UK], Australia, and New Zealand) to reduce the potential harms associated with prescription opioids, stimulants, and benzodiazepines. The aim of this report is to provide a better understanding of existing efforts and inform potential future policy directions for reducing prescription drug harms.

It should be noted that the Environmental Scan serves only to illustrate the range of the possible policy options for achieving safe and effective use of opioids, stimulants, and benzodiazepines. It does not recommend one particular policy option over another. Because health systems differ markedly from jurisdiction to jurisdiction, the precise forms of prescribing and dispensing policies and practices in any given jurisdiction, whatever their potential merits, may not always be easily transferred to any other jurisdiction.

^a For the purposes of this report, the term "opioid" refers only to prescription opioids.

Methodology

This Environmental Scan synthesizes the information gathered from four different sources.

First, a limited literature search was conducted to inform this report, using the following bibliographic databases: PubMed and the Cochrane Library (2014, Issue 9). The search was limited to English-language documents published between January 1, 2010 and October 3, 2014. No methodological filters were applied. Conference abstracts were excluded from the search results. Grey literature was identified by searching relevant sections of CADTH's Grey Matters checklist (<http://www.cadth.ca/resources/grey-matters>), as well as through a focused Internet search.

Second, relevant information was synthesized from Health Canada's consultations with regulatory colleges of physician and surgeons, dentists, and nurses from various Canadian provinces. Such information is cited in this report as "personal communication."

Third, this Environmental Scan has synthesized information from the CADTH Environmental Scan titled *Narcotics, Benzodiazepines, Stimulants, and Gabapentin: Policies, Initiatives, and Practices Across Canada, 2014*.²

Fourth, in May 2015, CADTH conducted a survey of federal, provincial, and territorial public drug plans (referred to in this report as the 2015 CADTH survey of public drug plans) to gather information on formulary and reimbursement practices, and prescription-writing and -dispensing policies for addressing prescription drug harms. The purpose of the survey was to gather up-to-date information on related policies, as reported in the 2014 CADTH Environmental Scan *Narcotics, Benzodiazepines, Stimulants, and Gabapentin: Policies, Initiatives, and Practices Across Canada*.² Out of the 18 public drug plans^b surveyed, results of the CADTH 2015 survey are available for nine provincial jurisdictions (British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, Quebec, New Brunswick, Newfoundland and Labrador, and Nova Scotia), as well as Yukon Territory, and two federal public drug plans (Health Canada's Non-insured Health Benefits Program [NIHB] and the Department of National Defence and Canadian Armed Forces drug benefit plan). The survey results are presented in Tables 6 through 24 in Appendix 1; additional details are available in Tables 25 and 26 (Appendix 2). The

^b Public drug plans from the following provinces and territories were surveyed: Alberta, British Columbia, Saskatchewan, Manitoba, Ontario, Quebec, New Brunswick, Nova Scotia, Prince Edward Island, Newfoundland and Labrador, Yukon, and Northwest Territories. The following federal public drug plans were also surveyed: the Non-Insured Health Benefit Program, Interim Federal Health Program, Correctional Services of Canada, National Defense Health Services, Veterans Affairs Prescription Drug Program, and the Royal Canadian Mounted Police.

survey questionnaire is presented in Appendix 3. In some cases, the information made available through survey responses has been augmented by information reported in CADTH's 2014 Environmental Scan on narcotics, benzodiazepines, stimulants, and gabapentin,² as well as recent information from other sources.

This Environmental Scan does not provide a comprehensive review of all subject areas covered and does not recommend any particular approach that may be taken. This Environmental Scan explores only existing policies and strategies that aim to reduce harms from prescription opioids, stimulants, and benzodiazepines in the following five areas of prescribing and dispensing these drugs: education; formulary and reimbursement policies and systems; writing and dispensing requirements; prescription drug–monitoring programs (PDMPs); and regulatory measures and oversight activities. In the area of reimbursement policies, this Scan is largely confined to those in the public sector. Only in the US are policies in both the public and private sectors (e.g., health-maintenance organizations and private insurers) the subject of attention. Further, policies and programs – such as harm reduction through treatment programs, medication “take-back” programs, public education programs, and enforcement policies – are outside the scope of this Scan.

It should be noted that this report is a point-in-time appraisal of the current state of affairs in a dynamic health policy and regulatory world. Health systems, or at least components of them, are continually evolving to confront the prescription drug challenges at hand.

SECTION 1: Mandatory Education for Prescribing and Dispensing Opioids, Stimulants, and Benzodiazepines

1.1 Mandatory Education Requirements for Prescribing and Dispensing Opioids, Stimulants, and Benzodiazepines

In this report, “mandatory education” refers to additional educational requirements for health care professionals (physicians, dentists, nurse practitioners, and pharmacists) *after* the completion of their standard training and certification to practice. Training opportunities (e.g., continuing education [CE]) related to opioid (for pain management and opioid substitution therapy), stimulant, or benzodiazepine prescribing or dispensing that are completed *voluntarily* by a health care professional are *excluded* from this Scan.¹⁸ However, CE that earns participants credits to maintain (or renew) their professional licence to practice is briefly discussed.

This subsection finds that mandatory education requirements are generally not attached to standards of practice. However, mandatory education requirements for opioids, stimulants, and/or benzodiazepines prescribing (and sometimes dispensing) are found:

- Within quality assessment and assurance programs run by health profession regulatory bodies across most of the jurisdictions studied
- In some US state government laws (although not yet in US federal government law)
- Within initiatives to extend opioids, stimulants, and/or benzodiazepines prescribing authorities to a broader range of health care professionals than at present.

Mandatory education requirements for prescribing and dispensing opioids, stimulants, or benzodiazepines are also found in other contexts, including prescribing and dispensing opioid substitution therapy (Section 1.2); addressing professional misconduct such as inappropriate prescribing or dispensing (Section 1.3); and facilitating accreditation processes (Section 1.4).

This Environmental Scan examined at least two standards of practice statements from each country and, within each country, at least one standard of practice statement each for the medical, pharmacy, nursing, and dental health professions.¹⁹⁻³²

1.1.1 Mandatory Education on Prescribing Opioids, Stimulants, and Benzodiazepines for Practising Health Care Professionals

Canada

- Standards of Practice:^c Professional regulatory bodies (studied in this Scan) in Canada have standards of practice, but none were identified that directly incorporated mandatory education on opioids, stimulants, and/or benzodiazepines.
- CE to maintain membership in a professional regulatory body and maintain a professional designation: Professional regulatory bodies across Canadian health sectors generally require that members undertake continuing professional education as a condition for continued membership and maintaining professional designations. A sample of these requirements was examined during this Scan.^{31,33,34} Although CE courses related to opioids, stimulants, and/or benzodiazepines are offered in Canada (e.g., through MAINPRO and MDcme.ca), completion of these particular courses are not mandatory to keep a licence to practice.
- Quality assessment and assurance (QAA) programs:^d Many professional regulatory authorities in Canada are required by law to run these programs. Professional regulatory bodies are using their QAA programs to strengthen prescribing and dispensing practices, including through members’ participation in and compliance with educational requirements. For example, in British Columbia, the *Health Professions Act*

^c In this report, the term “standards of practice” is defined as the minimum standard of professional behaviour and ethical conduct on a specific topic or issue.²⁰

^d Quality assessment and assurance programs go by various names (e.g., they are sometimes referred to as “quality improvement and assurance” programs). For the purposes of this Environmental Scan, they are defined as programs authorized by a professional regulatory organization and requiring the participation of members. Such programs are found across all jurisdictions covered by this Scan.

establishes that one objective of a regulatory college is “...to establish and maintain a continuing competency program to promote high practice standards amongst registrants.”³⁵

- The College of Physicians and Surgeons of British Columbia has established a Prescription Review Program. This is a practice quality assurance activity established to assist physicians in the utilization of opioids, benzodiazepines, and other potentially addictive medications with appropriate caution for the benefit of their patients. The work of the Prescription Review Program is informed by the provincial PharmaNet database.³⁶
- The College of Dental Surgeons of British Columbia has required that courses in pain management or courses dealing with a particular class of drugs be completed by dentists under its QAA program.
- The College of Registered Nurses of British Columbia (CRNBC) is working to incorporate controlled drug prescribing elements into its QA program to prepare for the new prescribing authority for nurse practitioners. CRNBC is collaborating with Colleges of Physicians and Surgeons, the College of Pharmacists, and the Ministry of Health (Christine Daly, Nursing Policy Consultant, Vancouver, BC: personal communication, August 11, 2014).

In May 2015, the Canadian federal government announced funding of \$3.6 million over three years for six projects of national scope to improve prescribing practices for prescription drugs that have a high risk of abuse or addiction. These projects will support the development of new, evidence-based guidelines, training, and tools for physicians and other regulated health care professionals, such as nurse practitioners and pharmacists, who have the authority to prescribe or dispense drugs. These resources are expected to improve education for health care professionals to help them prevent and address the abuse of prescription drugs. The new guidelines are expected to better prepare prescribers of pain and other medications for prescribing these drugs in a safe, effective, and appropriate manner.³

United States

Various federal- and state-level initiatives in the US are underway to promote (and, in some instances, mandate) additional training for prescribers to minimize inappropriate prescribing of opioids.

- One of the recent examples is the President’s 2016 financial year budget, which includes investments to intensify efforts to reduce opioid misuse and abuse, including \$133 million in new funding. Through this funding, the US Department of Health and Human Services (HHS) has identified three priority areas to focus such efforts on: providing training

and educational resources, including updated prescriber guidelines, to assist health professionals in making informed prescribing decisions and address the overprescribing of opioids (through investment in PDMPs and data-sharing, among others); increasing use of naloxone; and expanding the use of medication-assisted treatment.¹⁵

- The Federation of State Medical Boards’ *Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain* is designed to “...promote the public health by encouraging state medical boards to adopt consistent policy regarding the treatment of pain, particularly chronic pain, and to promote patient access to appropriate pain management and, if indicated, substance abuse and addiction treatment.”³⁷ The introduction to the Model Policy highlights that limited physician knowledge can be a contributing factor to inadequate treatment of pain and inappropriate prescribing of opioids.³⁷ The Model Policy itself makes no reference to opioids education activities. The Policy does state: “Understanding pain: The diagnosis and treatment of pain is integral to the practice of medicine...In order to cautiously prescribe opioids, physicians must understand the relevant pharmacologic and clinical issues in the use of such analgesics, and carefully structure a treatment plan that reflects the particular benefits and risks of opioid use for each individual patient.”³⁷ The policy also states: “Physicians who treat patients with chronic pain should be encouraged to also be knowledgeable about the treatment of addiction, including the role of replacement agonists such as methadone and buprenorphine.”³⁷
- The US government’s national strategy, *Epidemic: Responding to America’s Prescription Drug Abuse Crisis*, sets out proposed measures to improve health provider education, including: “Work with Congress to amend federal law to require practitioners (such as physicians, dentists, and others authorized to prescribe) who request DEA (Drug Enforcement Administration) registration to prescribe controlled substances to be trained on responsible opioid-prescribing practices as a precondition of registration.”¹⁴
- The US Food and Drug Administration (FDA) Risk Evaluation and Mitigation Strategies (REMS) process requires that, under certain circumstances as a condition for drug approval, drug manufacturers must identify when prescribers should have specific training or experience or special certifications. In 2012, the FDA approved a “system-wide” REMS covering extended-release (ER) and long-acting (LA) opioid analgesics.³⁸ As part of the REMS, all ER and LA opioid analgesic companies must provide:

- Education for prescribers of these medications, which will be provided through accredited CE activities supported by independent educational grants from ER and LA opioid analgesic companies
- Information that prescribers can use when counselling patients about the risks and benefits of ER or LA opioid analgesic use.³⁹

However, there is no legal requirement for prescribers to participate in the education activities made available by product sponsors in compliance with the REMS. The FDA outlines that companies will be expected to achieve certain FDA-established goals for the percentage of prescribers of ER and LA opioids who complete the training, as well as assess prescribers' understanding of important risk information over time.⁴⁰ Further research is required to understand how many prescribers have participated in the education activities on offer.

- The FDA finalized a *Blueprint for Prescriber Education* in 2013. It forms part of the ER and LA opioid analgesic REMS. CE activities provided under the *Blueprint* focus on the safe prescribing of ER and LA opioid analgesics and consist of core content that takes about three hours to complete. The content is directed at prescribers of ER and LA opioid analgesics, but may also be relevant for other health care professionals (e.g., pharmacists). The coursework is not intended to be exhaustive nor a substitute for a more comprehensive pain management course. Accrediting bodies and CE providers have to ensure that the CE activities developed under this REMS are in compliance with the CE standards of the Accreditation Council for Continuing Medical Education, or the CE standards of another accrediting body as appropriate to the prescribers' medical specialty or health care profession.³⁹
- Although legislative initiatives at the US federal level that include mandatory education requirements for prescribing and dispensing controlled substances have been advanced, none have yet been enacted.⁴¹ However, legislation requiring mandatory education for prescribers and dispensers has been passed at the US state government level.^{42,43} The following two examples were identified during this Scan:
 - In 2012, the state of New Mexico amended the *New Mexico Pain Relief Act* and now requires that: "A (licensing board of a health care provider) ... shall require non-cancer pain management continuing education as determined by its rules for health care providers under the board's jurisdiction who hold a federal drug enforcement administration registration and licensure to prescribe opioids."⁴⁴

- In 2013, the state of Utah passed the *Continuing Education for Prescription Drugs* bill, which requires certain prescribers of controlled substances to complete at least four hours of CE as a requisite for licence renewal among other mandatory education requirements. The Utah legislation incorporates by reference the FDA *Blueprint for Prescriber Education* and its *Extended-Release and Long-Acting Opioid Analgesics Risk Evaluation and Mitigation Strategy*.⁴⁵

- In 2005, the American Dental Association adopted a *Statement on the Use of Opioids in the Treatment of Dental Pain* that does not require but encourages dentists to: "...undertake continuing education about the appropriate use of opioid pain medications in order to promote both responsible prescribing practices and limit instances of abuse and diversion."⁴⁶

There has been a growing call in the US for mandatory education for doctors who prescribe opioids. In 2011, the American Society of Interventional Pain Physicians advocated for legislation that would require health care professionals who prescribe opioids to receive specialized training.⁴⁷ However, the American Academy of Family Physicians has concerns with government (state)-mandated continuing medical education as a prerequisite to DEA or other licensure due to "...the limitations on patient access to legitimate pain management needs that may occur."^{43-45,48} The American College of Physicians states that it favours a balanced approach to permit safe and effective medical treatment utilizing controlled substances and efforts to reduce prescription drug abuse, but: "... educational, documentation, and treatment requirements toward this goal should not impose excessive administrative burdens on prescribers or dispensers."⁴⁹

United Kingdom

- No specific reference to education on opioids, stimulants, and benzodiazepines is made within the UK's General Medical Council's *Good Medical Practice* or the UK's General Pharmaceutical Council *Standards for Continuing Professional Development*.²⁷
- In the UK, a system of local Controlled Drugs Accountable Officers (CDAOs) ensures adherence to the regulatory requirements for controlled drugs in designated facilities, such as the National Health Service (NHS) and private hospitals. *The Controlled Drugs (Supervision of Management and Use) Regulations 2013* require CDAOs to ensure that individuals involved in prescribing, supplying, administering, or disposing of controlled drugs receive appropriate training.³⁴ The Regulations cover all controlled drugs (including growth hormones, steroids, etc.) and are not specific to opioids, stimulants, and benzodiazepines.⁵⁰ The UK Department of Health's guidance on the meaning of the Regulations states:

“CDAOs should therefore ensure that all individuals working with CDs [controlled drugs], either as employees of the designated body or as a commissioned or contracted service provider, have received appropriate training to enable them to carry out their responsibilities in accordance with the appropriate legislation. A training requirement should be included within all service level agreements or commissioning/contracting agreements. This can include anyone prescribing, supplying, administering, transporting, or disposing of CDs. Induction training should include the necessary aspects required to ensure the safe use and management of CDs, supported by regular updates as and when appropriate. The CDAO must ensure appropriate organizational processes are established and are effective in communicating information about CDs on the premises to all relevant individuals. The CDAO may wish to hold regular briefing sessions with relevant individuals. These sessions may include examples of good practice, issues or concerns to be aware of, any changes to SOPs (standard operating procedures) and where to find additional educational resources.”⁵⁰

Further research is required to understand whether the training requirements within “all service level agreements or commissioning/contracting agreements” include mandatory education on opioids, stimulants, and benzodiazepines specific to appropriate prescribing or dispensing.

Australia

- No specific reference to education on opioids, stimulants, and benzodiazepines is made within the Royal Australian College of General Practitioners’ *General Standards* or the Pharmaceutical Society of Australia’s *Standard and Guidelines for Pharmacists Providing a Staged Supply Service for Prescribed Medicines*. The latter document states: “Ultimately, pharmacists should make their own assessment of the adequacy of their capabilities for providing a staged supply service and undertake relevant training... to meet any identified learning needs.”¹⁹

New Zealand

- In 2010, the Medical Council of New Zealand issued three statements on good prescribing practices that “outline the standards expected of doctors” and that “may be used by the Health Practitioner’s Disciplinary Tribunal, the Council, and the Health and Disability Commissioner as a standard by which your conduct is measured.”^{25,26} The statement *Good*

Prescribing Practice advises: “Take part in clinical audit, peer review, and continuing medical education to maintain and improve your prescribing skills, knowledge, and expertise.”²⁵ This advice is of general application; it is not specific to prescription drugs that are prone to misuse. A second Council statement, *Prescribing Drugs of Abuse*, makes no reference to prescriber education of any kind.²⁶

1.1.2 Extension of Prescribing Authority

Canada, the US, the UK, Australia, and New Zealand are all considering, or have already taken, action to extend prescribing and dispensing authority for various drugs or classes of drugs to a broader range of health care professionals. The extent to which these authorities cover opioids, stimulants, and benzodiazepines is a subject for further research.⁵¹⁻⁵⁴ These extensions of authority are often accompanied by mandatory education requirements for the health workers concerned.

The extension of prescribing authority to pharmacists has been a long-term trend across all jurisdictions covered by this Scan. It exhibits considerable diversity in forms depending on the prescribing model.⁵⁵ Further research is required to understand whether the prescribing authority (for pharmacists) is extended to include opioids, stimulants, or benzodiazepines.

Canada^e

- The Nurses Association of New Brunswick has made it mandatory for all nurse practitioners to complete an approved education program before they are granted authority to prescribe narcotics and controlled substances (Dawn Torpe, Nurses Association of New Brunswick, Fredericton, NB: personal communication, June 12, 2015). The College of Registered Nurses of Nova Scotia and the Association of Registered Nurses of Newfoundland and Labrador have both approved mandatory controlled drugs education as a condition of licensure.²⁸ It is currently outside the scope of practice for nurse practitioners in Ontario to prescribe controlled substances.⁵⁷ In Prince Edward Island (PEI), regulations already allow the Association of Registered Nurses of Prince Edward Island to authorize nurse practitioners to prescribe narcotics and other medications, but additional training and education are required.⁵⁸

^e In October 2014, the Canadian Council of Registered Nurse Regulators announced that it will conduct a survey as part of its Nurse Practitioner Practice Analysis project. The survey is expected to provide a comprehensive description of nurse practitioner practice and education requirements.⁵⁶

- Further research is required to identify prescribing privileges for opioids, stimulants, and benzodiazepines that have been, or are being, extended to Canadian pharmacists.

United States

- The US gives authority to pharmacists to prescribe under collaborative agreements, but further research is required to determine how US state law may govern pharmacists in the prescribing of opioids, stimulants, and benzodiazepines.⁵⁹

United Kingdom

- The Department of Health announced in April 2012 that changes to *The Misuse of Drugs Regulations* mean that appropriately qualified nurses and pharmacists will now be able to prescribe controlled drugs (with the exception of diamorphine, cocaine, and dipipanone for the treatment of addiction).^{54,60} The changes relating to prescribing and mixing of controlled drugs by independent nurse and pharmacist prescribers also apply to midwives who are registered as independent nurse prescribers.^{52,54,60} As a result, for example, as of June 2015:

“...Midwives are now able to either supply or administer controlled drugs to expecting mothers or patients. The record-keeping requirements in respect of MSOs (Midwife Supply Orders) under regulation 21 are also amended with the effect that the name of an expecting mother or patient for whom controlled drugs are obtained and administered or supplied also needs to be recorded as part of records kept by midwives.”⁶¹

Australia and New Zealand

- Both Australia and New Zealand have extended or are considering extending prescribing privileges to qualified nurses and pharmacists.⁶² Further research is required to identify whether this includes prescribing privileges for opioids, stimulants, or benzodiazepines.

In summary, mandatory education requirements to prescribe or dispense opioids, stimulants, and benzodiazepines are generally not attached to standards of practice. They may be incorporated into QAA programs and are embodied in some US state government laws (but are not yet found within US federal law), and they may accompany the extension of prescribing authorities to pharmacist and nurses. In general, such education requirements appear to focus primarily on opioids.

The following subsections show that mandatory education requirements for prescribing and dispensing opioids, stimulants,

or benzodiazepines are also found in other contexts, including prescribing and dispensing opioid substitution therapy (Section 1.2); addressing professional misconduct (i.e., inappropriate prescribing) (Section 1.3); and facility accreditation processes (Section 1.4).

1.2 Mandatory Education Requirements for Prescribing and Dispensing Opioid Substitution Therapy

The terminology for prescribing opioid medications for the treatment of opioid dependence is not yet standardized internationally.⁶³ The term “opioid substitution therapy” is used in this Scan and refers to medication-assisted treatment using opioids (including methadone, buprenorphine, and buprenorphine/naloxone [e.g., Suboxone]).

There are mandatory education requirements for prescribing and dispensing opioid substitute therapy across many jurisdictions reviewed in this Scan.

Canada

In Canada, physicians must receive an exemption under Section 56 of the *Controlled Drugs and Substances Act* for prescribing methadone.⁶⁴ Health Canada’s Methadone Program requires that applicants who request an exemption have appropriate education and a letter of support from their provincial regulatory body.⁶⁵ Provincial regulatory bodies have set out mandatory education requirements as a condition for supporting applications for a methadone exemption. Mandatory education requirements are also determined by the provincial regulatory bodies for prescribing Suboxone (buprenorphine/naloxone). In summary:

- There are mandatory education requirements for prescribing methadone (to manage opioid dependence) across all provinces, but there are differences in their content. For example, the College of Physicians and Surgeons of Ontario (CPSO) and the Nova Scotia College of Physicians and Surgeons require that a physician complete the Centre for Addiction and Mental Health’s Opioid Dependence Treatment Core Course before obtaining a methadone exemption.^{66,67} The College of Physicians and Surgeons of British Columbia requires “attendance at the Methadone 101 Workshop sponsored by the College of Physicians and Surgeons; approved preceptorship with a physician; a review of their prescription profile from the PharmaNet database; interview with a member of the College registrar staff; and agreement to undertake a minimum of 12 hours of continuing medical education in addiction medicine each year.”²⁰

- At least one provincial pharmacy college has set a mandatory education requirement for dispensing methadone. The College of Pharmacists of British Columbia (CPBC) requires, as of February 1, 2014, that all pharmacy managers, staff, relief pharmacists, and pharmacy technicians employed in a community pharmacy that provides pharmacy services related to methadone maintenance treatment (MMT) must have successfully completed the mandatory CPBC MMT training program. They must also have implemented all necessary practice requirements identified in the CPBC *Methadone Maintenance Treatment Policy Guide* (2013).⁶⁸
- Mandatory education requirements for prescribing or dispensing buprenorphine are evolving across provincial jurisdictions. At least five provinces (British Columbia, Alberta, Manitoba, PEI, and Newfoundland and Labrador) now have mandatory education requirements.
 - The College of Physicians and Surgeons of Alberta (CPSA) has said: "As of November 2013, physicians are no longer required to have a methadone exemption in order to prescribe buprenorphine in opioid-dependent patients... Courses considered appropriate are the online buprenorphine education. Physician must provide confirmation of course completion to the CPSA."⁶⁹
 - The CPSO's 2007 *Policy on Buprenorphine Hydrochloride for the Treatment of Opioid Dependence* recommends but does not mandate education courses. In May 2015, the CPSO Council rescinded the existing buprenorphine policy and transitioned relevant information from the policy into a frequently asked questions document. A briefing note prepared for the CPSO Council states: "As the original concerns about buprenorphine have proven unfounded, and prescribing guidelines now exist, the policy has little relevance today."^{70,71}
 - The College of Physicians and Surgeons of British Columbia limits the prescribing of buprenorphine plus naloxone to physicians with a registered licence who have completed the necessary training course, and who are authorized to prescribe methadone for the treatment of opioid dependence.²⁰

United States

- The US *Drug Addiction Treatment Act of 2000* (DATA 2000) sets out mandatory education requirements for physicians prescribing buprenorphine. The Act provides: "The physician has, with respect to the treatment and management of opioid-addicted patients, completed not less than eight hours of training..."⁷² The US Secretary of HHS has

discretion under DATA 2000 to publish regulations on other training or experience a physician must have to prescribe buprenorphine. It remains for further research as to whether this discretionary authority has been exercised.

- US federal law restricts the dispensing of methadone to federal- and state-approved opioid maintenance programs that are generally found in specialized facilities (community pharmacies may technically be eligible for accreditation and certification, but generally are not). The American Society of Addiction Medicine reports that in 2011, there were 1,189 facilities, public and private, accredited and certified by the federal body, Substance Abuse and Mental Health Services Administration (SAMHSA), as outpatient MMT programs.⁷³ Section 1.4 of this Scan provides an overview of mandatory education requirements found within the US accreditation process for pain clinics, including methadone clinics. In contrast to methadone, Suboxone (buprenorphine and naloxone) and Subutex (buprenorphine) are being made available through commercial US pharmacies. The FDA states: "Qualified doctors with the necessary DEA identification numbers will be encouraged to help patients locate pharmacies that can fill prescriptions for Subutex and Suboxone."⁷⁴

United Kingdom

- The *Drug Misuse and Dependence: UK Guidelines on Clinical Management* states that appraisal is mandatory for all clinicians working in the NHS and is good practice in other settings, and needs to be carried out according to current regulations.⁷⁵ The guidelines do not include education requirements on training on opioid substitution therapy.

Australia

- Australia's prescribing and dispensing requirements for methadone, buprenorphine, and buprenorphine/naloxone combinations are set out in state and territorial legislation and regulation. In New South Wales (NSW), approval to prescribe methadone and buprenorphine is granted by the Director-General of NSW Health. Physicians and nurse practitioners are required to complete specified courses and complete a workplace assessment (a clinical placement of two to three hours). These requirements and the professional record of the practitioner are assessed by the Pharmacotherapy Credentialing Subcommittee.⁷⁶ NSW has an extensive administrative process for a community pharmacy to "become a registered methadone and/or buprenorphine dosing point."⁷⁷ Further research is required to identify whether this process requires pharmacists to undertake mandatory opioid substitution therapy training.

New Zealand

- New Zealand's *Misuse of Drugs Act* provides that a "suitable medical practitioner" must take clinical leadership of addiction treatment with controlled drugs. A person specified in a government gazette notice is granted the power to approve other medical practitioners to prescribe controlled drugs for addiction treatment. This person (typically a clinical lead) must ensure that these authorized medical practitioners have the knowledge and skills to undertake the tasks delegated to them.⁷⁸

1.3 Mandatory Education Requirements for Prescribers and Dispensers in Cases of Inappropriate Prescribing and Dispensing

The main model for the regulation of health professionals across all Organisation for Economic Cooperation and Development jurisdictions is self-regulation by professional bodies.⁷⁹ All jurisdictions included in this Scan have professional bodies with disciplinary processes. Disciplinary actions in cases of inappropriate prescribing and dispensing of any therapeutic product — including opioids, stimulants, or benzodiazepines — may include a requirement that the individual concerned complete appropriate education courses.

For example, in October 2014, the Investigation Committee of the College of Physicians and Surgeons of Nova Scotia issued a reprimand to a Nova Scotia physician concerning his opioid- and opioid substitution therapy-prescribing practices. The Committee imposed conditions on the physician's licence to practise medicine, including that he be required to take the next available CPSO Medical Record Keeping Course at his own expense and that: "In the event that (he) does not register for the next offering of this course or successfully complete it, his licence to practice medicine will be suspended pending successful completion of the course."^{80,81}

The number of times in Canada that mandatory education has been included in disciplinary cases of inappropriate prescribing of opioids, stimulants, benzodiazepines, and opioid substitution therapy is not known.

1.4 Mandatory Education Requirements for Prescribers and Dispensers to Practice at Specialized Clinics and Pharmacy Settings (e.g., Pain Management Clinics)

There are many accreditation processes for specialized clinics and pain treatment centres (including those offering opioid substitution therapy) within each jurisdiction. Within accreditation standards, there may be mandatory education requirements; however, further research is required to understand how these processes work with respect to education requirements for opioids, stimulants, or benzodiazepines. Examples of national accreditation bodies are Accreditation Canada (AC); the Joint Commission in the US; the Australian Council of Healthcare Standards; New Zealand's Health Quality and Safety; and the Care Quality Commission in the UK.⁸²⁻⁸⁶ There are also various other not-for-profit accreditation organizations, such as the Commission on Accreditation of Rehabilitation Facilities (CARF) (a US-based organization that also operates in Canada, Europe, and the US), and the Council on Accreditation (also based in the US and providing accreditation services in Canada). Both CARF and the Council on Accreditation offer accreditation services for opioid treatment facilities.^{87,88}

Canada

There are more than 200 publicly and privately funded "multidisciplinary pain treatment facilities" in Canada.¹⁸ Further research is required to identify how many of these facilities are subject to accreditation processes that include mandatory education requirements for prescribing opioids (including opioid substitution therapy), stimulants, or benzodiazepines. AC, formerly known as the Canadian Council on Health Services Accreditation, is the country's main accreditation body for health services. AC's *Medication Management Standards* include "training and competency evaluation."⁸²

United States

State licensing and accreditation of "pain clinics": The US National Alliance for Model State Drug Laws (NAMSDL) reports that, as of April 2014, nine states have adopted specific Acts regulating pain clinics.⁸⁹ NAMSDL also reports that the legal definition of a pain management clinic differs from state to state, but these entities are generally defined as a specific location at which patients are prescribed or dispensed controlled substances for treatment of a chronic pain condition.⁸⁹ NAMSDL identifies nine states that have pain clinic Acts: Florida, Georgia, Kentucky, Louisiana,

Mississippi, Ohio, Tennessee, Texas, and West Virginia.⁸⁹ These nine states require that clinic practitioners and employees meet specified training or educational thresholds including, but not limited to, completion of continuing medical education and board certification through the American Board of Pain Medicine.⁸⁹

Among all US states, actions taken by the State of Florida have possibly received the most media attention. Between 2010 and 2012, the following major actions were taken by the State of Florida:

- January 4, 2010: Pain clinics required to register
- February 2010: Operation Pill Nation: DEA and state and local law enforcement begin investigation of pain clinics
- October 1, 2010: Pain clinic regulation expanded
- February 23, 2011: Operation Pill Nation – joint law-enforcement raids begin
- July 1, 2011: Physician dispensing prohibited and statewide regional strike forces activated
- September 1, 2011: Mandatory reporting to prescription drug-monitoring program begins
- July 1, 2012: Wholesale distributor regulations expanded.

The US Centers for Disease Control and Prevention (CDC) reports, “The temporal association between the legislative and enforcement actions and the substantial declines in prescribing and overdose deaths, especially for drugs favoured by pain clinics, suggests that the initiatives in Florida reduced prescription drug overdose fatalities.”⁹⁰

US educational requirements within pain facility accreditation processes: US federal regulations require that all clinical staff within opioid treatment programs receive specific training in medication-assisted treatment.

To obtain certification from SAMHSA, an organization must meet the federal opioid treatment standards; be the subject of a current, valid accreditation by an accreditation body or other entity designated by SAMHSA; and comply with any other conditions for certification established by SAMHSA.⁹¹

The US federal government’s standards for accreditation are now being revised. The most recent draft (2013) sets out education requirements for certification and accreditation, including: “All staff members receive continuing education on opioid addiction treatment and related subjects. Staff may be qualified for their positions through training, education, and/or experience.”⁹²

United Kingdom

Since 2005, the UK has seen changes in accreditation and management systems for health care professionals and the facilities in which they work. This change has been driven in part by the Shipman Inquiry reports, issued between 2001 and 2004.⁹³ As described in Section 1.1.1, a system of local CDAOs has been established to ensure adherence to the regulatory requirements for controlled drugs (including opioids, stimulants, and benzodiazepines) in designated facilities, such as the NHS and private hospitals.⁹⁴ The CDAOs have the responsibility of ensuring workers in these facilities undertake CE on controlled drugs consistent with their work responsibilities and roles.

1.5 Clinical Practice Guidelines

This section provides an overview of clinical practice guidelines (CPGs) on prescribing opioids (including opioid substitution therapy), stimulants, and benzodiazepines. While many standards of practice may make general reference to the importance of CPGs, no instances were identified in which a standard of practice directly incorporated a CPG.

- A basic search of CPGs for each drug class of interest (opioids, stimulants, and benzodiazepines) was conducted for this Environmental Scan within the three major CPG databases with international reach: the Guidelines International Network,⁹⁵ the US National Guideline Clearinghouse database,⁹⁶ and the UK’s National Institute for Health and Care Excellence (NICE) guidance database.⁹⁷ The search results suggest there are many CPGs that directly or indirectly address the clinical use of opioids, stimulants, benzodiazepines, and opioid substitution therapy, and that the number of CPGs retrieved on stimulants and benzodiazepines is smaller than that of opioids. For example, the US National Guideline Clearinghouse database returned 104 results using the search “benzodiazepines,” 167 results using the search term “opioids,” and 47 results using both terms. In Canada, the Canadian Medical Association also maintains an “Infobase” of Canadian CPGs.⁹⁸ Under the category of “pain,” the database contains a total of 14 clinical guidelines (but other clinical guidelines for treatment of other conditions may also be relevant). Of these 14 guidelines, four are found to directly reference opioids, although in a variety of therapeutic circumstances. Of these, three are found to reference the potential for opioid harms and one addresses the potential efficacy of non-opioid treatment for pain.

Canada

- Among the CPGs identified by this Environmental Scan, the *Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain* was the most widely refereed CPG in the context of prescribing opioids.⁹⁹ The guideline was published and updated by the National Opioid Use Guideline Group (NOUGG). NOUGG is a collaboration of the 10 Colleges of Physicians and Surgeons across Canadian provinces, the Federation of Medical Regulatory Authorities of Canada, the Yukon Medical Council, and the Government of Nunavut. In developing the guideline, NOUGG had an additional goal to “develop and implement a knowledge transfer strategy that ensures the guideline moves into practice as a useful decision-making tool for physicians treating patients with chronic non-cancer pain.”⁹⁹ NOUGG created the National Faculty to guide and assist with moving the recommendations to practice.⁹⁹
 - This CPG is widely recognized by regulatory bodies and associations across Canada. It is also widely cited by health stakeholders in other jurisdictions, including the US. A number of Canadian regulatory colleges have also referred to the Guidelines as an educational tool. For example, the Prescribing Policy of the CPSO draws attention to the *Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain*.^{99,100} However, the policy states that “...the guideline is not intended to be used as a policy or standard of practice, but as a practical resource to provide Canadian physicians with the best available information, research and consensus of opinion on this topic.”¹⁰⁰
 - The *Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain* is also used in developing training materials. For example, the staff of the Association of Registered Nurses of Newfoundland and Labrador participated in the development of *Opioids for Chronic Non-Cancer Pain: Using the Canadian Guideline in Your Practice*, an online course for nurse practitioners who prescribe opioids. This course was developed through a partnership with Memorial University of Newfoundland and McMaster University’s Michael G. DeGroote National Pain Centre (Association of Registered Nurses of Newfoundland and Labrador, St. John’s, Newfoundland and Labrador: personal communication, September 2014).
 - In May 2015, Health Canada announced that \$433,000 would be provided to McMaster University to update the existing *Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain* and to develop e-tools for prescribers.^{3,6,101}
- There are various other CPGs on opioids for pain management and opioid substitution therapy from Canada and abroad that are cited by individual Canadian professional regulatory bodies:
 - The *Clinical Best Practice Guidelines: Assessment and Management of Pain*, issued by the Registered Nurses’ Association of Ontario, includes recommendations on the use of opioids.¹⁰²
 - The Michael G. DeGroote National Pain Centre website provides links to eight clinical guidelines for the treatment of pain.¹⁰³
 - The Collège des médecins du Québec has developed guidelines on the basics of chronic pain and opiates (2009); using methadone in the treatment of opiate addiction (developed in cooperation with the Ordre des pharmaciens du Québec in 1999); and buprenorphine in the treatment of opiate dependence (2009) (Ernest Prigent, Director of Practice Enhancement Division, Collège des médecins du Québec, Montréal, QC: personal communication, June 2015).
 - At its November 13, 2014 meeting, the Council of the Royal College of Dental Surgeons approved, in principle, proposed guidelines on *The Role of Opioids in the Management of Acute and Chronic Pain in Dental Practice*.¹⁰⁴
 - Health Canada’s Methadone Program website refers users to the document *Best Practices: Methadone Maintenance Treatment* published by Health Canada in 2002.⁶⁵ Many Canadian provincial governments and regulatory bodies have issued guidelines for methadone and other opioid substitution therapies over the past decade.⁶⁶⁻⁶⁸

Standards of practice often make reference to the importance of drawing on CPGs. For example, the CPSO states that CPGs “... do not define a standard of care, but may inform the standard of care.”¹⁰⁵ No standards of practice reviewed during this Environmental Scan directly incorporated a specific CPG on opioid, stimulants, benzodiazepines, or opioid substitution therapy.

United States

- The CDC has identified common features of eight expert-developed CPGs for prescribing opioids for chronic pain.¹⁰⁶ Seven of the guidelines were authored by US organizations.^{99,106-113} The *Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain* is also included in this study. The study identifies seven common elements across the guidelines, including “Considering all treatment options, weighing benefits

and risks of opioid therapy, and using opioids when alternative treatments are ineffective.¹¹⁰⁶

- The CDC reports on an additional recommendation element appearing in several guidelines: “Using data from prescription drug monitoring programs to identify past and present opioid prescriptions at initial assessment and during the monitoring phase.”¹¹⁰⁶ These CDC findings are largely consistent with a similar study by Cheung et al. (2014).¹¹⁴ The Cheung study examines seven CPGs for opioid prescribing. Four of these are the same as those included in the CDC study, while three others are authored by organizations in Singapore, the UK, Australia, and New Zealand.¹¹⁴
- One example of the US process for developing a CPG for opioids is the Washington State *Interagency Guideline on Opioid Dosing for Chronic Non-cancer Pain: An Educational Aid to Improve Care and Safety With Opioid Therapy*. The Guideline was developed by Washington State health officials and physicians who specialize in pain management. Boards and commissions that set practice standards reviewed the Guideline. The workgroup also received input from others in state government and the medical and scientific community. The Agency Medical Directors’ Group that sponsored this Guideline consists of the medical directors of five Washington State agencies: Corrections, Health, Health Care Authority, Labor and Industries, and the state’s Medicaid program.¹¹³

There are many opioid, stimulant, and benzodiazepine prescribing guidelines found across other jurisdictions.^{63,76,92,99,115-121} Further research is required to understand whether they are directly incorporated into standards of practice. Examples are listed below.

United Kingdom

- The European Centre for Monitoring Drugs and Drug Addiction reports that 34 “guidelines” for treatment of drug addiction have been published in the UK.¹²² Twenty of these guidelines refer to the appropriate clinical use of opioids, stimulants, benzodiazepines, or opioid substitution therapy.
- NICE has published two opioid substitution therapy guidelines: *Methadone and Buprenorphine for the Management of Opioid Dependence* (TA114), and *Naltrexone for the Management of Opioid Dependence* (TA115).^{119,120,123,124} The UK has published a national opioid substitution therapy guideline *Drug Misuse and Dependence: UK Guidelines on Clinical Management*. This guideline, which draws on and refers to other NICE guidelines, takes extended note of the varying endorsements that apply to its application by UK jurisdictions.⁷⁵
- In the UK, there have been some major efforts in developing CPGs on benzodiazepines.¹²⁵

Australia

- Several clinical guidelines for opioids have been issued by Australian health authorities. The governments of Queensland and Western Australia have jointly issued a *Quick Clinical Guideline for the Use of Opioids in Chronic Non-malignant Pain*.¹²¹
- Australia’s National Health and Medical Research Council’s Clinical Practice Guidelines Portal cites one guideline for opioid substitution therapy (*Methadone and Buprenorphine Guidelines for Pharmacists in South Australia*). In 2014, the Australian Department of Health issued a national guideline titled *Clinical Guidelines and Procedures for the Use of Methadone in the Maintenance Treatment of Opioid Dependence*.¹¹⁶
- In 2004, Australia’s National Centre for Education and Training on Addiction Consortium issued a guideline for health professionals covering “alcohol and other drugs.” It contains a section on good clinical practice for prescribing benzodiazepines.¹²⁶

SECTION 2: Formulary and Reimbursement Strategies, Policies, and Measures

The CCSA report *First Do No Harm: Responding to Canada's Prescription Drug Crisis* draws attention to the important role of third-party payers (ministries of health, federal and provincial public drug benefit programs, provincial and territorial worker compensation boards, and private insurers) in reducing prescription drug harms.¹⁶ The present and future place of formulary and reimbursement strategies, policies, and measures to combat prescription drug abuse were also raised during the hearings of the Standing Senate Committee on Social Affairs, Science and Technology and received attention within its October 21, 2014 interim report *Prescription Pharmaceuticals in Canada: Unintended Consequences*.¹²⁷ In this context, this section highlights areas of current practice as they relate to opioids (including opioids used for opioid substitution therapy, such as methadone, buprenorphine, and the combination of buprenorphine and naloxone), stimulants and benzodiazepines. These areas include drug scheduling; reimbursement restrictions; payer incentives for pharmacist interventions; designated prescriber or pharmacy programs; access and reimbursement conditions for tamper-resistant products; and access and reimbursement conditions for naloxone.

As in Section 1, reference is made to the experience of the US, UK, Australia, and New Zealand in each of these areas. However, much of the focus is on Canada and draws in part on a CADTH survey of public drug plan authorities conducted in May 2015. Survey responses provide useful insight into the directions being taken to reduce prescription drug harms within Canadian public drug plans today.

2.1 Scheduling of Opioids, Stimulants, and Benzodiazepines

Drugs are assigned to certain categories (commonly known as “schedules”) as per specific regulations in a given country. In general, such categorization (i.e., scheduling) of a drug is based on the risk profile of the given drug; e.g., abuse potential of the drug. To some extent, the schedule of the drug dictates how the drugs are sold in the country, such as whether a prescription is required, or any requirement to fill a prescription within certain number of days. This in turn affects how the drugs are prescribed or dispensed in a given country. From time to time, countries have rescheduled a drug to a more restrictive category to potentially reduce the harms associated with it.

Canada

In Canada, the *Controlled Drugs and Substances Act* (CDSA) and its regulations provide a framework for the control of substances that can alter mental processes and that may produce harm to an individual or to society when diverted to an illicit market.¹²⁸ Regulations under the CDSA set out the framework governing activities with controlled substances and precursors in Canada, including their production, sale, provision, importation, and exportation, including sections outlining licence and permit regimes for the conduct of activities with applicable classes of substances.¹²⁹

Under the CDSA, prescription opioids, stimulants, and benzodiazepines are classified as Schedule I, III, and IV, respectively. Their use is legal only when they are prescribed by licensed practitioners and used by the person for whom they are prescribed.¹³⁰⁻¹³² “Double-doctoring” (i.e., obtaining a prescription from more than one practitioner without telling the prescribing practitioner about other prescriptions received in the past 30 days) can result in imprisonment.

In addition to legal implications, CDSA and its regulations can set a minimum standard of how the controlled drugs are prescribed or dispensed in Canada. For example, the *Benzodiazepines and Other Targeted Substances Regulations* under the CDSA state:¹³³

- “52. A pharmacist may only refill a prescription for a targeted substance if
- (a) the practitioner who prescribed it expressly directs that the prescription may be refilled and specifies the number of refills;
 - (b) the pharmacist makes a record of each refill in accordance with section 53;
 - (c) less than one year has elapsed since the day on which the prescription was issued by the practitioner;
 - (d) at least one refill remains on the prescription; and
 - (e) in the case where an interval between refills has been specified by the practitioner, it has expired
53. A pharmacist who fills or refills a prescription for a targeted substance must record the following information:
- (f) the date the prescription was filled or refilled;

- (g) the quantity of the targeted substance provided at the original filling and at each refill;
- (h) the pharmacist's name or initials; and
- (i) the number assigned to the prescription."

United States

In the US, substances that have high potential for abuse that may lead to severe psychological or physical dependence are classified under Schedule II of the US *Controlled Substances Act*, whereas substances classified under Schedule III are recognized to have less potential for abuse than substances in Schedules I (i.e., substances that have no currently accepted medical use in the US, a lack of accepted safety for use under medical supervision, and a high potential for abuse) or II, and abuse may lead to moderate or low physical dependence or high psychological dependence.¹³⁴ The drugs that are classified under Schedule II have additional restrictions.

Similar to Canada, the scheduling of drugs in the US can also affect how they are prescribed or dispensed. For example, the DEA enacted a Final Rule on October 6, 2014 that rescheduled hydrocodone, the most prescribed opioid in the US, under Schedule II of the US *Controlled Substances Act*.¹³⁵⁻¹³⁷ The FDA reports that some of the key changes that will occur with the reclassification of hydrocodone from a Schedule III to a Schedule II drug are as follows:

- "If a patient needs additional medication, the prescriber must issue a new prescription; phone-in refills for these products are no longer allowed.
- In emergencies, small supplies can be authorized until a new prescription can be provided for the patient.
- Patients will still have access to reasonable quantities of medication, generally up to a 30-day supply."¹³⁸

As a result of the scheduling change, the Texas Health and Human Services Commission (which operates the Vendor Drug Program, the formulary for the Texas Medicaid and Children's Health Insurance Program reimbursement systems) announced that certain nurses and physicians will no longer be able to prescribe hydrocodone except in a hospital setting. It also announced that:

"The Vendor Drug Program will not allow refills on any prescription written prior to October 6 for clients enrolled in Medicaid, the Children with Special Health Care Needs Services program, the Kidney Health Care program, or the Texas Women's Health Program (TWHP). This direction also applies to the clients enrolled in Medicaid Managed Care or the Children's Health Insurance Program (CHIP)."¹³⁹

United Kingdom

The *Misuse of Drugs Regulations 2001* divides controlled drugs into five schedules. Schedule 2 includes more than 100 drugs, including most opioids (e.g., oxycodone, hydrocodone, and hydromorphone) and the major stimulants (e.g., methylphenidate and amphetamine).¹⁴⁰ In contrast, Schedule 3 contains a number of substances that are perceived as being open to abuse, but less likely to be abused than Schedule 2 controlled drugs. Schedule 4 is split into two parts; Part 1 contains most of the benzodiazepines.¹⁴¹

In 2014, the UK government rescheduled the opioid tramadol as a Schedule 3 drug. The UK's Advisory Council on the Misuse of Drugs recommended this action as a means of reducing the drug's potential harms.¹⁴² The implications of the rescheduling decision are further explained by one UK pharmaceutical organization as follows:

"...it means that all prescriptions for tramadol will have to comply with controlled drug Schedule 3 requirements from 10th June 2014:

- Prescriptions for Tramadol will only be valid for 28 days from date of issue.
- The prescription must clearly state the form (e.g., tablets, capsules), strength, and dose. The dose must be as specific as possible: 'take one as directed' is acceptable; however, 'take as directed' is not.
- The quantity prescribed must be written in words and figures. The total quantity supplied should not exceed 30 days, unless in exceptional circumstances as with all other controlled drugs. Tramadol will no longer be prescribed on 'batch' repeat dispensing prescriptions.
- Tramadol, as a Schedule 3 controlled drug, cannot be prescribed using EPS (electronic prescription service)."¹⁴³

Australia and New Zealand

Drug scheduling and rescheduling decisions in Australia and New Zealand may carry similar implications for prescribing and dispensing as do those in Canada, the US, and the UK.¹⁴⁴ For example, in February 2014, the Government of Western Australia rescheduled alprazolam in the Standard for the Uniform Scheduling of Medicines and Poisons to a Schedule 8 medicine (from a Schedule 4). This step was taken due to increasing public health concerns over the misuse and abuse of this medication. Schedule 8 medicines are controlled drugs that have a high risk of abuse and addiction. They have extra legal restrictions on how they are stored, prescribed, and dispensed. For example, due to this change, the alprazolam prescriptions are valid for six months only.¹⁴⁵

New Zealand's schedule of controlled drugs contains supply restrictions. Class A and B controlled drugs are restricted to a one-month supply. Class C controlled drugs are restricted to a three-month supply dispensed at one-monthly intervals unless otherwise specified by the prescriber.¹⁴⁴

2.2 Formulary Listing and Reimbursement Conditions and Requirements for Opioids, Stimulants, and Benzodiazepines

Many public and some private drug plan formularies can be accessed to identify the reimbursement conditions that apply to any given opioid, benzodiazepine, and stimulant product within that plan.¹⁴⁶ Despite a number of studies available on specific formulary listing and reimbursement practices, a comprehensive appraisal (e.g., covering all opioids, benzodiazepines, and stimulants) of the impact of these restrictions on reducing harm was not identified during the literature review conducted for this Environmental Scan.^{116,147-149}

This subsection first focuses on formulary listing and reimbursement conditions and requirements for opioids, benzodiazepines, and stimulants in Canada. The review is largely based on information provided by public drug plans across Canada in response to the 2015 CADTH survey. The survey results relevant to this subsection are presented in Tables 6 through 14 in Appendix 1; additional details are provided in Appendix 2. Responses received provide insight into some of the directions being taken to reduce prescription drug harms within Canada.

This subsection also presents information on formulary listing and reimbursement conditions and requirements for drugs used in opioid substitution therapy in the US. This information supports the view that there may be common restrictions across both public and private payers in the US and Canada (and perhaps—although this is a subject for further research—in the UK, Australia, and New Zealand).

Canada

The 2015 CADTH survey respondents (public drug plans) provided the following information on reimbursement policies for opioids, stimulants, and benzodiazepines:

- Twelve public drug plans responded that methadone is a benefit under their program and eight of them list it with criteria. Ten public drug plans responded that buprenorphine/naloxone (Suboxone) is a benefit under their program, and nine of them list it with criteria. Only one survey respondent

covers naloxone (Department of National Defense and the Canadian Armed Forces). Listing criteria are also applied to certain opioids (in 10 public drug plans), to certain stimulants (nine public drug plans), and to benzodiazepines (two public drug plans). (See Appendix 1, Tables 6 and 7.)

- Details of the listing criteria and approval processes for opioids, stimulants, and benzodiazepines are outlined in Appendix 2. Restrictions on opioids are varied, as some public drug plans will require special authorization for sustained-release oxycodone (e.g., OxyNEO), or fentanyl. Some restrictions are program-specific, such as for palliative care. Restrictions on stimulants mostly apply to methylphenidate.
- Quantity limits are set for methadone and buprenorphine/naloxone (Suboxone) in four and three public drug plans, respectively, and for opioids (seven public drug plans), stimulants (five public drug plans), and benzodiazepines (six public drug plans) (Appendix 1, Table 8). Specific information is contained in Appendix 1, Table 9. Several public drug plans also reported dosage restrictions for these drugs (Appendix 1, Table 10).
- None of the survey respondents reported specific listing restrictions for high-dose opioids except for Newfoundland and Labrador (Appendix 1, Table 11). However, NIHB clients who are prescribed opioid doses above the opioid "watchful dose" (set at 450 mg of morphine equivalent) are required to provide a rationale for using higher doses.
- Drugs subjected to refill restrictions (in addition to federal regulations) include methadone in seven public drug plans, buprenorphine plus naloxone in six public drug plans, opioids in eight public drug plans, stimulants in seven public drug plans, and benzodiazepines in six public drug plans (Appendix 1, Tables 12 and 13).
- Saskatchewan's public drug plan reported delisting meperidine and pentazocine due to poor safety profile and abuse potential, and the Yukon Territory's public drug plan reported delisting benzodiazepines from the Chronic Disease formulary due to reported abuse. NIHB has also delisted some opioids and benzodiazepines (Appendix 1, Table 14).

United States

Findings from three recent studies on opioid substitution therapy reimbursement policies point to general considerations and factors (e.g., the role that public reimbursement plans may play) that may also be found in other jurisdictions.

In July 2014, the New England Comparative Effectiveness Public Advisory Council received the *Management of Patients with Opioid Dependence: A Review of Clinical, Delivery System, and Policy Options Final Report*. The report includes a review of the listing and reimbursement measures of public and private payers for a range of drugs used in the treatment of opioid dependence (Tables 1 and 2).¹⁵⁰

Table 1: New England State Medicaid Agency Coverage Policies for Medications Used in Opioid Dependence Treatment¹⁵⁰

| State | Brand: Suboxone (film), Zubsolv (tablet) Generic: buprenorphine/naloxone (tablet) | Buprenorphine (tablet) | Brand: Revia (tablet), Vivitrol (injection) Generic: Naltrexone (tablet) |
|---------------|--|---|---|
| Connecticut | + (Suboxone only) • Use of any other agents requires PA | o | + (generic oral only) • Use of any other agents requires PA |
| Maine | + (Suboxone only, max dose = 16 mg) • Clinical criteria applied to Suboxone use • Lifetime limit of 24 months for use of Suboxone unless PA approved • Use of any other agents requires PA | + (during pregnancy only) | + (generic oral only) • Use of any other agents requires PA |
| Massachusetts | + (generic tablet w/dose <16 mg per day) • PA required for generic tablet >32 mg/day, and doses between 16 and 32 mg depending on duration of therapy • PA required for Suboxone, Zubsolv | • PA required | + (generic oral, Vivitrol) • PA required for Revia |
| New Hampshire | • PA required for Suboxone o (Zubsolv) | • PA required | o (Revia and generic) + (Vivitrol)* |
| Rhode Island | • PA required | • PA required | • PA required |
| Vermont | + (Suboxone, max dose = 16 mg/day) • PA required for generic tablet (max dose = 16 mg/day) • Clinical criteria applied to Suboxone use • Authorized use up to 1 year for Suboxone and buprenorphine/naloxone • Max days' supply for Suboxone and buprenorphine/naloxone = 14 days o (Zubsolv) | • PA required (max dose = 16 mg/day) • Authorized use up to 1 year for buprenorphine • Max days' supply for buprenorphine = 14 days | + (generic oral only) • PA required for Revia • PA required for Vivitrol (max dose = 1 injection/30 days) |

* Additional data regarding Medicaid coverage from American Society of Addiction Medicine (ASAM). Advancing access to addiction medicines (2013). <http://www.asam.org/docs/advocacy/implications-for-Opioid-Addiction-Treatment>. Accessed March, 2014

+: coverage policy identified; o: no coverage policy identified; PA: prior authorization

Source: Reproduced with permission from the Institute for Clinical Economic Review. Management of patients with opioid dependence: a review of clinical, delivery system, and policy options; 2014.¹⁵⁰

Table 2: New England Private Coverage Policies for Medications Used in Opioid Dependence Treatment¹⁵⁰

| Payer | Brand: Suboxone (film), Zubsolv (tablet) Generic: buprenorphine/naloxone (tablet) | Buprenorphine (tablet) | Brand: Revia (tablet), Vivitrol (injection) Generic: Naltrexone (tablet) |
|---|--|---|--|
| Blue Cross Blue Shield of Massachusetts | <ul style="list-style-type: none"> • PA required for all agents [max dose = 16 mg/day (11.4 mg for Zubsolv)] • Quantity limits = 30–90 units per prescription based on medication strength | <ul style="list-style-type: none"> • PA required (max dose = 16 mg/day) | <ul style="list-style-type: none"> + (Revia and generic only) ◦ (Vivitrol) |
| Blue Cross Blue Shield of Rhode Island | <ul style="list-style-type: none"> • PA required for Suboxone, buprenorphine/naloxone • Quantity limits = 30–90 units per 30 days based on medication strength ◦ (Zubsolv) | <ul style="list-style-type: none"> • PA required • Quantity limit = 11–12 tablets/90 days | ◦ |
| Blue Cross Blue Shield of Vermont | <ul style="list-style-type: none"> + <ul style="list-style-type: none"> • Quantity limit = 90 units per prescription | + | <ul style="list-style-type: none"> + (generic only) ◦ (Vivitrol) |
| ConnectiCare | <ul style="list-style-type: none"> + <ul style="list-style-type: none"> • Quantity limit for Suboxone = 90 film strips/month | + | <ul style="list-style-type: none"> + (generic only) • PA required for Vivitrol |
| Harvard Pilgrim Health Care | + | + | + |
| Tufts Health Plan | <ul style="list-style-type: none"> • PA required for Suboxone, Zubsolv, buprenorphine/naloxone with 12-month limit on coverage | <ul style="list-style-type: none"> • PA required (max dose = 24 mg/day) with 12-month limit on coverage • Quantity limits = 90–120 units per 30 days based on medication strength | + |

+: coverage policy identified; ◦: no coverage policy identified; PA: prior authorization

Source: Reproduced with permission from the Institute for Clinical Economic Review. Management of patients with opioid dependence: a review of clinical, delivery system, and policy options; 2014.¹⁵⁰

The report found that private payers set various conditions of access to opioid dependence treatments. Blue Cross Blue Shield of Vermont, ConnectiCare, and Harvard Pilgrim Health Care are found to place few restrictions on the use of Suboxone (buprenorphine plus naloxone), Zubsolv (buprenorphine plus naloxone) and the generic tablet. Conversely, the Blue Cross Shield of Massachusetts, Blue Cross & Blue Shield of Rhode Island, and Tufts Health Plan require prior authorization for use of these medications with dose and quantity limits applied. In addition, Medicaid restrictions are found to influence private payer behaviour to a degree:

“Similar to Medicaid restrictions, BCBSMA (Blue Cross Blue Shield of Massachusetts) limits the maximum daily dose of Suboxone and the generic tablet to 16 mg and to 11.4 mg for Zubsolv.

Quantity limits based on medication strength vary widely for a 30-day prescription (generally 30 to 90 units for film strips or tablets). Criteria for approved use also include a treatment plan and enrolment in behavioural/psychosocial therapy.¹⁵⁰

In 2013, the US Treatment Research Institute (TRI) surveyed two commercial plans in each of the 10 largest states (by population) in the US and the largest small group plans in those states.¹⁵¹ They sought information about coverage and benefits, as well as any restrictions on benefits such as prior authorization, quantity limits, step therapy (“fail first”) requirements, duration limitations, and network requirements that may limit patient access to drugs used in opioid substitution therapy. The survey found the following:¹⁵¹

- “Inclusion on a plan’s formulary does not equate to access due to additional utilization management requirements. The most common requirements include prior authorization, quantity and dosage limits, and step therapy. Other limitations beyond these include: limiting medications to detoxification only; limiting duration of treatment with medications; and restricting access to innetwork providers only. However, TRI reports that ‘often the limitations are not supported by evidence-based practices.’
- The most widely available medication for opioid substitution therapy is Suboxone (buprenorphine/naloxone) across the plans studied. The expectation is that with new formulations becoming available, such as the generic version of Suboxone and an implantable version of buprenorphine, it will become even more available. Whether that will translate into greater use is not clear because the generic version may serve only as a substitute.
- Only a small number of plans cover extended-release, injectable naltrexone (Vivitrol) and it is generally covered as both a medical and a pharmacy benefit with significant cost implications for patients.
- Although evidence-based practice strongly suggests that clinical treatment, including counselling, should accompany use of medications, that requirement was rarely found in the health plans surveyed.
 - No plans were identified that provide coverage for methadone in OTPs [opioid treatment programs]. TRI reports that it completed a query of the American Association for the Treatment of Opioid Dependence but did not reveal any commercial insurer that is providing coverage and benefits for methadone in OTPs.¹⁵¹

A 2013 study by the American Society of Addiction Medicine (ASAM) found that the US Medicare and Medicaid public programs set the trends for private reimbursement plan design and that they are “...a reference model for state and county coverage reform initiatives, commercial payers, health care organizations, medical and other professional societies and health plans, including Medicare and Medicaid accountable care organizations.”⁷³

The ASAM study underlines that public and private drug dependence treatment coverage requirements are broadening in the US, partly as a result of the passage of the *Affordable Care Act*. Yet Medicaid agencies are looking simultaneously for new ways to spread finite funding across all medical and behavioural health benefits: “As a result, increasing numbers of Medicaid programs are imposing limitations on coverage for the opioid pharmacotherapies and counselling that comprise Medication-Assisted Treatment (MAT).”⁷³

2.3 Payer Incentives for Pharmacist Interventions

Payer incentives for pharmacists for appropriate dispensing are present in Canada and Australia, although not all of these incentives are targeted at opioids, benzodiazepines, and stimulants. Further research is required to identify what payer incentives for pharmacists for appropriate dispensing may be present in the US, the UK, and New Zealand.

Canada

Results from CADTH’s 2015 survey of public drug plans provide an overview of Canadian public drug plan incentives for pharmacist interventions to help reduce prescription drug harms (Appendix 1, Table 15). Some examples include:

- Interaction fees (i.e., pharmacists’ interaction with patients): Public drug plans that pay for interaction fees include British Columbia, Nova Scotia, and NIHB. For example, BC PharmaCare pays an “interaction fee” to pharmacists for witnessing the ingestion of methadone, but does not pay a fee for buprenorphine plus naloxone. This is based on the reduced risk of drug diversion and the formulation of the product (buprenorphine plus naloxone is supplied as sublingual tablets that require up to 10 minutes for dissolution).
- Refusal-to-fill fees: British Columbia, Alberta, Saskatchewan, Ontario, Nova Scotia, and Newfoundland and Labrador offer “refusal-to-fill” fees when a pharmacist declines to fill a prescription if she or he suspects abuse or misuse. For example, in British Columbia, pharmacists are compensated for interception of prescriptions that result in cost savings to PharmaCare (provided the patient’s deductible had been paid). Valid reasons for refusal include significant drug–drug interaction; previous adverse reaction; therapeutic duplication; subtherapeutic dose; dangerously high dose; treatment failure; overuse; suspicion of polypharmacy visits or double-doctoring; and falsified prescription. Alberta pharmacists (under the Compensation for Pharmacy Services plan) may claim an Assessment for Refusal to Fill a Prescription based on potential overuse or misuse, or a falsified or altered prescription. Saskatchewan’s Ministry of Health (MH) reimburses pharmacies for refusing to fill certain medications when misuse or abuse is suspected, including when a pharmacist determines the prescription has been altered or falsified, or if multi-pharmacy use or double-doctoring are suspected.
- Medication review fees: Although not specific to opioids, benzodiazepines, and stimulants, Nova Scotia’s Basic Medication Review Service (approximately 20 to 30 minutes

to complete) is an insured service funded by the Nova Scotia Seniors' Pharmacare Program and is provided to patients who meet criteria in community pharmacies. Eligible patients must be taking three or more prescription medications that are covered by Pharmacare Programs for the treatment of a chronic condition.¹⁵²

2.4 Designated Prescriber or Pharmacy Programs

A number of programs and policies that restrict a patient to a single pharmacy or prescriber for accessing opioids, benzodiazepines, and stimulants are present in Canada, the US, the UK, and New Zealand.

Canada

Results from CADTH's 2015 survey of public drug plan authorities provide an overview of the current program landscape regarding restrictions on single pharmacy and prescriber (Appendix 1, Tables 16, 17, and 18). According to the survey, single pharmacy–designation policies are found in seven public drug plans, and prescriber restriction policies are found in five public drug plans. The following are three examples from Canada on designated pharmacy agreements (as stated by the survey respondents):

- Manitoba's MH is able to use its Drug Program Information Network to restrict a patient to filling prescriptions at a particular pharmacy. This restriction is initiated at the request of the physician and with the agreement of the patient. Where the MH is the sole payer for the cost of the prescribed medication for a patient, the MH has the authority to limit reimbursement to only one pharmacy, with or without the consent of the patient. The pharmacy filling the prescriptions must contact the drug program to "open" the patient's file before it can begin dispensing for that individual.
- The "Programme Alerte" was created in Quebec in 1985 by the L'Ordre des pharmaciens du Québec (OPQ) to encourage the appropriate use of drugs. Under this program, patients are identified who are misusing substances that are known to be habit-forming (mainly benzodiazepines and opioids). This identification is based on criteria such as visits to multiple pharmacies or physicians, or when habit-forming drug therapy overlaps are found. When a patient has been identified, a warning is sent by a designated OPQ staff member to the pharmacist and neighbouring pharmacies about that patient. When the patient visits a pharmacy, he or she is invited to select one physician and one pharmacy for his or her drug therapy needs.

- In addition, CADTH's Environmental Scan Report, *Narcotics, Benzodiazepines, Stimulants, and Gabapentin: Policies, Initiatives, and Practices Across Canada* (2014), reports that in PEI, pharmacists, physicians, and patients may enter into a unified agreement that limits the patient's use to a single pharmacy. An email confirming the agreement is then sent out to all pharmacies through the Drug Information System.²

United States

In the US, designated pharmacy programs are commonly known as Patient Review and Restriction (PRR) programs. The CDC reports that PRRs enable state Medicaid programs to rein in a Medicaid patient's overuse, and possible abuse, of physician services and prescription drugs without having to terminate Medicaid benefits altogether. "They do this by allowing Medicaid programs to restrict patients suspected of over-utilization to a single designated provider, pharmacy, or both."¹⁵³ The CDC has also referenced five published studies that "...have illustrated that PRR programs can reduce expenditures, use of controlled substances, or both."¹⁵³ A 2013 report from the Robert Wood Johnson Foundation found that 46 states and the District of Columbia (DC) have a designated pharmacy program under the state's Medicaid plan, in which individuals suspected of misusing controlled substances must use a single prescriber and pharmacy.¹⁵⁴

United Kingdom

In the UK, patients can be permanently registered with only one general practitioner practice at a time. According to the UK government, this limits the scope for seeking simultaneous prescriptions from different practices (i.e., double-doctoring).⁹⁴

New Zealand

In New Zealand, a Restriction Notice may be issued in one of two circumstances: where there is clear evidence that the person has been obtaining medication from a number of different practitioners over a prolonged period and is likely to seek further supplies, or where the person is addicted or habituated to a medicine or has been obtaining it from several sources and is likely to seek further supplies. The Restriction Notice is a legal document issued by the Medical Officer of Health and can limit prescribing to a named person and often one pharmacy for dispensing.¹⁵⁵

2.5 Reimbursement Conditions for Tamper-Resistant Products

The term "tamper-resistant product" is used in this Environmental Scan to refer to formulations with properties that resist crushing, cutting, chewing, dissolution, or other forms of tampering. The science of abuse deterrence is evolving; hence, there is an ongoing debate on what constitutes a tamper-resistant product.

Canada

The 2015 CADTH survey of public drug plans explored whether tamper-resistant products were currently listed under Canadian public drug plans (Appendix 1, Table 19), and whether adding a tamper-resistant product to a drug benefit plan would generally result in the delisting of its equivalent non-tamper-resistant product. However, the responses provided to date largely focus on the single case of OxyContin and OxyNEO.

The following examples of the treatment of tamper resistance within formularies and reimbursement decision-making processes were identified during this Scan and suggest possible areas for further research:

- In jurisdictions in which listing recommendations and reasons are made public, examples can be found where tamper-resistance properties or lack thereof are a consideration in listing decisions. In Ontario in 2010, the Committee to Evaluate Drugs (CED) for the Ontario Drug Benefit Plan issued its recommendation *not* to list Tramadol Hydrochloride Extended-Release. Among other considerations, the CED also expressed “significant concerns with safety of the extended-release formulation if crushed or chewed. There were also concerns with the potential for abuse and dependence, a significant issue with other narcotic pain relievers.”¹⁵⁶
- Purdue Pharma withdrew OxyContin (used to treat moderate to severe pain) from the Canadian market in March of 2012 and launched a new product, OxyNEO, which is marketed for its tamper-resistant properties.¹⁵⁷ CADTH’s 2015 survey results confirmed that, in spite of the marketed tamper-resistant properties of OxyNEO, not all public drug plans in Canada listed OxyNEO – even as OxyContin was discontinued. In addition, most of the drug plans that have listed OxyNEO have done so under the Exceptional Drug Status program or special authorization. These survey results are consistent with the more detailed analysis of listing and reimbursement actions for OxyNEO published by the Patented Medicine Prices Review Board and DrugCoverage.ca (Appendix 1, Table 20).

2.6 Delisting of Opioids, Benzodiazepines, or Stimulants (Individual Drug or Drug Class) From Formularies

This Scan identified one instance when benzodiazepines were delisted as a *class* of drug. Hoebert et al. (2012) reported that to

limit misuse and save costs, on January 1, 2009, benzodiazepines were excluded from the Dutch reimbursement list when used as anxiolytic, hypnotic, or sedative. Their study of this delisting measure found it was associated with a moderate decrease in the number of incident diagnoses and initiation of benzodiazepine use in patients with newly diagnosed anxiety or sleeping disorders and that “This finding indicates that in settings where no such reimbursement opportunities exist, physicians have room to reduce benzodiazepine prescribing.”¹⁵⁸ The Scan did not explore whether this delisting action remains in effect today.

In the 2015 CADTH survey of public drug plans, Saskatchewan’s public drug plan reported delisting meperidine and pentazocine due to poor safety profile and abuse potential, and Yukon Territory’s public drug plan reported delisting benzodiazepines from the Chronic Disease formulary because of reported abuse. NIHB has also delisted some opioids and benzodiazepines (Appendix 1, Table 14).

2.7 Access and Reimbursement Conditions for Naloxone

As described in this subsection, there is a trend toward liberalizing access conditions for naloxone in Canada, the US, and Australia, although at different paces. Naloxone is reimbursed under public health drug plans in Australia. In Canada, naloxone is not reimbursed by any of the public drug programs that participated in the CADTH 2015 survey of public drug plans (with the exception of the Department of National Defense Canadian Armed Forces drug benefit plan). Further research is required to identify naloxone reimbursement circumstances in the US and New Zealand.

Canada

In Canada, naloxone is manufactured and distributed by three pharmaceutical companies, namely Sandoz Canada Inc., Omega Laboratories Limited, and Alveda Pharmaceuticals Inc.¹⁵⁹⁻¹⁶¹ The auto-injector formulation of naloxone is not yet available on the Canadian market. Except for the Department of National Defense Canadian Armed Forces drug benefit plan, naloxone is not reimbursed by any of the public drug programs that participated in the CADTH 2015 survey of public drug plans. However, there are several regional and provincial initiatives that make naloxone accessible through other mechanisms.

Streetworks, a multi-service outreach program for harm reduction and primary health care education in Edmonton, started the first naloxone program in Canada in 2005. Toronto’s public health harm-reduction program, the Works, began its naloxone program in 2011. In 2012, Ontario and British Columbia (through harm-reduction services) launched provincial initiatives to provide naloxone education and kits at harm-reduction distribution sites.^{4,5}

In August 2012, the BC Centre for Disease Control launched the BC Take Home Naloxone pilot program to provide overdose prevention and response training to people at risk. Training can be performed by a health care provider (e.g., a nurse). A physician must prescribe the kit to a named patient. The program uses single-dose glass ampoules to eliminate contamination risks and simplifies the dosage for administration.⁴

In Ontario, as of October 7, 2013, naloxone distribution organizations that are eligible to take part in the Provincial Naloxone Distribution Program are able to access naloxone from the Ministry of Health and Long-Term Care. Organizations that are eligible to participate in the program include:

- “Public health units that manage a core needle syringe program
- Community-based organizations that have been contracted by the local public health unit to manage a core needle syringe program
- Ministry-funded hepatitis C teams.”^{4,5}

Toronto Public Health’s Preventing Overdose in Toronto initiative is a comprehensive program of overdose prevention and response training, including naloxone dispensing. Clients are instructed by public health staff on overdose risk factors, recognizing signs and symptoms of overdose, calling 911, naloxone administration, stimulation and chest compressions, and post-overdose care. Training is offered to clients one on one or in small groups. Clients receive a naloxone kit that includes two 1 mL ampoules of naloxone hydrochloride (0.4 mg/mL) and are advised to return for a refill and debriefing if the naloxone kit is used. Toronto Public Health is now “exploring options for the development of an epi-pen like device/intra nasal device.”¹⁶²

In July 2015, Health Canada announced its intention to review the prescription-only status of naloxone. This review will determine whether the benefits of increasing access outweigh the risks of administration by a non-health professional and whether these risks can be mitigated with additional label instructions and training. (Government of Canada [Internet]. Ottawa (ON): Health Canada. Health Canada Reviewing Prescription Status of Overdose Treatment Naloxone; 2015 Jul 24 [cited 2015 Oct 20]. Available from: <http://news.gc.ca/web/article-en.do?nid=1006229>).

United States

An auto-injector formulation of naloxone has been approved by the FDA.

The United States started distributing naloxone in 1999 and, as of 2010, there were more than 180 community naloxone distribution programs in the US, with more than 53,032 participants and 10,171 uses of naloxone reported between 1996 and 2010.¹⁶³

The laws governing access to, and administration of, naloxone in the United States are complex and continually evolving.¹⁶⁴ The US National Association of Boards of Pharmacy (NABP) reports that, as of October 2014, at least 25 states have passed legislation to expand naloxone access and availability.¹⁶⁵ Requirements for who may prescribe, dispense, and administer the drug vary between US states. According to the NABP, of these 25 states, at least three have passed laws granting pharmacists authority, under certain conditions, to prescribe naloxone or dispense the drug without a prescription.¹⁶⁵ Currently, US states have an option under Medicare to reimburse take-home naloxone. Further research is required to identify how many states exercise this option.

A 2013 study by the non-profit Trust for America’s Health organization (with the support of the Robert Wood Johnson Foundation) gives a general picture of US laws pertaining to naloxone.¹⁵⁴ The study found the following:

- State laws have been necessary to overcome barriers that often prevent use of naloxone in emergency situations. Laws have been implemented to both encourage increased prescribing of such medication to those at risk of an overdose, and to protect those who administer naloxone to an overdosing individual from civil or criminal repercussions. Some states may be able to accomplish this through regulations.
- Seventeen states and DC currently have a law to help increase access and use of naloxone in emergency situations in order to reduce overdose deaths. A state received credit on this indicator if they possess any law that expands access to naloxone to lay administrators. These laws vary in their detail and scope. For instance, some of the laws include:
 - Removing civil liability for prescribers (California, Connecticut, Colorado, New Jersey, New Mexico, North Carolina, and Vermont)
 - Removing civil liability for lay administration (Colorado, DC, Kentucky, Massachusetts, New Jersey, New Mexico, New York, North Carolina, Rhode Island, and Virginia)
 - Removing criminal liability for prescribers (Colorado, Massachusetts, New Jersey, New Mexico, North Carolina, Rhode Island, Vermont, and Washington)
 - Removing criminal liability for lay administration (Colorado, DC, Kentucky, Massachusetts, New Jersey, New Mexico, North Carolina, Rhode Island, Virginia, and Washington).

Illinois removed criminal liability for possession of naloxone without a prescription. Several state laws allow third-party prescription of naloxone to a family member, friend, or other person in a position to assist a person at risk of experiencing an overdose, including Illinois, New York, Washington,

Massachusetts, North Carolina, Virginia, Kentucky, New Jersey, Maryland, and Vermont. Oregon's law allows those who have completed training to possess and administer naloxone.

Washington and Rhode Island are currently implementing collaborative practice agreements where naloxone is distributed by pharmacists.¹⁵⁴

United Kingdom

In 2012, the UK government's Advisory Council on the Misuse of Drugs (ACMD) undertook a review of naloxone's availability.¹⁶⁶ The ACMD reported back to the government in May 2012 and described the access conditions for naloxone as follows:

- Under the *Medicines Act 1968*, no one, except individual patients with a prescription and appropriate medical practitioners (or those acting under medical instructions, including nurses), is allowed to administer parenteral (injectable) prescription-only medicines.
- There is a limited list of exceptions to the restrictions of Section 7 of the *Medicines Act*.
- In June 2005, in the *Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order*, the UK added naloxone to that limited list of medicines. This means that currently:
 - Naloxone is an injectable, and therefore prescription-only, medicine that may be used by anyone for the purpose of saving life in an emergency;
 - Naloxone can be prescribed directly to a patient, or supplied via a Patient Group Direction (PGD) or Patient Specific Direction (PSD);
 - Prescribers should prescribe and supply naloxone only to a known patient with a medical condition that requires the medication, and with the patient's informed consent; and
 - Naloxone cannot currently be prescribed (or supplied using a PGD or PSD) to a caregiver, peer, or member of staff on behalf of a drug user, and cannot be given to anyone without the drug user's informed consent.

These conditions mean that naloxone is restricted under prescription-only supply, and that supplies cannot be held for general use on people in settings such as homeless hostels, or carried by outreach workers, for example.¹⁶⁶

- The ACMD made three recommendations to the UK government:
 - Recommendation 1: Naloxone should be made more widely available, to tackle the high numbers of fatal opioid overdoses in the UK

- Recommendation 2: Government should ease the restrictions on who can be supplied with naloxone
- Recommendation 3: Government should investigate how people supplied with naloxone can be suitably trained to administer it in an emergency and respond to overdoses.

More generally, the Chair of the ACMD stated:

"Critics have suggested that naloxone provision in the community could encourage people to use drugs more dangerously, if they know naloxone is available. The ACMD is not aware of any significant body of evidence that naloxone provision encourages increased heroin use ... Naloxone has been provided locally to service users and caregivers for some years in the UK. In Scotland and Wales, recent successful pilots have led to national programs. The NTA (National Treatment Agency) in England ran a naloxone and overdose program for families and caregivers, but there has been no similar roll-out across the country. Last year, the Scottish Lord Advocate allowed naloxone to be provided to some services without prescription, for use in an emergency. Through the use of a Patient Group Direction, nurses or pharmacists can distribute the drug to people at risk of overdose.¹⁶⁷ This is commendable because Scottish drug treatment and homeless hostel staff can now hold it ready for use, and Scottish medical professionals supplying naloxone are protected in cases of liability."^{166,168}

In July 2014, the UK's Parliamentary Under Secretary of State for Public Health informed the ACMD that "work is in train" (in progress) to take forward the recommendation by the ACMD that naloxone should be more widely available.¹⁶⁹ In February 2015, Public Health England (PHE) reported that the legislative change expected to come into force in October 2015 is likely to mean that naloxone is made exempt from prescription-only medicine requirements when it is supplied by a drug service commissioned by a local authority or the NHS.¹⁷⁰ According to PHE, naloxone may then be supplied to any individual needing access and in all cases:

- It may be supplied for the purpose of making naloxone available for saving a life in an emergency; and
- There will be no need for the usual prescription-only medicine requirements, just a requirement that the supply is suitably recorded.¹⁷⁰

PHE also observed, "There is some interest in nasal delivery of naloxone but a suitable product has not been licensed for use. However, a non-injectable product would likely not need to be prescription-only and could be easier for non-medical staff to administer."¹⁷⁰

Australia

In Australia, naloxone is a Schedule 4 medication and, therefore, must be prescribed by a doctor or a nurse practitioner.¹⁷¹

Naloxone is listed under Australia's Pharmaceutical Benefits Scheme and is available in a minijet 400 mcg/1 mL solution. Each prescription (containing five minijets) costs a health care card holder AUD\$6.00 (or AUD\$36.10 for a person without a health care card).¹⁷¹

The Australian National Council on Drugs (ANCD) describes itself as "the principal advisory body to government on drug policy."¹⁷¹ In September 2012, the ANCD issued a position statement on naloxone availability in Australia; it contains an overview of naloxone access conditions in that country:

- As naloxone is currently a Schedule 4 (prescription-only) medication licensed for the treatment of opioid overdose, there are no direct legal barriers to providing naloxone on prescription to persons at risk of overdose.¹⁷¹
- In December 2011, a program to train potential overdose witnesses in overdose management and provide naloxone on prescription to people at risk of opioid overdose was launched in the Australian Capital Territory (ACT). The Implementing Expanded Naloxone Availability in the ACT (IENAACT) program aims to train 200 participants over two years. Take-home doses of naloxone will be prescribed to eligible participants by a general practitioner on completion of the training.¹⁷¹
- Although no direct legal barriers to providing naloxone on prescription exist, "There are, however, several issues to consider in promoting the availability of naloxone beyond prescription and training programs over the longer term that need to be addressed, including availability to emergency services and front-line staff, legal liability, rescheduling, and training programs."¹⁷¹

The ANCD statement goes on to report that:

- "Most Australian states and territories do have 'good Samaritan' laws that protect lay people from liability when acting in an emergency. However, in some states such as the ACT and New South Wales, these laws would exclude administration by anyone affected by drugs, and not all areas of Australia have such legislation. Legislation would be required at both the state/territory and Commonwealth levels to protect members of the general population who administer naloxone in emergency situations from criminal prosecution or civil liability, and to clarify the duty of care required in such situations. Good Samaritan legislation to protect lay people administering naloxone from civil liability claims has been implemented in the UK and US states. Existing state and territory good Samaritan legislation and legislation governing needle and exchange programs in Australia may also provide some guidance."¹⁷¹

- Naloxone is currently included in Schedule 4 (S4; prescription-only medicine). Rescheduling of naloxone to Schedule 3 (S3; pharmacist only medicine) or Schedule 2 (S2; pharmacy medicine) would facilitate expanded availability. This would enable all ambulance workers, frontline staff, and the general population to obtain and administer naloxone. In some areas including New York, California, New Mexico, and Connecticut in the USA, naloxone can be prescribed to third-party lay people; and in Italy, naloxone can be obtained as an over-the-counter medication. No adverse consequences from providing access to naloxone through these arrangements have been reported in the literature."¹⁷¹

In light of these and other considerations, the ANCD recommended:

1. "That programs to expand the availability of naloxone as a prescription medication for potential overdose victims be instituted in all Australian states and territories;
2. That in the longer term, naloxone be rescheduled to be made available as a pharmacist-only medicine (S3) or as a pharmacy medicine (S2);
3. That expanding the availability of naloxone be accompanied by appropriate programs that train potential overdose witnesses in comprehensive overdose prevention and management strategies, including naloxone administration;
4. That expanding the availability of naloxone be subject to ongoing evaluation and monitoring, and that this evaluation be utilized to further develop the training programs and material provided;
5. That procedures are investigated to allow all emergency services workers, alcohol and other drug workers, and needle and exchange workers, to be authorized to administer naloxone;
6. That all states and territories pass legislation that will protect all people from legal liability arising from the administration of naloxone in emergency situations;
7. That options are investigated for obtaining current, quality data on overdose deaths occurring in Australia."¹⁷¹

It is a subject for future research which, if any, of these recommendations have been taken up by the Australian federal, state, or territorial governments.

SECTION 3: Prescription-Writing and Prescription-Dispensing Strategies, Policies, and Measures

3.1 Prescription Requirements

This subsection highlights examples of different prescription requirements for opioids, benzodiazepines, and stimulants found in Canada and other jurisdictions; e.g., refills, prescription validity period, and record-keeping and personal identification requirements.

3.1.1 Refills

Canada

In Canada, drugs are regulated at both the federal and provincial level. Federal laws such as the *Controlled Drugs and Substances Act*, *Narcotic Control Regulations*, *Food and Drug Regulations*, and *Benzodiazepines and Other Targeted Substances Regulations* outline prescription requirements such as refills, part-fills, written or verbal prescriptions, record-keeping, and loss or theft reporting.

As reported in Section 2.1.2 in this Environmental Scan (see Tables 12 and 13 in Appendix 1), results from the 2015 CADTH survey of public drug plans identified instances where early refill and multiple refill restrictions are tied to drug reimbursement policies. For example, the Saskatchewan Drug Plan will not reimburse more than three prescriptions for the same product and individual in any 45-day period, unless adequate documentation for exceeding the limit is provided by the pharmacist. However, as stated earlier, refill restrictions are not attached only to reimbursement policies.

United States

The CDC reports that prescription drug limit laws vary across the US.¹⁷² For example, in New York State, no refills are allowed for prescriptions for Schedule II medications (including anabolic steroids) and benzodiazepines.¹⁷³

New Zealand

In New Zealand, a maximum days' supply is outlined for controlled drugs. The days' supply limit is dependent on the prescriber of the medication. For example, for medical practitioners, prescriptions are limited to one month for Class A and Class B controlled drugs and three months for Class C controlled drugs (dispensed at one-month intervals unless otherwise specified by the prescriber).¹⁷⁴

3.1.2 Personal Identification

Canada

Public drug plans may require patients to present proof of identification to the prescriber or pharmacist at the time of prescribing and/or dispensing of opioids, benzodiazepines, and stimulants. Some jurisdictions also require pharmacists to keep a record of the patient's identification. Table 21 in Appendix 1 presents such requirements in various Canadian jurisdictions for each of the drug classes of interest. The table illustrates that requirements to present or record personal identification practices vary between jurisdictions.

United States

The CDC reports that, as of June 2013, 24 states have laws mandating that pharmacists check identification before dispensing; all but one of these specifies the circumstances under which the requirement applies.¹⁷² However, the same CDC report finds that only 10 states apply identification laws to the dispensing of prescriptions for specific controlled substances or schedules, either generally or under particular circumstances.

A Georgia law, for example, requires pharmacists to demand, inspect, and document a government-issued or similar identification from individuals picking up prescriptions for Schedule II controlled substances only.¹⁷² A New Mexico regulation requires dispensers to verify identification of individuals receiving new prescriptions for controlled substances in Schedules II through IV. An Illinois statute requires individuals to identify themselves with two forms of identification before pharmacists may dispense Schedule V controlled substances.¹⁷²

United Kingdom

In the UK, a pharmacist is required to ask for proof of identity when dispensing a Schedule 2 controlled medicine, such as morphine or pethidine. The patient is asked to sign the back of the prescription to confirm receipt of the drug. In cases where an individual is collecting a controlled drug on behalf of someone else, they are legally required to show the pharmacist proof of identity, if asked, and certain controlled drugs will require a letter of authorization from the patient. To collect a Schedule 3 controlled medicine such as pentazocine, a patient need only sign the back of the prescription.¹⁷⁵ Further research is required to understand how these requirements may change in light of proposals to move to electronic prescribing for Schedule 2 and 3 controlled drugs (they cannot be prescribed electronically at present).

3.1.3 Prescription Validity Periods

Validity periods for prescriptions vary across jurisdictions and specific products.

Canada

In Canada, the validity of the prescription for monitored drugs may be dependent on provincial programs and/or federal regulations. The 2015 CADTH survey of public drug plans suggests that, in general, the validity of prescription periods is fairly consistent (i.e., one year after the prescription is issued) across provincial jurisdictions and that federal drug plans like NIHB generally follow provincial standards (Table 22, Appendix 1).

The data reported in Table 22 in Appendix 1 present the high-level aggregated responses, and there are a number of small differences, depending on the jurisdiction and the drug product. For example, in British Columbia, for the Controlled Prescription Program and for all drugs listed under Schedule 1A of the Drug Schedules Regulation of the British Columbia *Pharmacy Operations and Drug Scheduling Act* (including many opioids), the prescription expires after midnight on the fifth day following the date of issuance by the prescriber. However, one exception is methadone, which is not subject to this specific limitation (although other limitations apply to methadone).

As per the results from the 2015 CADTH survey of public drug plans in Canada, prescription validity periods (and other conditions) are not always established by third-party payers, but other authorities, such as professional colleges, can also set the standards. For example, in Alberta, the Alberta College of Pharmacists Standards of Practice for Pharmacists and Pharmacy Technicians provides that a prescription for a benzodiazepine or other target substance, as defined in federal *Controlled Drugs and Substances Act* regulations, shall not be refilled for a period of greater than 12 months after the prescription was written, and a Schedule 1 drug may not be refilled for a period greater than 18 months after the prescription was first filled. In New Brunswick, the *New Brunswick Pharmacy Act and Regulations* govern prescription validity period requirements (in New Brunswick, prescriptions expire one year from the original date on the prescription, not one year from the date of first dispensing).

United States

The number of days after a prescription is issued during which a pharmacist is allowed to fill a prescription varies by state. For example, in California, prescriptions for all controlled substances (Schedules II to V) are valid for six months from the date written.¹⁷⁶ In Delaware, prescriptions for controlled substances

(Schedules II and III) become void unless dispensed within seven days of the original date of the prescription or the prescriber requests otherwise.¹⁷³

United Kingdom

The *Misuse of Drugs Regulations* include five schedules that classify all controlled medicines and drugs. Schedule 1 has the highest level of control, whereas medications in Schedule 5 have a much lower level of control. In the UK, prescriptions for controlled medicines in Schedules 2, 3, and 4 are valid for only 28 days.¹⁷⁵

Australia

In Australia, prescription validity may vary by state laws. For example, in Queensland and South Australia, prescriptions for controlled drugs are valid for six months after the original prescription is written.¹⁷⁷

New Zealand

In New Zealand, prescriptions for Class A and Class B controlled drugs must be dispensed within seven days of the prescribing date. Prescriptions for Class C controlled drugs must be dispensed within six months of the prescribing date.¹⁴⁴

3.2 Tamper-Resistant Prescription Drug Pad Programs

Over the past three decades, a standard physical tool for managing controlled drugs — including opioids, stimulants, and benzodiazepines — has been a requirement for prescribers to write the prescriptions in specified forms of prescription pads. In general, a prescriber is required to keep one copy of a prescription (for various periods depending on the jurisdiction) with the other two copies kept by, respectively, the pharmacist and regulatory College. In Canada, these prescribing requirements have often been called “triplicate prescription pad programs,” although internationally they are generally called “multiple copy prescription programs” (MCPs). When MCPs were introduced in the US during the 1980s and 1990s, they were often viewed as a law-enforcement tool as much as they may also have served as a harm-reduction tool.^{178,179}

MCPs remain a feature of the environment for prescribing and dispensing prescription drugs in Canada and other jurisdictions today. However, their relative position within the tool kit of measures for reducing harms from prescription drugs is changing across all jurisdictions examined, partly as a result of the application of new information and communications technologies within PDMPs (see also Section 4 of this Environmental Scan).

Canada

In Canada, five provinces (British Columbia, Alberta, Manitoba, Nova Scotia, and Newfoundland and Labrador) have paper-based MCPPs in place. In addition, the Yukon also adheres to Alberta's triplicate prescription pad program. In these jurisdictions, with the exception of Newfoundland and Labrador, MCPPs are being integrated with other electronic PDMPs. Ontario and Saskatchewan no longer require MCPPs and rely solely on the electronic PDMP. The opioids, benzodiazepines, and stimulants that are covered by the paper-based MCPPs vary between provinces (Appendix 1, Table 23).

In addition, Table 24 in Appendix 1 illustrates the various reporting systems (e.g., broadcast emails to area pharmacies, reporting to licensing bodies, etc.) in place for reporting forged or illegal prescriptions across the Canadian public drug plans surveyed by the CADTH 2015 survey.

United States

In the US, paper-based prescription monitoring programs were increasingly common across states during the 1980s and were accompanied by prescriber and dispenser requirements to use MCPPs.¹⁷⁸ One study found that by 2004, of the eight states that had enacted MCPPs as part of their monitoring programs, all except California had terminated their multiple copy prescription component (duplicate or triplicate).¹⁸⁰

The move away from MCPPs in the US is being accelerated through the implementation of the US Department of Justice's 2010 Interim *Final Rule on Electronic Prescriptions for Controlled Substances*.¹⁸¹ In New York State, for example, new regulations issued in 2013 reflect the new federal rules and authorize a practitioner to issue an electronic prescription for controlled substances in Schedules II through V. They allow a pharmacist to accept, annotate, dispense, and electronically archive such prescriptions. Existing official New York State prescription forms may generally be used only in the event of a power outage or technical failure, or under other specified exceptional circumstances.¹⁸² However, MCPPs remain as a legacy system in some state jurisdictions. As recently as August 2014, the US DEA said: "Neither the CSA [*Controlled Substances Act*] nor DEA regulations require prescriptions to be prepared in triplicate. The DEA recognizes that some states, such as Texas and California, require the use of triplicate prescription forms for some or all controlled substances."¹⁸³

United Kingdom

In the UK, a special form is used for any *private* prescription (i.e., prescriptions paid for by the patient) of Schedule 2 and 3 controlled drugs dispensed by community pharmacists. In

England, these forms, along with NHS-dispensed controlled drug prescriptions, have to be sent to the NHS Business Services Authority (NHSBSA) for examination and monitoring purposes. Records of these prescriptions are held in a central database hosted by the NHSBSA, so that prescription activity for Schedule 2 and 3 controlled drugs can be monitored by NHS England and the NHSBSA. CDAOs are able to search the NHSBSA database to look at all prescriptions for one prescriber.¹⁸⁴ Individual prescribers can then be held to account for all their controlled drug prescribing. The NHS prescription forms are used in the NHS system and there is a space on the back where the patient signs for the medication.¹⁸⁵

Australia

In Australia, states and territories have issued regulations and codes on forms of prescriptions for controlled substances, including specified opioids, benzodiazepines, and stimulants. For example, the Government of Western Australia's *Schedule 8 Medicines Prescribing Code* provides that: "In accordance with the *Poisons Regulations 1965*, prior written authorization from the CEO (Chief Executive Officer of the Western Australian Department of Health) is required by practitioners wishing to prescribe flunitrazepam for each individual patient. This unique authorization number must be handwritten by the prescriber on the prescription prior to presentation at a pharmacy. If there is no authorisation number, the pharmacist must refuse to dispense and will be required to contact the practitioner. An authorisation will only be issued if the application is accompanied by written support from an appropriate consultant i.e., psychiatrist, sleep medicine physician or neurologist."¹⁸⁶

The *Prescribing Code* was amended in 2014 to add other benzodiazepines (e.g., alprazolam) but with slightly different prescription-writing forms and requirements:

"Written authorisation from the CEO is required by practitioners wishing to prescribe alprazolam for each individual patient for a period greater than 60 days. This authorization number does not need to appear on the prescription. Consultant support is not required for applications if prescribing is for approved indications and in dosages within the normal therapeutic range. Practitioners wishing to prescribe alprazolam for an RDA (registered drug addict) for any period of time will require prior authorization and appropriate consultant support."¹⁸⁶

New Zealand

In New Zealand, new legislative changes will allow prescriptions for controlled drugs to be generated electronically instead of handwritten.⁸⁵ At the present time, specified controlled drugs need

to be written on a triplicate prescription form, including Class A and Class B controlled drugs (which cover many opioids, stimulants, and/or benzodiazepines). The *Misuse of Drugs Regulations 1977* requires that these controlled drugs be written in the authorized prescriber's handwriting on a form provided by the Director-General of Health. Monitoring of all Class A and B controlled drug prescription information is carried out by the MH.¹⁴⁴

SECTION 4: Prescription Drug Monitoring Programs

PDMPs, or prescription monitoring programs (PMPs), in general are used to collect and distribute data about the prescription and dispensation of controlled drugs. Jurisdictions have instituted PDMPs to assist prescribers, payers, dispensers, and/or law-enforcement agencies to support the appropriate and legitimate use of drugs, and deter their abuse and misuse. PDMPs can take the form of mandatory electronic prescriptions, real-time monitoring systems that operate on data input at the point of sale, systems that use retrospective data captured over a period of time, and paper-based multiple prescription drug pad programs (also see Section 3.2 for information on tamper-resistant prescription drug pad programs).

Section 4.1 of this report highlights major PDMP models and design features within Canada, the US, the UK, Australia, and New Zealand. Section 4.2 addresses PDMP requirements for prescribers and dispensers and uses of PDMP data. Section 4.3 briefly discusses the effectiveness of PDMPs.

4.1 Prescription Drug Monitoring Programs Models and Features

Canada

In April 2015, the CCSA published the study *Prescription Monitoring Programs in Canada: Best Practice and Program Review*.¹ The study's authors observed that PDMPs (which they refer to as PMPs) cover a range of features and practices:

"Different PMPs may vary in models of administrative oversight, specific drugs targeted for monitoring, methods of data collection, types of interventions, and levels of information sharing. There is limited supporting research evidence for many aspects of PMPs at this time; however, the volume of research reports is increasing each year, proving a growing evidence base in this area."¹

The CCSA reports that, as of April 2015, there are seven provinces with some form of PDMP (British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, Newfoundland and Labrador, and Nova Scotia) and one territory (Yukon) that is linked with the Alberta program (although it reports to the Yukon Medical Council specifically about the Yukon).¹ Two provinces have programs under development (New Brunswick and PEI).¹ It should be noted that Newfoundland and Labrador does not use its tamper-resistant prescription drug program for monitoring purposes.¹

The majority of the PDMPs across Canadian jurisdictions monitor one or more opioids, benzodiazepines, or stimulants, although the precise range of specific opioids, stimulants, or benzodiazepines varies across jurisdictions. Table 3 lists the drugs monitored by the PDMPs across Canadian provinces and territories. In addition, NIHB, a federal public drug plan, also has a prescription monitoring system in place.² NIHB's PMP also monitors opioids, stimulants, and benzodiazepines.²

Canadian PDMPs are attached to (and often funded by) provincial health agencies and with various forms of participation or support from provincial colleges of physicians, pharmacists, and other stakeholder groups.¹

As per the CADTH 2015 survey of public drug plans, Ontario and Saskatchewan have fully electronic PMPs (Appendix 1, Table 23).

One of the main purposes of PDMPs is to track inappropriate use of these drugs and to make the necessary intervention. Table 4 provides a summary of the questionable activity criteria (i.e., inappropriate use) tracked and the interventions made by each PDMP in Canada. The majority of the PDMPs track multi-doctoring or multi-pharmacy visits.¹ One of the common interventions made by the PDMPs is to inform the prescriber, dispenser, payer (i.e., the drug plan), or the licensing body of potential inappropriate use.¹

A more detailed summary table for each provincial PDMP is found in Appendix 5 of the CCSA report,¹ which highlights differences between provincial PDMPs regarding such dimensions as program administration, institutional partners, level of clinician access to patient profiles, and PMP evaluation process.¹

In 2014, Federal, Provincial and Territorial (FPT) Health Ministers, with the exception of Quebec, agreed to establish an FPT PMP Network with a mandate to focus on access and privacy related to prescription monitoring data. The Network also works to strengthen existing PMPs and help facilitate the creation of new PMPs, by sharing best practices, data, and advice (Jeff Klassen, Senior Policy Advisor, Health Canada, Ottawa, Ontario: personal communication, October 15, 2015). Currently, there is no central resource in Canada to track the evolving conditions of access and utilization of Canadian PDMPs.

In May 2015, Health Canada announced nearly \$4.3 million over five years for the Canadian Institute for Health Information (CIHI) to develop a coordinated national approach for the monitoring and surveillance of prescription drug abuse in Canada. CIHI will work with the provinces, territories, and other stakeholders on activities such as developing and enhancing data and information;

Table 3: Features of Prescription Drug Monitoring Program in Canadian Provinces and Territories – Program, Implementation Date, and Monitored Drugs¹

| Jurisdictions | Name of Program / Implementation Date | Monitored Drugs |
|---------------------------|---|---|
| British Columbia | CPP Implementation date: before 1993 | "Alfentanil, Anileridine, Buprenorphine, Butalbital, Butorphanol, Codeine (all single ingredient and combinations > 60 mg), Ethchlorvynol, Fentanyl, Hydrocodone, Hydromorphone, Levorphanol, Meperidine, Methadone, Methaqualone, Morphine, Oxycodone, Pentazocine, Propoxyphene, Sufentanil, Tapentadol" |
| | PRP | "Not limited to CPP drugs; also look at benzodiazepines and opioids" |
| Alberta | TPP Implementation date: 1986 | "Buprenorphine, Butorphanol, Dextropropoxyphene, Fentanyl/Sufentanil/Alfentanil, Hydrocodone, Hydromorphone, Meperidine, Methadone, Morphine, Oxycodone, Pentazocine, Tapentadol, Methylphenidate, Butalbital, Ketamine. <i>Note: In 2014/2015, there is a plan to add codeine, benzodiazepines, benzodiazepine receptor analogs, and other sedative-hypnotics for monitoring, but special prescriptions will not be required"</i> |
| Saskatchewan | PRP "Implementation date: in 2006 – changed from TPP" | "Anileridine, Buprenorphine, Butorphanol, Codeine, Fentanyl, Levorphanol, Hydrocodone, Hydromorphone, Meperidine, Amphetamines, Anabolic Steroids, Barbiturates, Benzodiazepines, Diethylpropion, Chloral Hydrate, Phentermine, Gabapentin" |
| Manitoba | Manitoba Prescribing Practices Program Implementation date: 1990 | "All sales reportable narcotics (including Methadone) and controlled drugs, Butalbital, Nalbuphine, Phenobarbital with codeine, Propoxyphene, Pentazocine, Phentermine, Diethylpropion, Butorphanol" |
| Ontario | NMS "Implementation date: In April 2012, pharmacies began submitting dispensing information on all monitored drugs to NMS. Full program features still being developed." | "Any controlled substance under federal <i>Controlled Drugs and Substances Act</i> , Tramadol, Tapentadol" |
| New Brunswick | The New Brunswick PMP <i>Under development</i> | "All schedules of drugs in the federal CDSA, Tramadol, Tapentadol, Zopiclone" |
| Nova Scotia | Nova Scotia PMP "Implementation date: 1992 (TPP), 2007 (electronic submission, the triplicate prescription pad replaced with a duplicate prescription pad)" | "Any drug that is a controlled drug under the federal CDSA and is listed in the Schedules of that Act, except testosterone when compounded for topical application for local effect and benzodiazepines" |
| PEI | <i>Under development</i> | "All controlled substances in federal CDSA" |
| Newfoundland and Labrador | TRPP <i>Note: TRPP is not a monitoring program. No data collected. The triplicate prescription pads are numbered, but no tracking is done.</i> | "Determined by federal narcotic or controlled drug categories in consultation with pharmacy board" |
| Quebec | <i>No PMP in place</i> | |
| Yukon Territory | <i>Alberta's TPP</i> | <i>See above for monitored drug list in Alberta's TPP</i> |
| Northwest Territory | <i>No PMP in place</i> | |
| Nunavut | <i>No PMP in place</i> | |

CDSA = *Controlled Drugs and Substances Act*; CPP = Controlled Prescription Program; NMS = Narcotics Monitoring System; PMP = Prescription Monitoring Program; PRP = Prescription Review Program; TPP = Triplicate Prescription Program; TRPP = Tamper-Resistant Prescription Drug Pad Program.

Source: Adapted with permission from Sproule B. Prescription monitoring programs in Canada: best practice and program review. Ottawa: Canadian Centre on Substance Abuse; 2015¹

Table 4: Features of Prescription Drug Monitoring Program in Canadian Provinces and Territories – Questionable Activity Criteria and Interventions¹

| Jurisdictions | Questionable Activity Criteria | Interventions |
|------------------|--|---|
| British Columbia | <p>PRP:</p> <ul style="list-style-type: none"> • “Patients with multiple opioids, high morphine equivalents • > 300 pills per dispense • Opioids plus benzodiazepines” <p><i>Not applicable for CPP.</i></p> | <p>PRP:</p> <ul style="list-style-type: none"> • “Professional Quality Assurance Process <ul style="list-style-type: none"> ◦ 1st, 2nd, and 3rd letters sent to physicians ◦ then attend interview and/or entire Prescription Review Committee • Risk Inquiry Committee” <p><i>Not applicable for CPP.</i></p> |
| Alberta | <ul style="list-style-type: none"> • “Multi-doctoring (3 or more physicians in 3 months) • High quantity (1,000 or more doses of TPP medication at one time) • High risk: 600 mg morphine equivalents daily from > 2 physicians and > 2 pharmacies” | <ul style="list-style-type: none"> • “Multi-doctoring: flagged monthly • High quantity: flagged monthly • High risk: flagged quarterly • Prescribers receive letters from TPP • Pharmacists receive notices about high-risk patients identified • Letters sent to regulatory bodies for nurse practitioners and pharmacists <p>CPSA operates the Physician Prescribing Practices Program, which is a quality improvement program that provides educational support to physicians. Specific interventions have targeted high prescribers of opioids and benzodiazepines or meperidine, prescribers to high-risk patients, and high dose prescribers”</p> |
| Saskatchewan | <ul style="list-style-type: none"> • “Early refills (pattern over time) • High dosages • Double-doctoring (3 or more physicians in calendar month) • Long-term/chronic use of benzodiazepines • Methadone (using inappropriate drugs with methadone) • Beers criteria for elderly (benzodiazepines, meperidine)” | <p>“Unsolicited reports sent to prescribers, dispensers, and licensure boards”</p> |
| Manitoba | <i>Information not available</i> | <i>Information not available</i> |

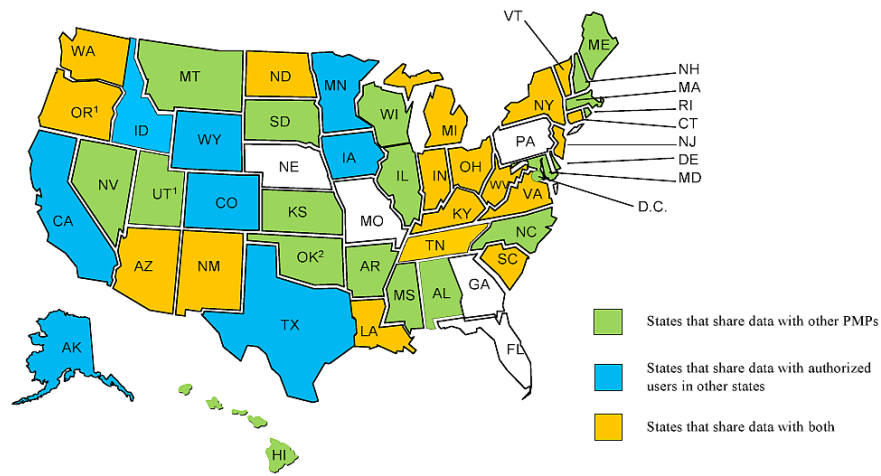
| | | |
|-----------------------------|--|--|
| <p>Ontario</p> | <ul style="list-style-type: none"> • “Double-doctoring: monitored drugs prescribed by 3 or more different prescribers in the past 28 days • Polypharmacy: obtained monitored drugs from 3 or more different dispensaries in the past 28 days • Refill too soon: a refill should not be required at this time • Fill/refill too late: a refill is overdue at this time • Duplicate drug other pharmacy: prior dispensing transaction exists for same patient, same DIN or interchangeable product, same date of service, different dispensary” | <p>Pilot stage</p> |
| <p>New Brunswick</p> | <ul style="list-style-type: none"> • “Multi-doctoring or multi-pharmacy alert: 2 or more prescriptions for 1 or more monitored drugs from 2 or more physicians or 2 or more pharmacies in consecutive 30 day period • 500 or more units of monitored drug at one time alert • Early/partial refill (not defined yet) or duplicate drug (same DIN same day) alert • May adjust all above criteria once PMP in place and feedback received” | <ul style="list-style-type: none"> • “College of Physicians can register physician with history of overprescribing with system to restrict what they can prescribe • If Patient Monitoring Agreement in place, physician or pharmacist can register patient with PMP (if patient consents) to restrict who can prescribe to them and where they can pick up monitored drugs (building on what is being done in practice) • All reports will be done in real time, proactive not reactive, intended primarily for prescribers and dispensers at point of prescribing and dispensing • Real-time system initiated alerts at time of prescribing and dispensing to prescribers and pharmacists based on criteria for questionable activity” |
| <p>Nova Scotia</p> | <ul style="list-style-type: none"> • “Multiple prescriber report (3 or more physicians) every 30 days • Every methadone patient monitored through weekly reports • Specific drug usage review for different types of drugs every 56 days • High-volume prescribers” | <ul style="list-style-type: none"> • “Methadone Program Monitoring: The program can assist methadone clinics in monitoring patients to ensure no other monitored drugs are being obtained during their treatment. • Patient/prescriber agreement monitoring: In situations where a prescriber deems a patient agreement to be appropriate, the NSPMP will monitor a patient’s profile to ensure adherence to the patient agreement. • Medical consultant: available as a resource to health care professionals, the Program and the Program’s committees. <p>If Program has reason to believe that doctor, dentist, or pharmacist may be practising in manner inconsistent with mandate of program, it may refer case on anonymous basis to program’s PRC for review and PRC can choose whether to refer individual to their licensing authority for further review. Program can provide licensing authority with information regarding activities of member of that licensing authority and shall provide licensing authority with all relevant information.</p> <p>If program has reasonable grounds to believe patient has committed offence, they must provide to appropriate law enforcement authority all necessary information including individual’s name, address, identification of drug or drugs in use, number of prescriptions dispensed, date of dispensing, and number of prescribers”</p> |

| | | |
|----------------------------------|--|---|
| Prince Edward Island | <i>To be determined</i> | <i>To be determined</i> |
| Newfoundland and Labrador | <i>TRPP is not a monitoring program. No data collected. The triplicate prescription pads are numbered, but no tracking is done.</i> | <i>"If physicians or patients previously flagged by provincial drug program then can place restrictions on them with TRPP (provincial drug program only includes those who used program not cash or any other type of transaction)"</i> |
| Yukon Territory | <i>Yukon is a participating member of the TPP with the CPSA. Yukon follows the same TPP as Alberta, but reports to Yukon Medical Council specifically about Yukon.</i> | |

CPP = Controlled Prescription Program; CPSA = College of Physicians and Surgeons of Alberta; DIN = drug identification number; NPSMP = Nova Scotia Prescription Monitoring Program; PMP = Prescription Monitoring Program; PRC = Practice Review Committee; PRP = Prescription Review Program; TPP = Triplicate Prescription Program; TRPP = Tamper-Resistant Prescription Drug Pad Program.

Source: Adapted with permission from Sproule B. Prescription monitoring programs in Canada: best practice and program review. Ottawa: Canadian Centre on Substance Abuse; 2015¹

Figure 1: Interstate Sharing of Prescription Monitoring Program Data Pursuant to Statute, Regulation, and/or Statutory Interpretation



PMP = prescription monitoring program.

Source: Reproduced with permission from the National Alliance for Model State Drug Laws. Compilation of state prescription monitoring program maps; 2014.¹⁸⁸

contributing to analysis and synthesis of data and information; and contributing to, and distributing, a national report on surveillance.⁶ It should be noted that this is a surveillance initiative rather than a prescription drug monitoring program.

United States

As of December 2013, 48 states and one territory (Guam) had operational PDMPs; New Hampshire and DC had enacted PDMP legislation (but the programs were not yet operational); and Missouri had pending PDMP legislation.⁷ The entity responsible for administering the PDMP varies by state and may be pharmacy boards, departments of health, professional licensing agencies, law-enforcement agencies, substance abuse agencies, or consumer protection agencies. Of the authorized PDMPs, nearly two-thirds are administered by either state pharmacy boards (19) or health departments (13).⁷

Opioids and stimulants are classified under US Controlled Drug Schedule II and benzodiazepines under Schedule III or IV. NAMSDL reports that all states with PDMPs have the authority to monitor all drugs within Schedules II, III, and IV.⁸⁹ Which opioids, stimulants, and benzodiazepines they actually do monitor is a subject for further research.

One area of focus at the US federal and state levels is achieving interoperability between the various state systems (Figure 1). The HHS reported to the US Congress in 2013 that a series of legal and technical interoperability challenges must be addressed.⁸ One of these challenges is the difference between state systems in their coverage of prescriptions written and dispensed. On this

topic, HHS reports that prescriber registration rates — defined as the proportion of prescribers who issued at least one controlled substance prescription in the previous three months and who had registered to use a PDMP — ranged from 1% (in newly operation states) to 82%. The median registration rate across PDMPs is 35%. HHS reports that the majority of states with PDMPs are experiencing “a steady increase” in registration rates.⁸ The Prescription Drug Monitoring Program Center of Excellence at Brandeis University is a national centre of expertise for PDMPs in the US. The Brandeis University PDMP Centre of Excellence reports that, as of 2012, just 28 states were sharing PDMP data with Medicaid or Medicare, eight with workers’ compensation programs, and only one state — Michigan — is known to have provided data to private health insurers.¹⁸⁷

Federal-level initiatives in the US to strengthen PDMPs are highlighted below:

- The US federal government has established two grant programs aimed at supporting state PDMPs: the Harold Rogers PDMP and funding through the *National All Schedules Prescription Electronic Reporting Act (NASPER)* of 2005.⁷
- The Harold Rogers PDMP was created to help law enforcement, regulatory entities, and public health officials to analyze data on prescriptions for controlled substances. The program assists states (including US territories) in the planning, implementation, and enhancement of their PDMPs.⁷
- NASPER requires the Secretary of HHS to award grants to states to establish or improve PDMPs. The two objectives of

Table 5: Access to Prescription Drug Monitoring Program (PDMP) Data Across Four Provincial PDMP Systems

| | BC | AB | SK | NS |
|--|----------------|----------------|----|----------------|
| Clients (patients) | ✓ | | | ✓ |
| Pharmacists | ✓ | ✓ | ✓* | ✓ |
| College of Pharmacists | ✓ | ✓ | | ✓ |
| Physicians | ✓ [†] | ✓ [‡] | ✓* | ✓ [§] |
| Hospitals and mental health facilities | ✓ | | | ✓ [¶] |
| College of Physicians and Surgeons | ✓ | ✓ | ✓ | ✓ |
| Other health product providers | ✓ | | | |
| Ministry of Health | ✓ | | | ✓ [¶] |
| Health care provider can request their own profile | | ✓ | | ✓ |
| College of Dentists | | ✓ | | ✓ |
| College of Veterinarians | | ✓ | | |
| Law Enforcement | | | | ✓ |
| Media, researchers, third-party insurers | | | | ✓ [¶] |

*Professionals registered with the program; [†] With patient consent (exception in emergency department, walk-in clinics and methadone clinics); [‡]Can request patient's profiles or their own profiles; [§]Can request patient profile and a prescriber peer comparison report; [¶]Aggregate data. AB = Alberta; BC = British Columbia; NS = Nova Scotia; SK = Saskatchewan

Source: Reproduced with permission from Furlan AD, et al. Overview of four prescription monitoring/review programs in Canada. *Pain Res Manag.* 2014 Mar;19(2):102-6¹⁹³

NASPER are to foster the establishment of state-administered PDMPs that providers can access for the early identification of patients at risk for addiction in order to initiate appropriate interventions, and to establish a set of best practices for new PDMPs and improvement of existing PDMPs.⁷

United Kingdom

The UK has a single NHS program, NHS Prescription Services (NHSPS). NHSPS operates a PDMP known as ePACT. This PDMP allows real-time online analysis of the previous 60 months of prescribing data held in the NHS Prescription Services' Prescribing Database, which records all prescriptions in the UK. This service is available to hospital trusts and primary care organizations and to "national users," including the Department of Health, NICE, and the Care Quality Commission. It is not known whether UK pharmacists and physicians can directly access ePACT prescription data or subsets of those data.

A subset of prescription data collected by the NHSPS is made available to CDAOs to fulfill their obligations to monitor the prescribing of Schedule 2 and 3 controlled drugs in the UK, including opioids, benzodiazepines, and stimulants. The prescribing reports made available to the CDAOs are designed to highlight potential causes for concern regarding the prescribing of controlled drugs by demonstrating variance in the prescribing of controlled drugs between organizations, and by identifying prescribers or organizations exhibiting unusual prescribing behaviour.¹⁸⁹

Australia

The Australian government and the Pharmacy Guild of Australia signed a pharmacy agreement in 2010 that provides for the development of Electronic Recording and Reporting of Controlled Drugs (ERRCD). The ERRCD initiative is intended to provide a nationally consistent system to collect and report on the prescribing of controlled drugs that will complement and support the current regulatory controls required by states and territories.¹⁹⁰ According to the Australian government and the Pharmacy Guild:

- The system will comprise a number of components, some of which will be Internet-based. It will provide a Web portal for both prescribers and pharmacists, and will integrate with pharmacy-dispensing systems to capture information relating to the provision of controlled drugs.
- The system will provide the capacity for state and territory regulators to access recorded information through a secure Web interface, allowing them to manage the system and respond as required to alerts raised by the system.
- During a clinical interaction, authorized prescribers and pharmacists may access data on a consumer via a secure Web portal that may help to inform their clinical decision-making.
- The ability of prescribers and pharmacists to view the history of controlled drugs that have been dispensed to a consumer will be a key feature of the system.¹⁹⁰

The ERRCD has not yet been fully developed or adopted as a national system.¹⁹¹ Further research is required to identify which opioids, benzodiazepines, and stimulants will be monitored under the ERRCD. An October 2014 editorial in the Australian peer-reviewed journal *Drug and Alcohol Review* reports: “The proposed Australian PMP will monitor only Schedule 8 controlled drugs, including stronger opioids such as oxycodone morphine and fentanyl, and the benzodiazepines flunitrazepam and alprazolam. The system will not monitor weaker opioids such as tramadol, codeine-paracetamol combinations and the majority of benzodiazepines, despite these also being important contributors to morbidity and mortality... The range of drugs covered is a crucial part of any PMP, and the range proposed for Australia does not cover the full range of pharmaceutical drugs with known significant non-medical use and harms.”¹⁹²

4.2 Prescription Drug Monitoring Program Coverage, Requirements for Prescribers and Dispensers, and Access

Different PDMPs within different jurisdictions have a range of requirements for prescribers and dispensers. Some of these requirements (such as any requirements to check patient identification) are not technically a requirement of the PDMP itself but rather are embedded in relevant laws and regulations for prescribing and dispensing drugs, including opioids, benzodiazepines, and stimulants.

Canada

A 2014 appraisal of four provincial PDMP programs (British Columbia, Alberta, Saskatchewan, and Nova Scotia) by Furlan et al. found that all programs include controlled substances (narcotics, barbiturates, and psychostimulants). Access to the database is available to pharmacists in all provinces. Physicians need consent from patients in British Columbia, and only professionals registered with the program can access the database in Alberta. The definition of inappropriate prescribing and dispensing is not uniform. Double-doctoring, double pharmacy, and high-volume dispensing are considered to be red flags in all programs.¹⁹³

Information assembled in the Furlan et al. study (Table 5) provides a summary of who can access PDMP data.

Privacy considerations are one of the key factors that influence decisions on who can access PDMP data (e.g., physicians or persons delegated by physicians), under what circumstances, for what purposes, and even where access can take place (e.g., within doctors’ offices or elsewhere).⁸

Available information from British Columbia illustrates the range of detailed access conditions that can prevail in any given PDMP system.

- The use of PharmaNet (the underlying infrastructure for the province’s PDMP) is not mandatory for physicians in a traditional clinic with no walk-in component. It is mandatory for physicians working in transient care settings or methadone maintenance programs to access patient prescription profiles through PharmaNet.^{194,195} Patient consent is necessary to access a PharmaNet profile, although, as pointed out by Furlan et al., no consent means no opioid prescription.¹⁹³ Furlan et al. reports that most British Columbian physicians do not have access to PharmaNet in their offices.¹⁹³
- Pharmacists in British Columbia can access PharmaNet information only in the performance of their professional duties. If a medication history is accessed when a prescription is not dispensed, the pharmacist must keep a record of the reason for the access. CPBC is responsible for monitoring and investigating inappropriate access by its members.¹⁹⁶

The more recent CCSA report (2015) presents information (see Appendix 5 of the CCSA report) on the level of access clinicians have to the patient profiles in the PDMPs. For example, Ontario clinicians have no direct access to patient profiles, whereas in Saskatchewan, all providers have access through the Prescription Information Program.¹

4.3 Assessments of Prescription Drug Monitoring Program Effectiveness

The literature review conducted for this Environmental Scan identified several academic and management studies of PDMPs, primarily of US origin. These studies consider the effectiveness of PDMPs from both operational and health outcome perspectives. A systematic review of these literatures is out of the scope of this Environmental Scan. However, key messages from some of the identified studies are presented below as an indicator of the potential effectiveness of PDMPs.

Operational Effectiveness

A growing body of evidence illustrates that, apart from interoperability between PDMP systems, a cultural challenge also exists in integrating PDMPs into workflows and clinical decision-making. One qualitative US study that investigated how clinicians use PDMPs found that routines for accessing PDMP data and how

clinicians respond to it vary widely.¹⁹⁷ The study states that “as PDMP use becomes more widespread, it will be important to understand what approaches are most effective for identifying and addressing unsafe medication use.”¹⁹⁷ This same point has been made in recent presentations on US PDMPs by an official from the NABP.¹⁹⁸

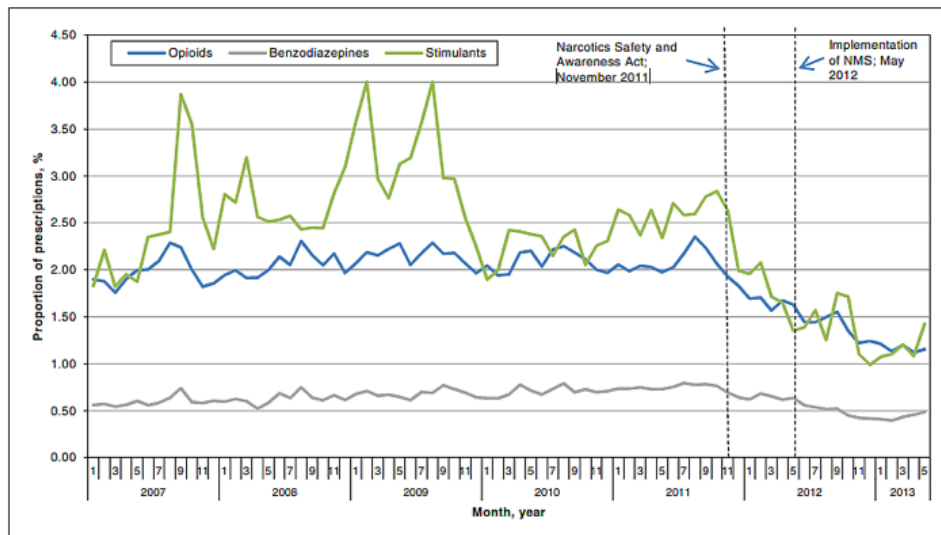
Health Outcomes

In the US, HHS reported to Congress, in 2012, that the literature on the impact of PDMPs on the abuse of opioid analgesics is increasing and that “research consistently suggests that PDMPs reduce the prescribing of Schedule II opioid analgesics.”⁸ HHS also acknowledges that not all of the available studies are positive. HHS cites one study that indicated there were compensatory increases in the prescribing of Schedule III opioids and no change in total prescribing in states with PDMPs compared with those without one.⁹ Yet another study found that states with PDMPs had lower substance abuse treatment rates for opioids from 1997 to 2003 compared with states without PDMPs.⁸

Gomes et al. evaluated the impact of the Government of Ontario’s *Narcotics Safety and Awareness Act* and Narcotics Monitoring System, a PDMP program on the rate of dispensing monitored drugs to beneficiaries of the public drug plan in Ontario that was highly likely to represent misuse.¹⁹⁹ The results of this time-series analysis of publicly funded prescriptions for opioids, benzodiazepines, and stimulants dispensed monthly in Ontario from January 2007 to May 2013 are presented in Figures 2 and 3. The authors concluded the following:

“The enactment of legislation requiring patient identification on prescriptions for monitored drugs and a prescription-monitoring program providing real-time data access to pharmacists led to substantial reductions in the prevalence of prescriptions for opioids and controlled substances that were highly likely to represent misuse.”¹⁹⁹

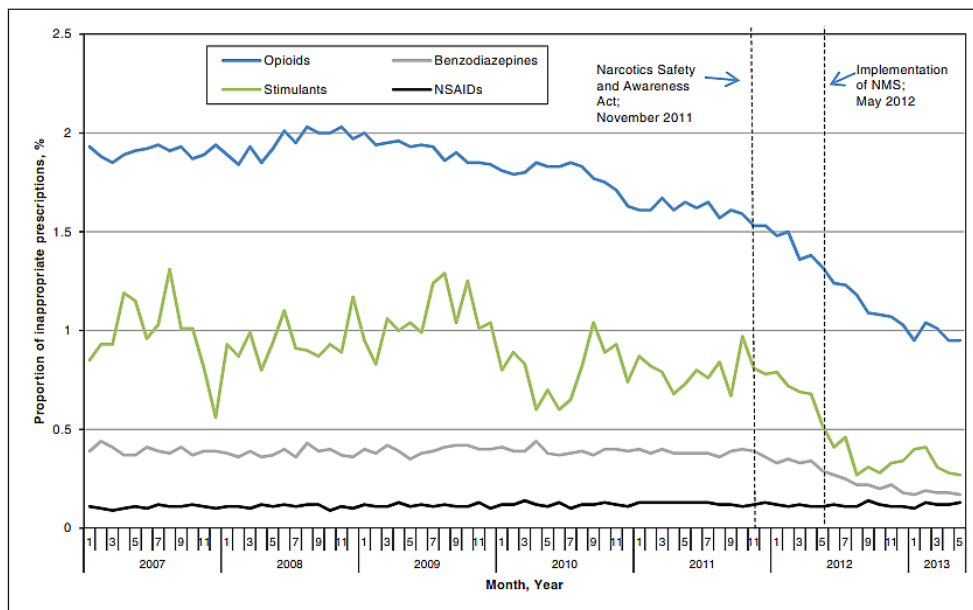
Figure 2: Prevalence of Potentially Inappropriate Prescriptions in Ontario, by Monitored Drug, Before and After Introduction of Safety Legislation and a Monitoring Program, January 2007 to May 2013



NMS = Narcotics Monitoring System.

Source: Reproduced with permission from Gomes T, et al. Impact of legislation and a prescription monitoring program on the prevalence of potentially inappropriate prescriptions for monitored drugs in Ontario: a time series analysis. CMAJ Open. 2014;2(4):E256-E261¹⁹⁹

Figure 3: Prevalence of Opioid, Benzodiazepine, and Stimulant Prescriptions Triggering Drug Utilization Review Warnings of Both Double-Doctoring and Polypharmacy in Ontario Before and After Introduction of Safety Legislation and a Monitoring Program, January 2007 to May 2013



NMS = Narcotics Monitoring System; NSAID = nonsteroidal anti-inflammatory drug.

Source: Reproduced with permission from Gomes T, et al. Impact of legislation and a prescription monitoring program on the prevalence of potentially inappropriate prescriptions for monitored drugs in Ontario: a time series analysis. CMAJ Open. 2014;2(4):E256-E261¹⁹⁹

SECTION 5: Other Regulatory and Oversight Activities

5.1 Measures to Incentivize the Innovation or Approval of Tamper-Resistant Opioids, Benzodiazepines, and Stimulants

The information reviewed during this Scan identified the following range of policy measures in the general topic area of incentives for tamper-resistant formulations of opioids, benzodiazepines, and stimulants, all of which could be the subject of further research.

Government Measures to Promote Company Investment in Tamper-resistant Formulations

Supported by a range of stakeholders, the Australian National Pharmaceutical Drug Misuse Framework for Action 2012–2015 identifies the need to promote the use of tamper-resistant technologies for targeted medicines as one of the recommended actions.¹⁴⁹

Government-Led Research Investments in Tamper Resistance

In 2013, the US National Institutes of Health and the US National Institute on Drug Abuse issued a “fast track” Small Business Innovation Research Grant notice. The notice states that proposals totalling US\$3 million will be considered for “Abuse-Resistant and Abuse-Deterrent Formulations and Devices to Avoid the Abuse, Misuse and Diversion of Prescription Opioids by Patients.”²⁰⁰

Regulatory Measures

Canada

In 2014, a comprehensive review on prescription drug abuse was completed by the Standing Committee of Health; it was recommended that the merits of tamper-resistant products should be considered by the Canadian government.²⁰² In June 2014, as part of its comprehensive approach to addressing prescription drug abuse, Health Canada posted a Notice of Intent to interested parties (for feedback) that described a proposal to develop new regulations for tamper-resistant formulations under the CDSA.²⁰²

The proposed regulation would require products containing specified controlled substances, or classes thereof, to have tamper-resistant properties in order to be sold in Canada.²⁰² In December 2014, Health Canada posted a *Draft Guidance Document: Tamper-Resistant Formulations of Opioid Drug Product Submissions* for stakeholder consultation.²⁰³ This draft guidance document is intended for the pre-market review of drug submissions when sponsors seek to obtain approval for opioid drug formulations with tamper resistance, and wish to include, in product monographs, scientific statements and claims regarding tamper resistance.²⁰³ To assist manufacturers in their efforts to bring tamper-resistant drugs to market, Health Canada is in the process of finalizing guidance to industry on the studies and information that are required to support Health Canada’s assessment of the tamper-resistant properties for controlled-release opioids.¹³

Most recently, in June 2015, a pre-consultation notice was posted for public consultation on the draft regulations, titled *Proposed Tamper-Resistant Properties of Drugs Regulations*. These draft regulations propose the following:¹³

- “Controlled-release solid oral dosage forms of oxycodone products, where oxycodone is the only medicinal ingredient, be required to have tamper-resistant properties.
- Within Health Canada, there will be one process for assessing a product’s tamper-resistant properties. Authorizations of tamper-resistant properties for the proposed Regulations would link to the existing drug submission and scientific review process under the *Food and Drugs Act*.
- A product will be considered tamper-resistant if its product monograph includes a statement that the product has a tamper-resistant property. The scientific evidence that will be included in the sponsor’s submission to support the statements and the acceptable statements of tamper-resistant properties in the product monograph are described in Health Canada’s guidance document, published in draft form for public consultation in, at http://www.hc-sc.gc.ca/dhp-mps/consultation/drug-medic/consult_draft_guid_opioid_ebauche_ld-eng.php (i.e., draft guidance posted for public consultation in Dec 2014²⁰³).
- The Regulations propose a three-year coming-into-force period to provide sufficient time for product reformulation and the necessary supply chain adjustments. The Regulations would apply to parties

authorized as licensed dealers (e.g., manufacturers, distributors, wholesalers) under the CDSA. Other parties regulated under the CDSA, including pharmacists, hospitals and practitioners, could deplete existing stock, or return it to distributors.

- Sponsors of products sold in Canada with approved tamper-resistant statements would be required to gather data on the abuse and abuse potential of these products. This information could be requested by the Minister, which would establish a mechanism to monitor the impact on abuse of the tamper-resistant formulation over time.
- In the event that the continued sale of a tamper-resistant product presents a risk to public health, safety or security, the Minister would have the authority to suspend the authorization for the sale and distribution of that product in Canada.¹³

United States

- In January 2013, the FDA released the draft *Abuse-Deterrent Opioids: Evaluation and Labeling Guidance for Industry*, which has two overarching goals:
 - Provide incentive for developing successful abuse-deterrent formulations of opioids and
 - Assure appropriate development and availability of generic drugs, reflecting their importance in US health care.^{204,205}

More than two years later, on April 1, 2015, the FDA issued its final guidance on the evaluation and labelling of abuse-deterrent opioids.²⁰⁶ The guidance calls on companies to conduct four major categories of study:

- Category 1: Laboratory-based in vitro manipulation and extraction studies
- Category 2: Pharmacokinetic studies
- Category 3: Clinical abuse potential studies
- Category 4: Post-market data analysis of actual abuse.

The guidance provides advice on the conduct of studies within each category. For example, category 1 studies should involve the use of a comparator, and should assess a product's susceptibility to being crushed, cut, grated, grinded, dissolve, and extracted. The FDA recommended that "studies should be designed with knowledge of the physicochemical properties of the product and the methods available to abusers to manipulate the product, and should be conducted on the to-be-marketed formulation."²⁰⁷

Development of the FDA guidance illustrates the scientific controversy surrounding abuse deterrence.²⁰⁷⁻²⁰⁹ The FDA news release announcing the final guidance states:

"While this final guidance does not address generic opioid products, the agency understands the importance of available generic options to ensure appropriate access to effective opioid drugs for patients who need them. The FDA is committed to supporting the development and use of generic drugs that have abuse-deterrent properties and is working on draft guidance in this area."²⁰⁶

The FDA draws on other regulatory instruments to incentivize the development of tamper-resistant drug formulations. For example, the FDA has four programs that are intended to facilitate and expedite development and review of new drugs to address unmet medical need in the treatment of a serious or life-threatening condition: fast track designation, breakthrough therapy designation, accelerated approval, and priority review.²¹⁰ For example, in July 2014, the FDA granted priority review designation to Purdue Pharma's once-daily, single-entity hydrocodone bitartrate tablet.²¹¹ Priority Review is granted by the FDA to applications for drugs that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared with standard applications.²¹¹ On November 20, 2014, the FDA approved the ER, single-entity hydrocodone product with abuse-deterrent properties, stating that the product's abuse-deterrent properties are consistent with the FDA's 2013 draft guidance for industry, *Abuse-Deterrent Opioids: Evaluation and Labeling*.⁹

The FDA has already approved some drugs with the abuse-deterrent labelling, such as for reformulated OxyContin (oxycodone hydrochloride controlled-release) tablets; Targiniq ER, a new ER pain reliever that contains a combination of oxycodone and naloxone; Embeda (morphine sulfate and naltrexone hydrochloride) ER capsules; and Hysingla ER (hydrocodone bitartrate), an ER opioid analgesic.⁹⁻¹²

Other Countries

Further research is required to identify similar regulatory measures in other jurisdictions intended to incentivize the development of tamper-resistant drug formulations. The European Medicines Agency is developing a draft guideline on the clinical development of medicinal products intended for the treatment of pain.²¹² The Agency's draft guidance makes no mention of tamper-resistance or abuse-deterrence formulations.

Conclusion

The issue of prescription drug abuse is common to all the jurisdictions studied in this Scan. Policies and strategies to reduce prescription drug harms are developed and executed by various public (federal-, provincial-, or state-level) authorities and private payers within each jurisdiction, such as public drug plans, private payers, regulatory agencies, professional regulatory bodies, and public health harm-reduction units. A varying combination of these policies and strategies are seen in each jurisdiction, including education and training, controlling and monitoring access to these drugs, and other regulatory measures. Most of the strategies identified by this Scan focused on opioids compared with benzodiazepines and stimulants.

Health care professionals are generally not mandated to undertake additional education (after they attain their professional degree) on appropriately prescribing opioids, stimulants, and/or benzodiazepines, except in instances of professional regulatory bodies' quality assurance process; as a part of addressing professional misconduct (i.e., inappropriate prescribing); when extending prescribing authority to nurses or pharmacists; in accreditation of pain clinics (in the US); or to receive an exemption to prescribe methadone, buprenorphine, or buprenorphine plus naloxone (e.g., Suboxone) to treat opioid dependence.

CPGs can also promote appropriate prescribing and dispensing. Among the CPGs identified by this Environmental Scan, the *Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain* was widely recognized in Canada, used in developing training tools, and referenced by medical authorities in the US. The number of CPGs identified by this report for stimulants and benzodiazepines was smaller than that of opioids.

Formulary listing and reimbursement strategies for opioids, stimulants, and benzodiazepines vary across the public drug plans in Canada. Some of these strategies used in Canada include prior approval or special authorization requirements; quantity or dose limits; listing certain formulations (e.g., tamper-resistant formulations of opioids) or delisting certain drugs or drug classes. In addition, payer incentives for pharmacists for activities such as "refusal to fill" for suspected misuse and abuse and restricting a patient to a single pharmacy or prescriber were also identified in Canada, as well as other countries.

Prescription-writing and -dispensing strategies to reduce prescription drug harms include refill restrictions, requirements for patients to present identification to prescribers and/or dispensers, requirements for pharmacists to keep a record of patients' identification, and limits on the prescription validity period. The 2015 CADTH survey of public drug plans illustrates that one or more of these requirements is in place in most Canadian jurisdictions, but the specific requirements vary.

Naloxone is a well-known drug used in case of opioid overdose. The Scan found that there is a trend toward reconsidering access requirements for naloxone in all the jurisdictions studied. In July 2015, Health Canada announced its intention to review the prescription-only status of naloxone. Most of the Canadian public drug plans do not list or reimburse for naloxone, but they are available in some Canadian cities and provinces through public health and harm-reduction units.

Monitoring the prescription of opioids, stimulants, and benzodiazepines, and subsequent intervention in case of misuse, is one of the tools for deterring prescription drug abuse. These PDMPs, either paper-based (i.e., use of tamper-resistant drug pads) or electronic, are found in most of the Canadian jurisdictions as well as other countries studied by this Scan. The majority of the PDMPs in Canada and other countries monitor one or more opioids, benzodiazepines, or stimulants, although the precise range of specific opioids, stimulants, or benzodiazepines varies across PDMPs. Similarly, the functionality, level of information stored in the PDMPs and access to information, types of questionable activity tracked by these PDMP, and the subsequent intervention vary.

Some jurisdictions are also promoting the development of tamper-resistant formulations of drugs that have the potential for misuse and abuse. The US government has promoted investment in tamper-resistant formulations of these prescription drugs through grants as well as changes in drug approval regulations, such as the FDA guidance for industry, *Abuse-Deterrent Opioids – Evaluation and Labeling*.²⁰⁶ The FDA has already approved some drugs with the abuse-deterrent labelling.⁹⁻¹² Similarly, Health Canada is currently consulting with Canadians on its draft *Proposed Tamper-Resistant Properties of Drugs Regulations*.¹³

Among the national jurisdictions covered by this Scan, the US appears to have made the most investment in programs and policies to address prescription drug harms.

Some of the emerging trends identified by this Scan are the development of educational tools to change prescriber behaviour; investment in improving access, scope, and functionality of PDMPs; reconsidering access requirements for naloxone; and regulatory agencies' exploration of tamper-resistant formulations of opioids. However, it should be noted that this Environmental Scan does not provide a comprehensive review of these policies, and it also does not appraise the effectiveness of these policies. Hence, it does not recommend one particular policy option over other. The Environmental Scan only serves to illustrate the range of the possible policy options and potentially inform future policy directions for achieving safe and effective use of opioids, stimulants, and benzodiazepines.

References

1. Sproule B. Prescription monitoring programs in Canada: best practice and program review [Internet]. Ottawa: Canadian Centre on Substance Abuse; 2015 Apr. [cited 2015 May 22]. Available from: <http://www.ccsa.ca/Resource%20Library/CCSA-Prescription-Monitoring-Programs-in-Canada-Report-2015-en.pdf>
2. Smith N, Quansah K, Chelak K, Fitzsimmons H. Narcotics, benzodiazepines, stimulants, and gabapentin: policies, initiatives, and practices across Canada, 2014 [Internet]. Ottawa: CADTH; 2014 Oct. (Environmental Scan; issue 45). [cited 2015 Aug 11]. Available from: http://www.cadth.ca/media/pdf/ES0285_Narcotics_BZD_Stimulants_Gabapentin_e.pdf
3. Government of Canada [Internet]. Ottawa: Health Canada. Background: improving prescribing practices for commonly abused prescription drugs; 2015 May 15 [cited 2015 May 22]. Available from: <http://news.gc.ca/web/article-en.do?nid=974739>
4. Toward the Heart. Take home naloxone: backgrounder [Internet]. Vancouver: BC Centre for Disease Control, Harm Reduction Program; 2012. [cited 2015 May 6]. Available from: http://towardtheheart.com/assets/uploads/files/Backgrounder_2012.08.29.pdf
5. Carter CI, Graham B. Opioid overdose prevention & response in Canada [Internet]. Vancouver: Canadian Drug Policy Coalition; 2013. [cited 2015 May 6]. Available from: http://drugpolicy.ca/wp-content/uploads/2014/07/CDPC_OverdosePreventionPolicy_Final_July2014.pdf
6. Government of Canada [Internet]. Ottawa: Health Canada. Background: funding to the Canadian Institute for Health Information to help address prescription drug abuse; 2015 May 15 [cited 2015 May 22]. Available from: <http://news.gc.ca/web/article-en.do?nid=974749>
7. Finklea K, Sacco LN, Bagalman E. Prescription drug monitoring programs [Internet]. Washington (DC): Congressional Research Service; 2014 Mar 24. Report No.: 7-5700. [cited 2015 Aug 11]. Available from: <http://fas.org/sgp/crs/misc/R42593.pdf>
8. The Office of the Assistant Secretary for Health. Prescription drug monitoring program interoperability standards: a report to congress [Internet]. Washington (DC): Department of Health and Human Services; 2013 Sep. [cited 2015 Aug 11]. Available from: http://www.healthit.gov/sites/default/files/fdasia1141report_final.pdf
9. U.S. Food and Drug Administration [Internet]. Silver Spring (MD): The Administration. FDA approves extended-release, single-entity hydrocodone product with abuse-deterrent properties; 2014 Nov 20 [cited 2015 May 22]. Available from: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm423977.htm>
10. U.S. Food and Drug Administration [Internet]. Silver Spring (MD): The Administration. FDA approves abuse-deterrent labeling for reformulated OxyContin; 2013 Apr 16 [cited 2015 Aug 4]. Available from: <http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm348252.htm>
11. U.S. Food and Drug Administration [Internet]. Silver Spring (MD): The Administration. FDA approves Targiniq ER with abuse-deterrent properties; 2014 Jul 23 [cited 2015 Aug 4]. Available from: <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm406290>
12. U.S. Food and Drug Administration [Internet]. Silver Spring (MD): The Administration. FDA approves labeling with abuse-deterrent features for third extended-release opioid analgesic; 2014 Oct 17 [cited 2015 Aug 4]. Available from: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm419288.htm>
13. Government notices: Department of Health, Controlled Drugs and Substances Act. Pre-consultation notice - proposed tamper-resistant properties of drugs regulations. Canada Gazette [Internet]. 2015 Jun 27 [cited 2015 Aug 4];149(26). Available from: <http://www.gazette.gc.ca/rp-pr/p1/2015/2015-06-27/html/notice-avis-eng.php>
14. Epidemic: responding to America's prescription drug abuse crisis [Internet]. Washington (DC): Executive Office of the President of the United States; 2011. [cited 2014 Oct 21]. Available from: http://www.whitehouse.gov/sites/default/files/ondcp/issues-content/prescription-drugs/rx_abuse_plan.pdf
15. U.S. Department of Health & Human Services [Internet]. Washington (DC): The Department. HHS takes strong steps to address opioid-drug related overdose, death and dependence; 2015 Mar 26 [cited 2015 Aug 4]. Available from: <http://www.hhs.gov/news/press/2015spres/03/20150326a.html>
16. Canadian Centre on Substance Abuse. First do no harm: responding to Canada's prescription drug crisis [Internet]. Ottawa: The Centre; 2013 Mar. [cited 2015 Aug 11]. Available from: <http://www.ccsa.ca/resource%20library/canada-strategy-prescription-drug-misuse-report-en.pdf>
17. Paperny AM. Updated: opioids killing more Ontarians than ever, coroner's numbers show. Global News [Internet]. 2014 Nov 9 [cited 2015 Aug 11]. Available from: <http://globalnews.ca/news/1625100/opioids-killing-more-ontarians-than-ever-coroners-numbers-show/>
18. Canadian Pain Coalition. Canadian pain clinic listing [Internet]. Oshawa (ON): The Coalition; 2015 Mar. [cited 2015 Aug 11]. Available from: http://www.canadianpaincoalition.ca/downloads/pain_clinics.pdf
19. Pharmaceutical Society of Australia. Standard and guidelines for pharmacists providing a staged supply service for prescribed medicines [Internet]. Deakin (AU): The Society; 2011 Mar. [cited 2015 Aug 11]. Available from: <http://www.psa.org.au/download/practice-guidelines/staged-supply-guideline.pdf>
20. College of Physicians and Surgeons of British Columbia: serving the public through excellence and professionalism in medical practice [Internet]. Vancouver: The College. 2015 [cited 2015 Aug 11]. Available from: <https://www.cpsbc.ca/>
21. College of Physicians & Surgeons of Nova Scotia [Internet]. Halifax: The College. Physician guidelines and policies; 2014 [cited 2015 Aug 11]. Available from: <http://www.cpsns.ns.ca/PhysicianGuidelinesandPolicies.aspx?CategoryId=2>
22. General Medical Council. Good medical practice [Internet]. Manchester (GB): The Council; 2013 Mar 25. [cited 2015 Aug 11]. Available from: http://www.gmc-uk.org/static/documents/content/Good_medical_practice_-_English_0914.pdf
23. Nursing and Midwifery Council. Standards for medicines management [Internet]. London (GB): The Council; 2015. [cited 2015 Aug 11]. Available from: <http://www.nmc.org.uk/standards/additional-standards/standards-for-medicines-management/>
24. American Dental Association. Principles of ethics and code of professional conduct [Internet]. Chicago (IL): The Association; 2012. [cited 2015 Aug 11]. Available from: http://www.ada.org/~/media/ADA/About%20the%20ADA/Files/code_of_ethics_2012.ashx
25. Medical Council of New Zealand. Good prescribing practice [Internet]. Wellington (NZ): The Council; 2010 Apr. [cited 2015 Aug 11]. Available from: <https://www.mcnz.org.nz/assets/News-and-Publications/Statements/Good-prescribing-practice.pdf>
26. Medical Council of New Zealand. Prescribing drugs of abuse [Internet]. Wellington (NZ): The Council; 2010 Apr. [cited 2015 Aug 11]. Available from: <https://www.mcnz.org.nz/assets/News-and-Publications/Statements/Prescribing-drugs-of-abuse.pdf>
27. General Pharmaceutical Council. Standards for continuing professional development [Internet]. London (GB): The Council; 2010 Sep. [cited 2015 Aug 11]. Available from: <http://www.pharmacyregulation.org/sites/default/files/Standards%20for%20continuing%20professional%20development%20s.pdf>

28. Association of Registered Nurses of Newfoundland and Labrador. Standards for nurse practitioner practice in Newfoundland & Labrador [Internet]. St. John's (NL): The Association; 2013 Jun. [cited 2015 Aug 11]. Available from: http://www.arnnl.ca/sites/default/files/Standards_for_NP_Practice_in_NL.pdf
29. The Royal Australian College of General Practitioners. Standards for general practices [Internet]. 4th ed. Melbourne: The College; 2010 Oct. [cited 2015 Aug 11]. Available from: http://www.nsmc.com.au/Uploads/Documents/RACGP%20Standards%20for%20General%20Practice%20%e2%80%93%204th%20Edition_20130514114447.pdf
30. Pharmaceutical Society of Australia. National competency standards framework for pharmacists in Australia [Internet]. Deakin (AU): The Society; 2010. [cited 2015 Aug 11]. Available from: <http://www.psa.org.au/download/standards/competency-standards-complete.pdf>
31. College of Physicians and Surgeons of Manitoba [Internet]. Winnipeg: The College. Continuing professional development; 2012 [cited 2015 Aug 11]. Available from: <http://cpsm.mb.ca/standards/continuing-professional-development>
32. College of Physicians and Surgeons of Ontario. The practice guide: medical professionalism and College policies [Internet]. Toronto: The College; 2009. [cited 2015 Aug 11]. Available from: http://www.cpso.on.ca/uploadedFiles/policies/guides/PracticeGuideExtract_08.pdf
33. Royal College of Physicians and Surgeons of Canada. A continuing commitment to lifelong learning: guide to maintenance of certification [Internet]. Ottawa: The College; 2014. [cited 2015 Aug 11]. Available from: http://www.royalcollege.ca/portal/page/portal/rc/common/documents/moc_program/moc_long_guide_e.pdf
34. The controlled drugs (supervision of management and use) regulations 2013 [Internet]. legislation.gov.uk; 2013. [cited 2015 Aug 11]. Available from: <http://www.legislation.gov.uk/uksi/2013/373/contents/made>
35. British Columbia Health Professions Act [RSBC 1996] Chapter 183 [Internet]. Victoria: 2015 Jul 29. [cited 2015 Aug 11]. Available from: http://www.bclaws.ca/civix/document/id/complete/statreg/96183_01
36. College of Physicians and Surgeons of BC. Quality assurance. College quarterly [Internet]. 2013 Mar [cited 2015 May 25];(79):5-7. Available from: http://www.cpsbc.ca/files/pdf/CQ_March_2013_Web.pdf
37. Federation of State Medical Boards. Model policy on the use of opioid analgesics in the treatment of chronic pain [Internet]. Washington (DC): The Federation; 2013 Jul. [cited 2015 Aug 11]. Available from: http://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/pain_policy_july2013.pdf
38. U.S. Food and Drug Administration [Internet]. Silver Spring (MD): The Administration. FDA introduces new safety measures for extended-release and long-acting opioid medications; 2012 Jul 9 [cited 2015 Aug 11]. Available from: <http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm310870.htm>
39. U.S. Food and Drug Administration. Introduction for the FDA blueprint for prescriber education for extended-release and long-acting opioid analgesics [Internet]. Silver Spring (MD): The Administration; 2014 Dec. [cited 2015 Aug 11]. Available from: <http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm361069.htm>
40. U.S. Food and Drug Administration. Extended-release (ER) and long-acting (LA) opioid analgesics risk evaluation and mitigation strategy (REMS) [Internet]. Silver Spring (MD): The Administration; 2015 Jun. [cited 2015 Aug 11]. Available from: <http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM311290.pdf>
41. National Alliance for Model State Drug Laws. 2013-2014 federal bills table [Internet]. Charlottesville (VA): The Alliance; 2014 Sep 12. [cited 2015 Aug 11]. Available from: <http://www.namsdl.org/library/CE6B2DC4-D6AF-DA7E-D0B69F87331A6B79/>
42. National Conference of State Legislatures. Prevention of prescription drug overdose and abuse [Internet]. Washington (DC): The Conference; 2014 Jul 28. [cited 2015 Aug 11]. Available from: <http://www.ncsl.org/research/health/prevention-of-prescription-drug-overdose-and-abuse.aspx>
43. MyCME [Internet]. Paramus (NJ): Haymarket Medical Education. State license CME/CE requirements for physicians, nurse practitioners, and physician assistants; 2015 [cited 2015 Aug 11]. Available from: <http://www.mycme.com/state-licensing-cmece-requirements/section/3858/>
44. Pain relief act [Internet]. In: New Mexico statutes annotated. Santa Fe: The State of New Mexico; 1978. Chapter 24-2D [cited 2015 Aug 12]. Available from: <http://www.nmmb.state.nm.us/docs/statutes/PainReliefAct.pdf>
45. Continuing education for prescription drugs: 2013 general session [Internet]. Salt Lake City: Utah State Legislature; 2013. [cited 2015 Aug 12]. Available from: <http://le.utah.gov/~2013/bills/static/SB0214.html>
46. American Dental Association. Statement on the use of opioids in the treatment of dental pain [Internet]. Chicago (IL): The Association; 2005. [cited 2015 Aug 12]. Available from: <http://www.ada.org/en/about-the-ada/ada-positions-policies-and-statements/statement-on-opioids-dental-pain>
47. Partnership for Drug-Free Kids [Internet]. New York: Partnership for Drug-Free Kids; 2015. Calls grow for mandatory education for physician opioid prescribing; 2011 Oct 7 [cited 2015 Aug 12]. Available from: <http://www.drugfree.org/join-together/calls-grow-for-mandatory-education-for-physician-opioid-prescribing/>
48. American Academy of Family Physicians. Pain management and opioid abuse: a public health concern. Position paper [Internet]. Leawood (KS): The Academy; 2012 Jul. [cited 2015 Aug 12]. Available from: http://www.aafp.org/dam/AAFP/documents/patient_care/pain_management/opioid-abuse-position-paper.pdf
49. Kirschner N, Ginsburg J, Sulmasy LS, Health and Public Policy Committee of the American College of Physicians. Prescription drug abuse: executive summary of a policy position paper from the American College of Physicians. Ann Intern Med. 2014 Feb 4;160(3):198.
50. Controlled drugs (supervision of management and use) regulations 2013 [Internet]. London (GB): Department of Health; 2013 Feb. [cited 2015 Aug 12]. Available from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/214915/15-02-2013-controlled-drugs-regulation-information.pdf
51. Department of Health and Social Services. Explanatory memorandum to the National Health Service (physiotherapist, podiatrist or chiroprapist independent prescribers) (Miscellaneous Amendments) (Wales) Regulations 2014 [Internet]. Cardiff: The National Assembly for Wales; 2014 Aug 27. [cited 2015 Aug 11]. Available from: [http://www.assembly.wales/laid%20documents/sub-ld9904-em%20explanatory%20memorandum%20to%20the%20national%20health%20service%20\(physiotherapist,%20podiatrist%20or%20chiroprapist%20independent/sub-ld9904-em.pdf](http://www.assembly.wales/laid%20documents/sub-ld9904-em%20explanatory%20memorandum%20to%20the%20national%20health%20service%20(physiotherapist,%20podiatrist%20or%20chiroprapist%20independent/sub-ld9904-em.pdf)
52. General Pharmaceutical Council [Internet]. London (GB): The Council; 2015. Pharmacist independent prescriber; [cited 2015 Aug 12]. Available from: <http://www.pharmacyregulation.org/education/pharmacist-independent-prescriber>
53. Health Professions Regulatory Advisory Council (HPRAC). Prescribing and administration of drugs by non-physician health professionals: a literature review [Internet]. Toronto: The Council; 2008 Nov. [cited 2015 Aug 12]. Available from: http://www.ccnm.edu/sites/ccnm/files/pdfs/news_events/press_releases/hprac/drugs_review.pdf
54. GOV.UK [Internet]. London (GB): Government of the United Kingdom, Department of Health. Nurse and pharmacist independent prescribing changes announced; 2012 Apr 23 [cited 2015 Aug 12]. Available from: <https://www.gov.uk/government/news/nurse-and-pharmacist-independent-prescribing-changes-announced>

55. Tonna AP, Stewart D, McGaig D. An international overview of some pharmacist prescribing models. *Journal of the Malta College of Pharmacy Practice* [Internet]. 2008 [cited 2015 Aug 12];(14):20-6. Available from: <http://www.cff.org.br/userfiles/105%20-%20TONNA%20AP%20An%20international%20overview%20of%20some%20pharmacists%20prescribing%20models.pdf>
56. Canadian Council of Registered Nurse Regulators (CCRN). CCRNR [Internet]. Beaverton (ON): The Council; 2015. Nurse practitioner practice analysis project; [cited 2015 Aug 11]. Available from: <http://www.ccrnr.ca/np-practice-analysis.html>
57. College of Nurses of Ontario [Internet]. Toronto: College of Nurses of Ontario; c2015. Controlled substances; 2014 Mar 18 [cited 2015 Jun 2]. Available from: <http://www.cno.org/kickers/controlled-substances/>
58. The Guardian [Internet]. Charlottetown (PEI): The Guardian. More training needed before nurse practitioners can prescribe narcotics: Currie; 2014 Nov 5 [cited 2015 Aug 12]. Available from: <http://www.theguardian.pe.ca/News/Local/2014-11-05/article-3929601/More-training-needed-before-nurse-practitioners-can-prescribe-narcotics%3A-Currie/1>
59. National Center for Chronic Disease Prevention and Health Promotion. State law fact sheet: select features of state pharmacist collaborative practice laws [Internet]. Atlanta: Centers for Disease Control and Prevention; 2013 Dec. [cited 2015 Aug 12]. Available from: http://www.cdc.gov/dhdsp/pubs/docs/Pharmacist_State_Law.PDF
60. College of Pharmacists of British Columbia. Framework of professional practice [Internet]. Vancouver: The College; 2006 Mar. [cited 2015 Aug 12]. Available from: http://library.bcpharmacists.org/D-Legislation-Standards/D-2_Provincial_Legislation/1009-FPP.pdf
61. Drugs and Alcohol Unit, Home Office. Circular 019/2015: misuse of drugs (Amendment No. 2) (England, Wales and Scotland) regulations 2015 (S.I. 2015/891) [Internet]. London (GB): The Home Office; 2015 May 20. [cited 2015 May 26]. (Correspondence). Available from: <https://www.gov.uk/government/publications/circular-0192015-a-change-to-the-misuse-of-drugs-regulations-2001/circular-0192015-misuse-of-drugs-amendment-no-2-england-wales-and-scotland-regulations-2015-si-2015891>
62. Ministry of Health. 1 July 2014 changes to prescribing [Internet]. Wellington (NZ): The Ministry; 2014 Jun 30. [cited 2015 Aug 12]. Available from: <http://www.health.govt.nz/our-work/regulation-health-and-disability-system/1-july-2014-changes-prescribing>
63. Royal Australasian College of Physicians. Prescription opioid policy: improving management of chronic non-malignant pain and prevention of problems associated with prescription opioid use [Internet]. Sydney: The College; 2009 Apr. [cited 2015 Aug 12]. Available from: <https://www.racp.edu.au/docs/default-source/advocacy-library/prescription-opioid-policy.pdf>
64. Justice Laws Website [Internet]. Ottawa: Government of Canada. Controlled Drugs and Substances Act (S.C. 1996, c.19); 2015 Jul 21 [cited 2015 Aug 12]. Available from: <http://laws-lois.justice.gc.ca/eng/acts/c-38.8/page-22.html>
65. Health Canada [Internet]. Ottawa: Health Canada. Health concerns: methadone program; 2011 Jun 10 [cited 2015 Aug 12]. Available from: <http://www.hc-sc.gc.ca/hc-ps/substancontrol/exemptions/methadone-eng.php>
66. College of Physicians & Surgeons of Nova Scotia. CPSNS methadone maintenance treatment handbook [Internet]. Halifax: The College; 2012 May. [cited 2015 Aug 12]. Available from: <http://www.nspmp.ca/library/00000264-library.pdf>
67. College of Physicians and Surgeons of Ontario. Methadone program. Methadone maintenance treatment: program standards and clinical guidelines [Internet]. 4th ed. Toronto: The College; 2011 Feb. [cited 2015 Aug 12]. Available from: <http://www.cpso.on.ca/uploadedFiles/members/MMT-Guidelines.pdf>
68. College of Pharmacists of British Columbia. Professional practice policy-66. Methadone maintenance treatment [Internet]. Vancouver: The College; 2013 Sep 20. [cited 2015 Aug 12]. Available from: http://library.bcpharmacists.org/A-About_Us/A-2_Governance/5003-PGP-PPP66.pdf
69. College of Physicians & Surgeons of Alberta [Internet]. Edmonton: The College. Prescribing buprenorphine (Suboxone®) for opioid dependence; [cited 2015 Aug 12]. Available from: http://www.cpsa.ab.ca/Services/Physician_Prescribing_Practices/BuprenorphinePrescribing.aspx
70. College of Physicians and Surgeons of Ontario. Annual financial meeting of Council [Internet]. Toronto: The College; 2015 May. [cited 2015 May 25]. Available from: http://www.cpso.on.ca/CPSO/media/documents/Council/Council-Materials_May2015.pdf
71. College of Physicians and Surgeons of Ontario. Buprenorphine hydrochloride for the treatment of opioid dependence. Toronto: The College; 2012.
72. Substance Abuse and Mental Health Services Administration (SAMHSA). SAMHSA [Internet]. Rockville (MD): The Administration. Buprenorphine. Physician waiver qualifications. The Drug Addiction Treatment Act of 2000 (DATA 2000); [cited 2015 Aug 12]. Available from: http://buprenorphine.samhsa.gov/waiver_qualifications.html
73. American Society Of Addiction Medicine. Advancing access to addiction medications: implications for opioid addiction treatment [Internet]. Chevy Chase (MD): The Society; 2013. [cited 2015 Aug 12]. Available from: http://www.asam.org/docs/default-source/advocacy/aaam_implications-for-opioid-addiction-treatment_final
74. U.S. Food and Drug Administration [Internet]. Silver Spring (MD): The Administration. Drugs. Subutex and suboxone questions and answers; 2014 Jun 13 [cited 2015 Aug 12]. Available from: <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm191523.htm>
75. Department of Health (England). Drug misuse and dependence: UK guidelines on clinical management [Internet]. London (GB): The Department; 2007. [cited 2015 Aug 12]. Available from: http://www.nta.nhs.uk/uploads/clinical_guidelines_2007.pdf
76. New South Wales Department of Health. Opioid treatment program: clinical guidelines for methadone and buprenorphine treatment [Internet]. Sydney: The Department; 2006 Nov 22. [cited 2015 Aug 12]. Available from: http://www0.health.nsw.gov.au/policies/gl/2006/pdf/GL2006_019.pdf
77. New South Wales Department of Health. NSW opioid treatment program. Community pharmacy dosing point protocol [Internet]. Sydney: The Department; 2013 Nov. [cited 2015 Aug 12]. Available from: <http://www.health.nsw.gov.au/pharmaceutical/Documents/OTP-protocol-pharmacists.pdf>
78. Ministry of Health (NZ). Prescribing controlled drugs in addiction treatment. Section 24 Misuse of Drugs Act 1975 [Internet]. Wellington (NZ): The Ministry; 2014. [cited 2015 Aug 12]. Available from: <http://www.health.govt.nz/system/files/documents/publications/prescribing-controlled-drugs-in-addiction-treatment-may14-v4.pdf>
79. Bourgeault IL, Grignon M. A comparison of the regulation of health professional boundaries across OECD countries. *European Journal of Comparative Economics* [Internet]. 2013 [cited 2015 Aug 12];10(2):199-223. Available from: <http://eaces.liuc.it/18242979201302/182429792013100205.pdf>
80. College of Physicians and Surgeons of Nova Scotia. Decision of Investigation Committee "A" [Internet]. Halifax: The College; 2014 Oct 2. [cited 2015 May 21]. Available from: <http://www.cpsns.ns.ca/Portals/0/PDFcomplaints/Dr.%20Philip%20Davis%20-%20Full%20Decision%20-%20October%202014.pdf>
81. Henderson J. Nova Scotia doctors sanctioned for overprescribing narcotics. CBC [newspaper online] [Internet]. 2014 Dec 2 [cited 2015 Aug 12]. Available from: <http://www.cbc.ca/news/canada/nova-scotia/nova-scotia-doctors-sanctioned-for-overprescribing-narcotics-1.2857453>

82. Medication management standards. Ottawa: Accreditation Canada; 2013.
83. The Joint Commission [Internet]. Oak Brook (IL): The Commission. 2015 [cited 2015 Aug 12]. Available from: <http://www.jointcommission.org/>
84. The Australian Council on Healthcare Standards [Internet]. Ultimo (AU): The Council. 2015 [cited 2015 Aug 12]. Available from: <http://www.achs.org.au/>
85. Health Quality & Safety Commission New Zealand [Internet]. Wellington (NZ): The Commission. 2015 [cited 2015 Aug 12]. Available from: <http://www.hqsc.govt.nz/>
86. Care Quality Commission [Internet]. Newcastle upon Tyne (GB): The Commission. 2015 [cited 2015 Aug 12]. Available from: <http://www.cqc.org.uk/>
87. Province of British Columbia [Internet]. Victoria: Government of British Columbia; 2015. COA, CARF accrediting bodies; [cited 2015 May 25]. Available from: http://www.mcf.gov.bc.ca/accreditation/coa_carf.htm
88. CARF International [Internet]. Toronto: CARF International; 2015. CARF Canada; [cited 2015 May 25]. Available from: <http://www.carf.org/Programs/CARFCanada/>
89. National Alliance For Model State Drug Laws. Prescription drug abuse, addiction and diversion: overview of state legislative and policy initiatives, a three part series. Part 2: state regulation of pain clinics and legislative trends relative to regulating pain clinics. Executive summary [Internet]. Charlottesville (VA): The Alliance; 2014. [cited 2015 Aug 12]. Available from: <http://www.namsdl.org/library/88669EDF-19B9-E1C5-3165C7077276D8E1/>
90. Johnson H, Paulozzi L, Porucznik C, Mack K, Herter B, Hal Johnson Consulting and Division of Disease Control and Health Promotion, Florida Department of Health. Decline in drug overdose deaths after state policy changes - Florida, 2010-2012. MMWR Morb Mortal Wkly Rep [Internet]. 2014 Jul 4 [cited 2015 Aug 12];63(26):569-74. Available from: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6326a3.htm>
91. Chapter 1: Public Health Service, Department of Health and Human Services. Part 8: Certification of opioid treatment programs. Subpart B: Certification and treatment standards [Internet]. In: Title 42 - Public Health. Washington (DC): U.S. Public Health Service; 2007. p. 62-71 [cited 2015 Aug 12]. (Code of federal regulations). Available from: <http://www.gpo.gov/fdsys/pkg/CFR-2007-title42-vol1/pdf/CFR-2007-title42-vol1-sec8-11.pdf>.
92. Substance Abuse and Mental Health Services Administration (SAMHSA). Federal guidelines for opioid treatment draft [Internet]. Rockville (MD): The Administration; 2013 Apr. [cited 2015 Aug 12]. Available from: http://www.dpt.samhsa.gov/pdf/FederalGuidelinesforOpioidTreatment5-6-2013revisiondraft_508.pdf
93. Learning from tragedy, keeping patients safe: overview of the Government's action programme in response to the recommendations of the Shipman Inquiry [Internet]. London (GB): Government of the UK, Stationery Office; 2007 Feb. [cited 2015 Aug 12]. Available from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/228886/7014.pdf
94. Government response to the House of Commons Health Committee report of session 2014-15: accountability hearing with the Health and Care Professions Council [Internet]. London (GB): Government of the UK, Department of Health; 2014 Oct. [cited 2015 Aug 12]. Available from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/364280/43550_2902784_Cm_8916_Govt_Response_accessible.pdf
95. Guidelines International Network [Internet]. Berlin: Guidelines International Network. 2015 [cited 2015 Aug 12]. Available from: <http://www.g-i-n.net/gin>
96. National Guideline Clearinghouse [Internet]. Rockville (MD): National Guideline Clearinghouse; 1997 -. Interagency guideline on opioid dosing for chronic non-cancer pain: an educational aid to improve care and safety with opioid therapy; 2010 [cited 2015 Aug 12]. Available from: <http://www.guideline.gov/content.aspx?id=23792>
97. National Institute for Health and Care Excellence [Internet]. London (GB): The Institute; 2015. Find guidance; [cited 2015 May 25]. Available from: <http://www.nice.org.uk/Guidance>
98. Canadian Medical Association. CMA Infobase: clinical practice guidelines database (CPGs) [Internet]. Ottawa: The Association; 2015. [cited 2015 Aug 12]. Available from: <https://www.cma.ca/En/Pages/clinical-practice-guidelines.aspx>
99. National Opioid Use Guideline Group. Canadian guideline for safe and effective use of opioids for chronic non-cancer pain [Internet]. Hamilton (ON): McMaster University; 2010 Apr 30. [cited 2015 Aug 12]. Available from: <http://nationalpaincentre.mcmaster.ca/opioid/>
100. College of Physicians and Surgeons of Ontario. Policy statement #8-12: prescribing drugs [Internet]. Toronto: The College; 2012 Dec. [cited 2015 Aug 12]. Available from: http://www.cpso.on.ca/CPSO/media/uploadedfiles/policies/policies/policyitems/prescribing_drugs.pdf?ext=.pdf
101. Government of Canada [Internet]. Ottawa: Health Canada. Minister Ambrose talks prescribing practices with healthcare professionals in effort to curb prescription drug abuse; 2015 May 15 [cited 2015 Aug 12]. Available from: <http://news.gc.ca/web/article-en.do?crtr.sj1D=&crtr.mnthndVl=5&mrthd=advSrch&crtr.dpt1D=6676&nid=974759&crtr.lc1D=&crtr.tp1D=1&crtr.yrStrtVl=2015&crtr.kw=&crtr.dyStrtVl=14&crtr.aud1D=&crtr.mnthStrtVl=5&crtr.page=1&crtr.yrndVl=2015&crtr.dyndVl=16>
102. Registered Nurses' Association of Ontario. Assessment and management of pain [Internet]. 3rd ed. Toronto: The Association; 2013 Dec. [cited 2015 Aug 12]. (Clinical best practice guidelines). Available from: <http://rnao.ca/sites/rnao-ca/files/AssessAndManagementOfPain2014.pdf>
103. Michael G. DeGroot National Pain Centre. Guidelines [Internet]. Hamilton (ON): McMaster University. 2015 [cited 2015 Aug 12]. Available from: <http://nationalpaincentre.mcmaster.ca/guidelines.html>
104. Royal College of Dental Surgeons of Ontario. Memo regarding: proposed guidelines on the role of opioids in the management of acute and chronic pain in dental practice [Internet]. Toronto: The College; 2014 Dec 8. [cited 2015 Aug 12]. Available from: http://www.rcdso.org/Assets/DOCUMENTS/Consultations/RCDSO_3773_Memo_for_Guidelines_on_Role_of_Opioids_Dec2014_V.1.pdf
105. College of Physicians and Surgeons of Ontario [Internet]. Toronto: The College; 2015. About clinical practice guidelines; [cited 2015 Aug 12]. Available from: <http://www.cpso.on.ca/Policies-Publications/Positions-Initiatives/About-Clinical-Practice-Guidelines>
106. National Center for Injury Prevention and Control. Common elements in guidelines for prescribing opioids for chronic pain [Internet]. Atlanta (GA): Centers for Disease Control and Prevention; 2014. [cited 2015 Aug 12]. Available from: <http://www.cdc.gov/homeandrecreationalafety/pdf/CommonElementsinGuidelinesforPrescribingOpioids-a.pdf>
107. American Pain Society. Guideline for the use of chronic opioid therapy in chronic noncancer pain: evidence review [Internet]. Chicago (IL): The Society; 2009. [cited 2015 Aug 12]. Available from: <http://americanpainsociety.org/uploads/education/guidelines/chronic-opioid-therapy-cnccp.pdf>
108. Sundwall DN, Rolfs RT, Johnson E. Utah clinical guidelines on prescribing opioids for treatment of pain [Internet]. Salt Lake City: Utah Department of Health; 2009. [cited 2015 Aug 12]. Available from: <http://health.utah.gov/prescription/pdf/guidelines/final.04.09opioidGuidlines.pdf>
109. Management of Opioid Therapy for Chronic Pain Working Group. Management of opioid therapy for chronic pain [Internet]. Washington (DC): Department of Veterans Affairs; 2010. [cited 2015 Aug 12]. (VA/DoD Clinical practice guideline). Available from: http://www.va.gov/painmanagement/docs/cpg_opioidtherapy_fulltext.pdf
110. American College of Occupational and Environmental Medicine. ACOEM's guidelines for the chronic use of opioids. Elk Grove Village (IL): The College; 2011.

111. New York City Emergency Department discharge opioid prescribing guidelines [Internet]. New York: NYC Health; 2013. [cited 2015 Aug 12]. Available from: <http://www.nyc.gov/html/doh/downloads/pdf/basas/opioid-prescribing-guidelines.pdf>
112. American Society of Interventional Pain Physicians. American Society of Interventional Pain Physicians (ASIPP) guidelines for responsible opioid prescribing in chronic non-cancer pain [Internet]. Paducah (KY): The Society; 2012. [cited 2015 Aug 12]. Available from: <https://asipp.org/Guidelines.htm>
113. Washington State Agency Medical Directors Group. Interagency guideline on opioid dosing for chronic non-cancer pain: an educational aid to improve care and safety with opioid therapy [Internet]. Washington (DC): Agency Medical Directors' Group; 2010. [cited 2015 Aug 12]. Available from: <http://www.agencymeddirectors.wa.gov/Files/OpioidGdline.pdf>
114. Cheung CW, Qiu Q, Choi SW, Moore B, Goucke R, Irwin M. Chronic opioid therapy for chronic non-cancer pain: a review and comparison of treatment guidelines. Pain Physician [Internet]. 2014 Sep [cited 2015 Aug 12];17(5):401-14. Available from: http://www.painphysicianjournal.com/linkout_vw.php?issn=1533-3159&vol=17&page=401
115. Gowing L, Ali R, Dunlop A, Farrell M, Lintzeris N. National guidelines for medication-assisted treatment of opioid dependence [Internet]. Canberra: Australian Government; 2014 Apr. [cited 2015 Aug 12]. Available from: [http://www.nationaldrugstrategy.gov.au/internet/drugstrategy/Publishing.nsf/content/AD14DA97D8EE00E8CA257CD1001E0E5D/\\$File/National_Guidelines_2014.pdf](http://www.nationaldrugstrategy.gov.au/internet/drugstrategy/Publishing.nsf/content/AD14DA97D8EE00E8CA257CD1001E0E5D/$File/National_Guidelines_2014.pdf)
116. Henry-Edwards S, Gowing L, White J, Ali R, Bell J, Brough R, et al. Clinical guidelines and procedures for the use of methadone in the maintenance treatment of opioid dependence [Internet]. Canberra: Australian Government; 2003 Aug. [cited 2015 Aug 12]. Available from: [http://www.health.gov.au/internet/main/publishing.nsf/Content/D7138B36FFD6F4A6CA257BF000209CC4/\\$File/methadone_cguide.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/D7138B36FFD6F4A6CA257BF000209CC4/$File/methadone_cguide.pdf)
117. Queensland opioid treatment program: clinical guidelines 2012 [Internet]. Brisbane (AU): Queensland Health; 2012. [cited 2015 Aug 12]. Available from: <http://www.guild.org.au/docs/default-source/qld-branch-public/Professional-Services/clinical-guidelines.pdf?sfvrsn=0>
118. Ministry of Health. New Zealand practice guidelines for opioid substitution treatment [Internet]. Wellington (NZ): The Ministry; 2014. [cited 2015 Aug 12]. Available from: <http://www.health.govt.nz/system/files/documents/publications/nz-practice-guidelines-opioid-substitution-treatment-apr14.pdf>
119. National Institute for Health and Care Excellence. Methadone and buprenorphine for the management of opioid dependence [Internet]. London (GB): The Institute; 2007 Jan. [cited 2015 Aug 12]. (NICE technology appraisal guidance 114). Available from: <http://www.nice.org.uk/guidance/ta114/resources/guidance-methadone-and-buprenorphine-for-the-management-of-opioid-dependence-pdf>
120. National Institute for Health and Care Excellence. Naltrexone for the management of opioid dependence [Internet]. London (GB): The Institute; 2007 Jan. [cited 2015 Aug 12]. (NICE technology appraisal guidance 115). Available from: <http://www.nice.org.uk/guidance/ta115/resources/guidance-naltrexone-for-the-management-of-opioid-dependence-pdf>
121. Quick clinical guideline for the use of opioids in chronic non-malignant pain [Internet]. Brisbane (AU): Queensland Government; 2010. [cited 2015 Aug 12]. Available from: http://www.health.qld.gov.au/persistentpain/docs/ddu_quick_guide.pdf
122. European Monitoring Centre for Drugs and Drug Addiction [Internet]. Lisbon: The Centre. Country profile - United Kingdom; 2012 Mar 19 [cited 2015 Aug 12]. Available from: <http://www.emcdda.europa.eu/html.cfm/index5174EN.html?pluginMethod=eldd.countryprofiles&country=UK>
123. National Institute for Health and Care Excellence [Internet]. London (GB): The Institute; 2015. Guidance list; [cited 2015 Aug 12]. Available from: <http://www.nice.org.uk/guidance/published?type=cg>
124. National Institute for Health and Care Excellence. Drug misuse – psychosocial interventions [Internet]. London (GB): The Institute; 2007 Jul. [cited 2015 Aug 12]. (NICE clinical guideline 51). Available from: <https://www.nice.org.uk/guidance/cg51/resources/guidance-drug-misuse-psychosocial-interventions-pdf>
125. Ashton CH. benzo.org.uk [Internet]. Newcastle upon Tyne (GB): Royal Victoria Infirmary, Department of Psychiatry. Guidelines for the rational use of benzodiazepines: when and what to use; 1994 [cited 2015 Aug 12]. Available from: <http://www.benzo.org.uk/asgr.htm>
126. National Centre for Education and Training on Addiction (NCETA) Consortium. Alcohol & other drugs: a handbook for health professionals [Internet]. Canberra: Australian Government Department of Health and Ageing; 2004. [cited 2015 Aug 12]. Available from: [http://www.health.gov.au/internet/main/publishing.nsf/Content/E5203E6D5CBAA696CA257BF0001E02ED/\\$File/aodgp.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/E5203E6D5CBAA696CA257BF0001E02ED/$File/aodgp.pdf)
127. Standing Senate Committee on Social Affairs, Science and Technology. Prescription pharmaceuticals in Canada. Unintended consequences [Internet]. Ottawa: Parliament of Canada; 2014 Oct. [cited 2015 May 25]. Available from: <http://www.parl.gc.ca/Content/SEN/Committee/412/soci/rep/rep15oct14-e.pdf>
128. Health Canada [Internet]. Ottawa: Health Canada. Frequently asked questions: Narcotic Control Regulations; 2015 Jan 5 [cited 2015 Aug 6]. Available from: <http://www.hc-sc.gc.ca/ahc-asc/legislation/acts-reg-lois/acts-reg-lois/faq-ncr-rss-eng.php>
129. Health Canada [Internet]. Ottawa: Health Canada. Consultation: proposed regulations amending regulations under the Controlled Drugs and Substances Act with respect to the issuance of licences and permits; 2015 Jul 20 [cited 2015 Aug 6]. Available from: <http://hc-sc.gc.ca/hc-ps/consult/licences-eng.php>
130. Canadian Centre on Substance Abuse. Prescription opioids [Internet]. Ottawa: The Centre; 2015 Jul. [cited 2015 Aug 5]. Available from: <http://www.ccsa.ca/Resource%20Library/CCSA-Canadian-Drug-Summary-Prescription-Opioids-2015-en.pdf>
131. Canadian Centre on Substance Abuse. Prescription stimulants [Internet]. Ottawa: The Centre; 2015 Jul. [cited 2015 Aug 5]. Available from: <http://www.ccsa.ca/Resource%20Library/CCSA-Canadian-Drug-Summary-Prescription-Stimulants-2015-en.pdf>
132. Canadian Centre on Substance Abuse. Prescription sedatives [Internet]. Ottawa: The Centre; 2015 Jul. [cited 2015 Aug 5]. Available from: <http://www.ccsa.ca/Resource%20Library/CCSA-Canadian-Drug-Summary-Prescription-Sedatives-2015-en.pdf>
133. Justice Laws Website [Internet]. Ottawa: Government of Canada, Department of Justice. Benzodiazepines and Other Targeted Substances Regulations (SOR/2000-217); 2015 Jul 21 [cited 2015 Aug 6]. Available from: <http://laws-lois.justice.gc.ca/eng/regulations/SOR-2000-217/index.html>
134. DEA Office of Diversion Control [Internet]. Springfield (VA): U.S. Department of Justice, Drug Enforcement Administration. List of controlled substances; 2015 [cited 2015 May 6]. Available from: <http://www.deadiversion.usdoj.gov/schedules/>
135. Kmietowicz Z. Indian parliament votes to increase access to morphine. BMJ. 2014 Feb 24;348:g1744.
136. Throckmorton D, Dart RC. Pharmacy track: impact of abuse-deterrent formulations [Internet]. Poster presented at: National Rx Drug Abuse Summit. 2014 Apr 22; Atlanta (GA). [cited 2015 Aug 12]. Available from: <http://www.slideshare.net/OPUNITE/ph-3-throckmorton-dart>
137. Hood GA. Small change in opioid prescribing will have big impact. New York: Medscape; 2014 Oct 22.

138. FDAVoice [Internet]. Silver Spring (MD): U.S. Food and Drug Administration. Re-scheduling prescription hydrocodone combination drug products: an important step toward controlling misuse and abuse; 2014 Oct 6 [cited 2015 Aug 12]. Available from: <http://blogs.fda.gov/fdavoices/index.php/2014/10/re-scheduling-prescription-hydrocodone-combination-drug-products-an-important-step-toward-controlling-misuse-and-abuse/>
139. Texas Medicaid/CHIP Drug Vendor Program [Internet]. Midland (TX): Texas Health and Human Services Commission. Texas Medicaid/CHIP Drug Vendor Program news: current news; 2015 [cited 2015 Aug 12]. Available from: <http://www.txvendordrug.com/news/>
140. Home Office. List of drugs currently controlled under the misuse of drugs legislation [Internet]. London (GB): GOV.UK; 2012 Nov 5. [cited 2015 May 6]. Available from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/164222/controlled-drugs-list.pdf
141. National Prescribing Centre. A guide to good practice in the management of controlled drugs in primary care (England) [Internet]. 3rd ed. Liverpool (GB): The Centre; 2009 Dec. [cited 2015 Aug 12]. Available from: http://www.webarchive.org.uk/wayback/archive/20140627111125/http://www.npc.nhs.uk/controlled_drugs/resources/controlled_drugs_third_edition.pdf
142. Advisory Council on the Misuse of Drugs. ACMD consideration of tramadol [Internet]. London (GB): The Council; 2013 Feb 13. [cited 2015 Aug 12]. Available from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/144116/advice-tramadol.pdf
143. Sunderland Local Pharmaceutical Committee. Sunderland LPC [Internet]. Sunderland City (GB): The Committee. Controlled drug changes - Tramadol changes; 2014 May 22 [cited 2015 Aug 12]. Available from: <http://psnc.org.uk/sunderland-lpc/our-news/controlled-drug-changes-tramadol-changes/>
144. Ministry of Health. Frequently asked questions: controlled drugs prescribing [Internet]. Wellington (NZ): The Ministry; 2011 Jul 22. [cited 2015 Aug 12]. Available from: <http://www.health.govt.nz/system/files/documents/pages/controlled-drugs-prescribing-v1.pdf>
145. Drugs of dependence (Schedule 8 medicines) [Internet]. Perth: Government of Western Australia, Department of Health; 2015. [cited 2015 Aug 6]. Available from: http://www.public.health.wa.gov.au/2/1292/2/drugs_of_dependence_schedule_medicines.pm
146. Ministry of Health and Long-Term Care (ON), Exceptional Access Program (EAP). EAP reimbursement criteria for frequently requested drugs [Internet]. Toronto: The Ministry; 2015 Apr 1. [cited 2015 Aug 12]. Available from: http://www.health.gov.on.ca/en/pro/programs/drugs/pdf/frequently_requested_drugs.pdf
147. Traynor K. FDA advisers support rescheduling of hydrocodone products. *Am J Health Syst Pharm.* 2013 Mar 1;70(5):383-4.
148. Fishman SM. Prescription drug monitoring programs serve a vital clinical need. *Pain Med.* 2011 Jun;12(6):845.
149. National Pharmaceutical Drug Misuse Framework for Action (2012-2015): a matter of balance [Internet]. Canberra: Australian Government; 2013. [cited 2015 Aug 12]. Available from: [http://www.nationaldrugstrategy.gov.au/internet/drugstrategy/Publishing.nsf/content/9C52D7D6E2C14A72CA257C3F001F009D/\\$File/National%20PDM%20Framework.pdf](http://www.nationaldrugstrategy.gov.au/internet/drugstrategy/Publishing.nsf/content/9C52D7D6E2C14A72CA257C3F001F009D/$File/National%20PDM%20Framework.pdf)
150. Institute for Clinical and Economic Review. Management of patients with opioid dependence: a review of clinical, delivery system, and policy options [Internet]. Boston: The Institute; 2014 Jul. [cited 2015 Aug 12]. Available from: <http://cepac.icer-review.org/wp-content/uploads/2014/04/CEPAC-Opioid-Dependence-Final-Report-For-Posting-July-211.pdf>
151. Chalk M, Alanis-Hirsch K, Woodworth A, Mericle A, Curtis B, McLoyd K. Report of commercial health plan medication coverage and benefits survey. Philadelphia: Treatment Research Institute; 2013.
152. Nova Scotia Pharmacare Programs. Pharmacists' guide [Internet]. Halifax: Nova Scotia Department of Health and Wellness; 2015 Aug 1. [cited 2015 Aug 12]. Available from: <http://novascotia.ca/dhw/pharmacare/documents/Pharmacare-Pharmacists-Guide.pdf>
153. Patient review & restriction programs: lessons learned from state Medicaid programs [Internet]. Atlanta (GA): Centers for Disease Control and Prevention, National Center for Injury Prevention and Control; 2012 Aug 27. [cited 2015 Aug 12]. Available from: http://www.cdc.gov/homeandrecreationalafety/pdf/PDO_patient_review_meeting-a.pdf
154. Levi J, Segal LM, Fuchs Miller A. Prescription drug abuse: strategies to stop the epidemic [Internet]. Washington (DC): Trust for America's Health; 2013. [cited 2015 Aug 12]. Available from: http://healthyamericans.org/reports/drugabuse2013/TFAH2013RxDrugAbuseRpt12_no_embargo.pdf
155. Moriarty H. Controlled drugs: what you need to know. *Medical Protection Society Casebook* [Internet]. 2014 Jan [cited 2015 Aug 12];22(1):5-7. Available from: <http://www.medicalprotection.org/newzealand/casebook-january-2014/controlled-drugs-what-you-need-to-know>
156. The Ministry of Health and Long-Term Care (ON). Tramadol hydrochloride ER [Internet]. Toronto: The Ministry; 2010 Jun. [cited 2015 Aug 12]. Available from: <http://www.health.gov.on.ca/en/pro/programs/drugs/ced/pdf/tridural.pdf>
157. Sun Life Financial. Minimal impact expected to private drug plans following switch from OxyContin to OxyNEO. *Focus Update: Group Benefits News* [Internet]. 2011 Apr 5 [cited 2015 Aug 12];(332). Available from: http://www.sunlife.ca/static/canada/Smallbusiness/Focus%20news/2012%20issues/332/332_%20focus_SA.pdf
158. Hoebert JM, Souverein PC, Mantel-Teeuwisse AK, Leufkens HG, van Dijk L. Reimbursement restriction and moderate decrease in benzodiazepine use in general practice. *Ann Fam Med* [Internet]. 2012 Jan [cited 2015 Aug 12];10(1):42-9. Available from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3262472/pdf/0100042.pdf>
159. Omega [Internet]. Montreal: Laboratoires Omega Ltée. Injectables; 2014 Mar [cited 2015 May 6]. Available from: <http://www.omegalaboratory.com/index.php/hospitalier1/injectables/>
160. PrNaloxone hydrochloride injection USP (naloxone hydrochloride) 0.4 mg/mL and 1.0 mg/mL. Therapeutic classification: opioid antagonist [product monograph] [Internet]. Boucherville (QC): Sandoz Canada Inc.; 2011 Nov 4. [cited 2015 May 6]. Available from: http://www.sandoz.ca/cs/groups/public/@sge_ca/documents/document/n_prod_1301129.pdf
161. PrNaloxone hydrochloride injection USP. 0.4 mg/mL. Therapeutic classification: opioid antagonist [product insert] [Internet]. Toronto: Alveda Pharmaceuticals Inc.; 2014 Mar. [cited 2015 May 6]. Available from: http://www.alvedapharma.com/PDF/PI4WS/ALV_Naloxone_Insert.pdf
162. Leece PN, Hopkins S, Marshall C, Orkin A, Gassanov MA, Shahin RM. Development and implementation of an opioid overdose prevention and response program in Toronto, Ontario. *Can J Public Health.* 2013 Apr 18;104(3):e200-e204.
163. Community-based opioid overdose prevention programs providing naloxone – United States, 2010. *MMWR Morb Mortal Wkly Rep* [Internet]. 2012 Feb 17 [cited 2015 Aug 12];61(6):101-5. Available from: <http://www.cdc.gov/mmwr/pdf/wk/mm6106.pdf>
164. Hewlett L, Wermeling DP. Survey of naloxone legal status in opioid overdose prevention and treatment. *J Opioid Manag.* 2013 Sep;9(5):369-77.
165. National Association of Boards of Pharmacy [Internet]. Mount Prospect (IL): The Association. NABP issues policy statement supporting the pharmacist's role in increasing access to opioid overdose reversal drug; 2014 Oct 20 [cited 2015 Aug 12]. Available from: <http://www.nabp.net/news/nabp-issues-policy-statement-supporting-the-pharmacist-s-role-in-increasing-access-to-opioid-overdose-reversal-drug>

166. Advisory Council on the Misuse of Drugs (ACMD). Consideration of naloxone [Internet]. London (GB): The Council; 2012 May. [cited 2015 Aug 12]. Available from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/119120/consideration-of-naloxone.pdf
167. Naloxone.org.uk. A life saving medication [Internet]. Liverpool (GB): Scottish Drugs Forum. 2015 [cited 2015 Aug 12]. Available from: <http://www.naloxone.org.uk/>
168. Katz NP, Birnbaum H, Brennan MJ, Freedman JD, Gilmore GP, Jay D, et al. Prescription opioid abuse: challenges and opportunities for payers. *Am J Manag Care* [Internet]. 2013 Apr [cited 2015 Aug 12];19(4):295-302. Available from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3680126/pdf/nihms-454480.pdf>
169. Naloxone. Letter from Jane Ellison MP, Parliamentary Under Secretary of State for Public Health to Professor Les Iversen, Chair, Advisory Council on the Misuse of Drugs [Internet]. London (GB): Government of the United Kingdom, Department of Health; 2014 Jul 15. [cited 2015 Aug 12]. Available from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/340711/lversonNaloxone.pdf
170. Take-home naloxone for opioid overdose in people who use drugs. Advice for local authorities and local partners on promoting the wider availability of naloxone to reduce overdose deaths from heroin and similar drugs [Internet]. London (GB): Public Health England; 2015 Feb. [cited 2015 May 25]. Available from: <http://www.nta.nhs.uk/uploads/take-home-naloxone-for-opioid-overdose-feb-2015.pdf>
171. Australian National Council on Drugs. ANCD position statement: expanding naloxone availability [Internet]. [Canberra]: The Council; 2012 Sep. [cited 2015 Aug 12]. Available from: <http://www.atoda.org.au/wp-content/uploads/ANCD-Position-Statement-Expanding-Naloxone-Availability-September-2012.pdf>
172. Menu of state prescription drug identification laws [Internet]. Atlanta (GA): Centers for Disease Control and Prevention; 2014. [cited 2015 Aug 12]. (Public health law). Available from: <http://www.cdc.gov/phlp/docs/menu-pdil.pdf>
173. State-by-state opioid prescribing policies. New York: Medscape; 2014.
174. New Zealand Ministry of Health [Internet]. Wellington (NZ): The Ministry. Controlled drugs; 2014 Jun 26 [cited 2015 Aug 12]. Available from: <http://www.health.govt.nz/our-work/regulation-health-and-disability-system/medicines-control/controlled-drugs>
175. NHS Choices [Internet]. Redditch (GB): NHS England. What is a controlled medicine (drug)?; 2013 Nov 12 [cited 2015 Aug 12]. Available from: <http://www.nhs.uk/chq/Pages/1391.aspx>
176. Board of Pharmacy [Internet]. Sacramento (CA): Government of California, Department of Consumer Affairs. Board of Pharmacy. Prescribing and dispensing controlled substance prescription forms; 2015 [cited 2015 Aug 12]. Available from: http://www.pharmacy.ca.gov/licensing/prescribe_dispense.shtml
177. Conditions of dispensing regarding controlled drugs prescriptions [Internet]. Brisbane (AU): Queensland Health; 2011 Apr. [cited 2015 Aug 12]. Available from: <http://www.health.qld.gov.au/ph/documents/ehu/circular1104.pdf>
178. Department of Health and Human Services, Office of the Inspector General. Multiple copy prescription programs: state experiences [Internet]. Washington (DC): Department of Health and Human Services (US); 1992 Jun. [cited 2015 Aug 12]. Available from: <https://oig.hhs.gov/oei/reports/oei-12-91-00490.pdf>
179. Richard G, Ojala V, Ojala A, Bowles SK, Banh HL. Monitoring programs for drugs with potential for abuse or misuse in Canada. *Can Pharm J (Ott)* [Internet]. 2012 Jul [cited 2015 Aug 11];145(4):168-71. Available from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3567799>
180. Fishman SM. Repeal of triplicate prescribing and the new security paper prescription requirement in California. *California Society of Anesthesiologists Bulletin* [Internet]. 2004 Apr [cited 2015 Aug 12];53(1). Available from: http://www.csaqh.org/pdf/bulletin/fishman041_rev.pdf
181. Department of Justice, Drug Enforcement Administration (DEA). 21 CFR parts 1300, 1304, 1306, and 1311. Electronic prescriptions for controlled substances; final rule. *Fed Regist* [Internet]. 2010 Mar 31 [cited 2015 Aug 12];75(61):16236-319. Available from: http://www.deadiversion.usdoj.gov/fed_regs/rules/2010/fr0331.pdf
182. New York State Department of Health, Bureau of Narcotic Enforcement. Frequently asked questions for electronic prescribing of controlled substances: EPCS [Internet]. Albany (NY): New York State Department of Health; 2015 Apr. [cited 2015 Aug 12]. Available from: http://www.health.ny.gov/professionals/narcotic/electronic_prescribing/docs/epcs_faqs.pdf
183. Department of Justice, Drug Enforcement Administration. Schedules of controlled substances: rescheduling of hydrocodone combination products from schedule III to schedule II. Final rule. *Fed Regist* [Internet]. 2014 Aug 22 [cited 2015 Aug 12];79(163):49661-82. Available from: <http://www.gpo.gov/fdsys/pkg/FR-2014-08-22/pdf/2014-19922.pdf>
184. Grieve S. The proposals to include schedules 2 and 3 controlled drugs within the scope of the Electronic Prescription Service [Internet]. London (GB): Government of the United Kingdom, Department of Health; 2014 Jul. [cited 2015 Aug 12]. Available from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/330865/EPS_and_CDs_Cons_Document.pdf
185. NHS Prescription Services. Controlled drug prescribing [Internet]. Newcastle (GB): NHS Business Services Authority; 2014 Jan. [cited 2015 Aug 12]. Available from: http://www.nhsbsa.nhs.uk/PrescriptionServices/Documents/PrescriptionServices/controlled_drug_prescribing.pdf
186. Department of Health, Public Health and Clinical Services Division, Pharmaceutical Services Branch. Schedule 8 medicines prescribing code [Internet]. Perth: Department of Health (AU); 2014. [cited 2015 Aug 12]. Available from: <http://www.public.health.wa.gov.au/cproot/4947/3/schedule-8-medicines-prescribing-code-version-3-web.doc>
187. PDMPs and third party payers meeting December 2012. Report of proceedings [Internet]. Waltham (MA): Brandeis University; 2014 Apr. [cited 2015 Aug 12]. Available from: http://www.pdmpexcellence.org/sites/all/pdfs/Brandeis_COE_PDMP_3rd_pty_payer_mtg_rpt.pdf
188. National Alliance For Model State Drug Laws. Compilation of state prescription monitoring program maps [Internet]. Charlottesville (VA): NAMSDL; 2014. [cited 2015 Aug 12]. Available from: <http://www.namsdl.org/library/593BC7A6-1372-636C-DD7A83E6A8F6F0BC/>
189. Secretary of State for the Home Department. Drugs: new psychoactive substances and prescription drugs [Internet]. London (GB): Government of the UK; 2014 May. [cited 2015 Aug 12]. Available from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/307865/New_psychoactive_substances_and_prescription_drugsPRINT.pdf
190. Electronic recording and reporting of controlled drugs [Internet]. Canberra: Australian Government Department of Health and Ageing; 2012 Apr. [cited 2015 Aug 12]. Available from: <http://5cpa.com.au/files/fact-sheet-electronic-recording-and-reporting-of-controlled-drugs/>
191. State Coroner's Court of New South Wales. Inquest into the deaths of Christopher Salib, Nathan Attard and Shamsad Akhtar [Internet]. Glebe (AU): Department of Justice New South Wales; 2014 Jun 27. [cited 2015 Aug 12]. Available from: <http://www.coroners.justice.nsw.gov.au/Documents/doctor%20shopping%20amended%20finding.pdf>
192. Nielsen S, Bruno R. Implementing real-time prescription drug monitoring: are we ready? *Drug Alcohol Rev*. 2014 Sep;33(5):463-5.

193. Furlan AD, MacDougall P, Pellerin D, Shaw K, Spitzig D, Wilson G, et al. Overview of four prescription monitoring/review programs in Canada. *Pain Res Manag* [Internet]. 2014 Mar [cited 2015 Aug 12];19(2):102-6. Available from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4028653/pdf/prm-19-102.pdf>
194. College of Physicians and Surgeons of British Columbia [Internet]. Vancouver: The College. Medical Practitioner Access to PharmaNet (MPAP); 2015 [cited 2015 Aug 13]. Available from: <https://www.cpsbc.ca/programs/prp/mpap>
195. College of Physicians and Surgeons of British Columbia. Professional standards and guidelines: Walk-in, urgent care and multi-physician clinics [Internet]. Vancouver: The College; 2015 Jun 26. [cited 2015 Aug 12]. Available from: <https://www.cpsbc.ca/files/pdf/PSG-Walk-In-Urgent-Care-Multi-Physician-Clinics.pdf>
196. British Columbia Ministry of Health [Internet]. Vancouver: The Ministry; 2015. PharmaNet; [cited 2015 Aug 12]. Available from: <http://www2.gov.bc.ca/gov/content/health/health-drug-coverage/pharmacare-for-bc-residents/pharmanet>
197. Hildebran C, Cohen DJ, Irvine JM, Foley C, O’Kane N, Beran T, et al. How clinicians use prescription drug monitoring programs: a qualitative inquiry. *Pain Med* [Internet]. 2014 Jul [cited 2015 Aug 11];15(7):1179-86. Available from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4180422/pdf/nihms630314.pdf>
198. Droz DE. Prescription monitoring programs (PMPs): what you need to know to help stop an abuse epidemic [webinar; Internet]. Hudson (OH): Wolters Kluwer CDI; 2014 Oct 1. [cited 2015 Aug 13]. Available from: <https://vimeo.com/108150118>
199. Gomes T, Juurlink D, Yao Z, Camacho X, Paterson JM, Singh S, et al. Impact of legislation and a prescription monitoring program on the prevalence of potentially inappropriate prescriptions for monitored drugs in Ontario: a time series analysis. *CMAJ Open* [Internet]. 2014 Oct 1 [cited 2015 May 22];2(4):E256-E261. Available from: <http://www.cmajopen.ca/content/2/4/E256.full.pdf>
200. National Institutes of Health, Office of Extramural Research. Grants & funding [Internet]. Bethesda (MD): National Institutes of Health (NIH). Funding opportunity announcement (FOA) number: RFA-DA-14-013, abuse-resistant and abuse-deterrent formulations and devices to avoid the abuse, misuse and diversion of prescription opioids by patients (SBIR)(R43/R44); 2013 Jul 16 [cited 2015 Aug 12]. Available from: <http://grants.nih.gov/grants/guide/rfa-files/RFA-DA-14-013.html>
201. Government’s role in addressing prescription drug abuse. Report of the Standing Committee on Health. 41st Parliament, Second Session [Internet]. Ottawa: Parliament of Canada; 2014 Apr. [cited 2015 Aug 12]. Available from: <http://www.parl.gc.ca/HousePublications/Publication.aspx?DocId=6434062&File=5>
202. Ianiro R. Government notices. Department of Health. Controlled Drugs and Substances Act. Notice to interested parties - Tamper resistance under the Controlled Drugs and Substances Act. *Canada Gazette* [Internet]. 2014 Jun 28 [cited 2015 Aug 12];148(26). Available from: <http://www.gazette.gc.ca/rp-pr/p1/2014/2014-06-28/html/notice-avis-eng.php>
203. Health Canada, Health Products and Food Branch, Therapeutic Products Directorate, Bureau of Policy, Science and International Programs. Notice: consultation on the draft guidance document: tamper-resistant formulations of opioid drug product submissions [Internet]. Ottawa: Health Canada; 2014 Dec 22. [cited 2015 May 22]. Available from: http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/consultation/drug-medic/draft_guid_opioid_ebauche_ld-eng.pdf
204. U.S. Food and Drug Administration. Guidance for industry: abuse-deterrent opioids - evaluation and labeling [Internet]. Silver Spring (MD): The Administration; 2015 Apr. [cited 2015 Aug 12]. Available from: <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm334743.pdf>
205. Throckmorton DC. Impact of abuse-deterrent formulations of opioids [Internet]. Poster presented at: National RX Drug Abuse Summit. 2014 Apr 21; Atlanta (GA). [cited 2015 Aug 12]. Available from: <http://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm395804.pdf>
206. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER). Abuse-deterrent opioids -- evaluation and labeling: guidance for industry [Internet]. Silver Spring (MD): FDA; 2015 Apr. [cited 2015 May 22]. Available from: <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm334743.pdf>
207. Regulatory Affairs Professionals Society (RAPS) [Internet]. Rockville (MD): The Society. FDA finalizes approach to abuse-deterrent opioids; 2015 Apr 1 [cited 2015 May 22]. Available from: <http://www.raps.org/Regulatory-Focus/News/2015/04/01/21878/FDA-Finalizes-Approach-to-Abuse-Deterrent-Opioids/>
208. Rubin R. Final guidance issued on abuse-deterrent opioids. *JAMA* [Internet]. 2015 May 5 [cited 2015 May 22];313(17):1704. Available from: <http://jama.jamanetwork.com/article.aspx?articleid=2281681>
209. Regulatory Affairs Professionals Society [Internet]. Rockville (MD): The Society. Should FDA pull non-abuse deterrent generic opioids off the market? PhRMA, BIO say yes; 2015 Jan 20 [cited 2015 May 22]. Available from: <http://www.raps.org/Regulatory-Focus/News/2015/01/20/21120/Should-FDA-Pull-Non-Abuse-Deterrent-Generics-Opioids-off-the-Market-PhRMA-Bio-Say-Yes/>
210. U.S. Food and Drug Administration. Guidance for industry: expedited programs for serious conditions - drugs and biologics [Internet]. Silver Spring (MD): The Administration; 2014 May. [cited 2015 Aug 12]. Available from: <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm358301.pdf>
211. Purdue Pharma: Innovative Healthcare Solutions [Internet]. Stamford (CT): Purdue Pharma. FDA grants priority review designation for Purdue Pharma’s once-daily hydrocodone bitartrate extended-release tablets formulated with abuse-deterrent properties; 2014 Jul 8 [cited 2015 Aug 12]. Available from: <http://www.purduepharma.com/news-media/2014/07/fda-grants-priority-review-designation-for-purdue-pharmas-once-daily-hydrocodone-bitartrate-extended-release-tablets-formulated-with-abuse-deterrent-properties/>
212. European Medicines Agency. Guideline on the clinical development of medicinal products intended for the treatment of pain: draft [Internet]. London (GB): The Agency; 2013 May 30. [cited 2015 Aug 12]. Available from: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2013/05/WC500143769.pdf
213. First Nations and Inuit Health, Benefits Information [Internet]. Ottawa: Health Canada. Non-insured health benefits program update. Introduction of dose limit for stimulants; 2015 Mar 5 [cited 2015 May 27]. Available from: <http://www.hc-sc.gc.ca/fni-hi-spnia/nihb-ssna/benefit-prestation/newsletter-bulletin-eng.php>
214. Patented Medicine Prices Review Board. Utilization of prescription opioids in Canada’s public drug plans, 2006/07 to 2012/13 [Internet]. Ottawa: The Board; 2014 Apr. [cited 2015 Aug 12]. Available from: http://www.pmprb-cepmb.gc.ca/CMFiles/NPDUIS/NPDUIS_Opioids_2014-04-16_EN.pdf
215. DrugCoverage.ca™: a guide to reimbursement [Internet]. Toronto: Shoppers Drug Mart Inc. 2012 [cited 2015 Aug 12]. Available from: <http://www.drugcoverage.ca/en-ca/>
216. Government of Saskatchewan, Drug Plan and Extended Benefits Branch. The prescription review program [Internet]. Regina (SK): Government of Saskatchewan; 2012. [cited 2015 Aug 12]. Available from: <http://formulary.drugplan.health.gov.sk.ca/PDFs/ThePrescriptionReviewProgram.pdf>
217. Department of Health and Community Services (NL). [Internet]. St. John’s: The Department. Tamper resistant prescription drug pad program; 2015 [cited 2015 Aug 12]. Available from: http://www.health.gov.nl.ca/health/prescription/hcp_tamperresistantdrugpad.html

218. Ministry of Health, Drug Plan and Extended Benefits Branch. Appendix A: exception drug status program [Internet]. Regina (SK): Government of Saskatchewan; 2015. [cited 2015 Aug 4]. Available from: <http://formulary.drugplan.health.gov.sk.ca/PDFs/APPENDIXA.pdf> Formulary appendix.
219. Information for pharmacists. Methadone reimbursement procedure. Provincial drugs programs [Internet]. Winnipeg: Manitoba Health, Health Living and Seniors; 2014 Oct 16. [cited 2015 Aug 4]. Available from: <http://mpa.in1touch.org/uploaded/web/Legislation/Methadone%20Procedure%20Notification%20-%20Pharmacists%20Fax.pdf>

APPENDIX 1: Survey Findings

Table 6: Opioid Substitution Therapies and Naloxone Included on Public Drug Plan Formularies

| Public Drug Plans | Metadone | Suboxone | Naloxone |
|---------------------------|----------|----------|----------|
| British Columbia | Yes | Yes | No |
| Alberta | Yes | Yes | No |
| Saskatchewan | Yes | Yes | No |
| Manitoba | Yes | No | No |
| Ontario | Yes | Yes | No |
| Quebec | Yes | Yes | No |
| New Brunswick | Yes | Yes | No |
| Nova Scotia | Yes | Yes | No |
| Newfoundland and Labrador | Yes | Yes | No |
| Yukon Territory | Yes | No | No |
| NIHB | Yes | Yes | No |
| DND | Yes | Yes | Yes |

DND = Department of National Defence Canadian Armed Forces drug benefit plan; NIHB = Health Canada Non-insured Health Benefits Program.

Source: Unless otherwise referenced, the information was gathered from the 2015 CADTH survey of federal, provincial, and territorial public drug plan authorities. Survey question: "Which of the following opioid substitution therapy medications are currently listed under your drug benefit plan?"

Table 7: Established Reimbursement Criteria

| Public Drug Plans | Opioid Substitution Medications | | Naloxone | Class of Medications | | |
|---------------------------|---------------------------------|----------|----------|----------------------|------------|-----------------|
| | Methadone | Suboxone | | Opioids | Stimulants | Benzodiazepines |
| British Columbia | Yes | Yes | NA | Yes | Yes | No |
| Alberta | No | No | NA | Yes ^a | No | No |
| Saskatchewan | Yes | Yes | NA | Yes | Yes | No |
| Manitoba | No | NA | NA | Yes | Yes | No |
| Ontario | Yes | Yes | NA | Yes | No | No |
| Quebec | No | Yes | NA | Yes | Yes | Yes |
| New Brunswick | Yes | Yes | NA | Yes | Yes | No |
| Nova Scotia | Yes | Yes | NA | Yes | Yes | No |
| Newfoundland and Labrador | Yes | Yes | NA | Yes | Yes | No |
| Yukon Territory | No | NA | NA | No | Yes | No |
| NIHB | Yes | Yes | NA | No | No | No |
| DND | Yes | Yes | NA | Yes | Yes | Yes |

DND = Department of National Defence Canadian Armed Forces drug benefit plan; NA = not applicable; NIHB = Health Canada Non-insured Health Benefits Program.

^aFentanyl only.

Notes: See Table 10 and Appendix 2 for more details, and for specific listing criteria. Manitoba and Yukon Territory do not cover Suboxone. None of the drug plans listed above covers naloxone, except for DND.

Source: Unless otherwise referenced, the information was gathered from the 2015 CADTH survey of public drug plans. Survey question: “Which of the following medications or class of medications are listed or reimbursed *with criteria* (special authorization, exceptional access program, exception drug status, prior authorization, off-formulary, limited use, etc.)?”

Table 8: Reimbursed with Limits

| Public Drug Plans | Opioid Substitution Medications | | Naloxone | Class of Medications | | |
|-------------------------------|---------------------------------|-----------------|----------|----------------------|-----------------|-----------------|
| | Methadone | Suboxone | | Opioids | Stimulants | Benzodiazepines |
| British Columbia ^a | Yes | Yes | NA | Yes | Yes | Yes |
| Alberta | Yes | Yes | NA | Yes | Yes | Yes |
| Saskatchewan | No | No | NA | Yes | No | Yes |
| Manitoba | No | NA | NA | No | No | No |
| Ontario | No | No | NA | No | No | No |
| Quebec | Yes | No | NA | No | No | No |
| New Brunswick | No | No | NA | Yes | Yes | Yes |
| Nova Scotia ^b | No ^b | No ^b | NA | No ^b | No ^b | No ^b |
| Newfoundland and Labrador | Yes | Yes | NA | Yes | Yes | Yes |
| Yukon Territory | No | NA | NA | No | No | No |
| NIHB | Yes | No | NA | Yes | Yes | Yes |
| DND | No | No | No | Yes | No | No |

DND = Department of National Defence Canadian Armed Forces drug benefit plan; NA = not applicable; NIHB = Health Canada Non-insured Health Benefits Program.

^a British Columbia has quantity limits on barbiturates.

^b The Nova Scotia drug plan does not have any quantity limits determined by the drug benefit plan.

Notes: See Tables 9 and 10 for details. Manitoba and Yukon Territory do not cover Suboxone. None of the drug plans listed above covers naloxone, except for DND.

Source: Unless otherwise referenced, the information was gathered from the 2015 CADTH survey of public drug plans. Survey question: "Which of the following medications or class of medications are listed or reimbursed with quantity limits as determined by the drug benefit plan (for example, dose limits, maximum day supply, maximum daily dose, quantity limits, annual quantity limits, limited number of prescriptions, weekly fills, etc.)?"

Table 9: Supply Limits or Annual Quantity Limits

| Public Drug Plans | Opioids | Stimulants | Benzodiazepines | Methadone | Suboxone | Comments |
|----------------------------|---|--|--|---|-----------------------------|---|
| British Columbia | Max 30 days' supply | Max 100 days' supply | Max 30 days' supply | Max 35 days' supply | Max 30 days' supply | |
| Alberta ^a | Max 31 days' supply (all programs) | Max 31 days' supply, but max 100 days' supply for AISH | Max 31 days' supply (all programs) | Not specified (see Table 8) | Not specified (see Table 8) | |
| Saskatchewan ^b | The number of prescriptions for reimbursement purposes is limited to 3 submissions in a 45-day period. | | | | | |
| Manitoba | No limits (see Table 8) | No limits (see Table 8) | No limits (see Table 8) | No limits (see Table 8) | NA | |
| Ontario | No limits (see table 8) | | | | | |
| Quebec | No limits (see Table 8) | No limits (see Table 8) | No limits (see Table 8) | Not specified (see Table 8) | No limits (see Table 8) | |
| New Brunswick ^c | Annual quantity limits based on defined doses over a specific duration (includes hydromorphone, morphine sulphate, and codeine phosphate) | Annual quantity limits based on defined doses over a specific duration | Annual quantity limits based on defined doses over a specific duration | No limits (see Table 8) | No limits (see Table 8) | Benzodiazepines, narcotics, and controlled drugs are limited to max 35 days' supply. Zopiclone also subject to annual quantity limit |
| Nova Scotia | The Nova Scotia drug plan does not have any quantity limits determined by the drug benefit plan | | | | | |
| Newfoundland and Labrador | Max 30 days' supply | Max 30 days' supply | Max 30 days' supply | Daily limits | Daily limits | |
| Yukon Territory | Max 100 days applies to all prescriptions for all drugs | | | | NA | |
| NIHB ^d | Max 30 days' supply | Not specified (see Table 8) | Not specified (see Table 8) | Max 30 days' supply for pain management | No limits (see Table 8) | |
| DND | Max 14 days' supply (for Demerol) | No limits (see Table 8) | No limits (see Table 8) | No limits (see Table 8) | No limits (see Table 8) | Usually dispensed as written, following federal regulations |

AISH = Alberta Assured Income for the Severely Handicapped; DND = Department of National Defence Canadian Armed Forces drug benefit plan; Max = maximum; NIHB = Health Canada Non-insured Health Benefits Program; QL = quantity limit.

^a Alberta's maximum days' supply policy is 100 days (although limits of 31 or 34 days may apply for some plans and drugs). Maximum days' supply applies to the health benefits programs transferred from Human Services as follows:

Central Nervous System drugs, 31 days; for AISH, 100 days.

Analgesics (includes opiate agonists, opiate partial agonists), 31 days for all programs.

Anxiolytics, sedatives, and hypnotics (includes barbiturates, benzodiazepines, miscellaneous drugs), 31 days for all programs.

Miscellaneous central nervous system drugs, 31 days; for AISH, 100 days.

In addition, Alberta Works may impose QLs for clients with high drug utilization.²

^bSaskatchewan limits the number of prescriptions for reimbursement purposes to 3 submissions in a 45-day period.

^cIf a beneficiary reaches his or her QL, the prescriber must call the Interactive Voice Response system to override the QL, which then activates the reimbursement. The claims system can accommodate an annual total milligram QL per drug group. Limits were set based on proxy doses over an anticipated treatment duration:

- Benzodiazepines with an indication for an anxiety disorder — annual QL based on maximum dose over a 12-month period (e.g., lorazepam max dose for generalized anxiety disorder 6 mg/day; annual QL = 2,160 mg).
- Benzodiazepines with only an indication for insomnia — annual QL based on maximum dose for 60 days to allow for multiple short courses (7 to 10 days) of therapy over a 12-month period (e.g., temazepam max dose of 30 mg/day; annual QL = 1,800 mg).
- Zopiclone — annual QL based on a max of 7.5 mg/day dose over a 12-month period; annual QL = 2,700 mg.
- Methylphenidate — annual QL based on max dose of 40 mg to 60 mg/day; annual QL = 18,200 mg.
- Codeine/APAP combination products — QL based on maximum APAP daily dose of 4 g/day.
- Opioid QLs preceded national guidelines and are were based on a defined dose over a specified duration:
 - Hydromorphone — annual QL based on a dose of 4 mg every 6 hours for 30 days; annual QL = 480 mg.
 - Morphine sulphate — annual QL based on a dose of 30 mg every 4 hours for 30 days; annual QL = 5,040 mg.
 - Codeine phosphate — annual QL based on a dose of 40 mg every 4 hours for 14 days; annual QL = 3,360 mg.

Quantities for other agents that require special authorization are managed through that process, for example. Also, prescribers can request the removal of a cancer or palliative care patient from the quantitative limits program for an indefinite period of time by calling a customer service representative and identifying the patient as such.

^dThe NIHB Program also has annual QLs.

Note: Manitoba and Yukon Territory do not cover Suboxone.

Source: Unless otherwise referenced, the information was gathered from the 2015 CADTH survey of public drug plans. Survey question: “Which of the following medications or class of medications are listed or reimbursed with quantity limits as determined by the drug benefit plan (for example, dose limits, maximum day supply, maximum daily dose, quantity limits, annual quantity limits, limited number of prescriptions, weekly fills, etc.)?”

Table 10: Dosage Restrictions

| Public Drug Plans | Opioids | Stimulants | Benzodiazepines | Methadone | Suboxone |
|-------------------------------|---|--|--|---|--|
| British Columbia ^a | Not specified (see Tables 7 and 8) | Not specified (see Tables 7 and 8) | Not specified (see Tables 7 and 8) | Must be dispensed as 10 mg/mL oral preparation (i.e., as commercially available Methadose) | Coverage limited to buprenorphine 2 mg + naloxone 0.5 mg combination tablet; and buprenorphine 8 mg + naloxone 2 mg combination tablet |
| Alberta | Fentanyl citrate injection, 0.05 mg/mL | Not specified (see Tables 7 and 8) | Not specified (see Tables 7 and 8) | Not specified (see Tables 7 and 8) | Not specified (see Tables 7 and 8) |
| Saskatchewan | Not specified (see Tables 7 and 8) | | | | |
| Manitoba | Not specified (see Tables 7 and 8) | Not specified (see Tables 7 and 8) | <i>No restrictions</i> (see Tables 7 and 8) | <i>No restrictions</i> (see Tables 7 and 8) | NA |
| Ontario | OxyNEO 60 mg and 80 mg tablets not funded under the EAP. OxyNEO 80 mg tablets funded under the Palliative Care Drugs mechanism. | <i>No restrictions</i> (see Tables 7 and 8) | <i>No restrictions</i> (see Tables 7 and 8) | Not specified (see Tables 7 and 8) | Not specified (see Tables 7 and 8) |
| Quebec | Not specified (see Tables 7 and 8) | Not specified (see Tables 7 and 8) | Not specified (see Tables 7 and 8) | Magistral solutions, tablets of 1 mg, 5 mg, 10 mg, and 25 mg, oral solution of 1 mg/mL, 10 mg/mL (Metadol) are covered without criteria | Not specified (see Tables 7 and 8) |

| | | | | | |
|----------------------------------|--|--|--|---|--|
| New Brunswick | Codeine (Codeine Contin) in 50 mg, 100 mg, 150 mg, and 200 mg tablets (controlled-release) and oxycodone and generics 5 mg, 10 mg, 20 mg tablets (immediate release) for treatment of mild to moderate cancer-related or chronic non-cancer pain. Fentanyl transdermal system 12 mcg/hr, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr and 100 mcg/hr. | Methylphenidate (Biphentin) in controlled-release capsules ranging from 10 mg to 80 mg. Requires request form from specialists in pediatric psychiatry, pediatricians, or GPs with expertise in ADHD. Concerta and generic brands will be considered for doses ranging from 18 mg to 54 mg extended-release tablets. Dexedrine listed as regular benefit (5 mg to 15 mg tablets) but only for those aged 18 years and older. | Not specified (see Tables 7 and 8) | 1 mg/mL oral solution and 10 mg/mL oral concentrate. Claims will be considered for the treatment of severe cancer-related or chronic non-malignant pain as an alternative to other opioids for methadone hydrochloride in 1 mg, 5 mg, 19 mg, and 25 mg tablets. Preparations compounded using Metadol tablets will not be considered. | Suboxone in 2 mg/0.5 mg and 8 mg/2 mg sublingual tables for the treatment of opioid dependence for patients in which methadone was contraindicated (also coverage for Naltrexone [REVIA] in 50 mg tablets for 12-week initial approval). |
| Nova Scotia | Not specified (see Tables 7 and 8) | Not specified (see Tables 7 and 8) | <i>No restrictions</i> (see Tables 7 and 8) | Not specified (see Tables 7 and 8) | Not specified (see Tables 7 and 8) |
| Newfoundland and Labrador | Opioids requiring special authorization are assessed using both the posted criteria along with the manufacturer's recommended dosing. Requests falling outside recommended dosing maximums or intervals are assessed on a case-by-case basis by our clinical pharmacists | Not specified (see Tables 7 and 8) | Not specified (see Tables 7 and 8) | Not specified (see Tables 7 and 8) | Not specified (see Tables 7 and 8) |
| Yukon Territory | <i>No restrictions</i> (see Tables 7 and 8) | Not specified (see Tables 7 and 8) | <i>No restrictions</i> (see Tables 7 and 8) | <i>No restrictions</i> (see Tables 7 and 8) | NA |
| NIHB^b | Clients over the NIHB opioid "watchful doses" currently set at 450 mg of morphine equivalents require rationale for the higher dose (e.g., palliative care or cancer patients) | 150 mg of methylphenidate equivalents. | 40 mg/day | Not specified (see Tables 7 and 8) | Not specified (see Tables 7 and 8) |

| | | | | | |
|-----|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|
| DND | Not specified (see Tables 7 and 8) | Not specified (see Tables 7 and 8) | Not specified (see Tables 7 and 8) | Not specified (see Tables 7 and 8) | Not specified (see Tables 7 and 8) |
|-----|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|---------------------------------------|

ADHD = attention-deficit/hyperactivity disorder; DND = Department of National Defence Canadian Armed Forces drug benefit plan; EAP = Exceptional Access Program; GP = general practitioner; hr = hour; NA = not applicable; NIHB = Health Canada Non-insured Health Benefits Program.

^a In British Columbia, buprenorphine is covered for patients who meet the “limited coverage” criteria and whose prescription has been written by a prescriber who is approved and has entered into the Collaborative Prescribing Agreement.

^b The Health Canada NIHB Program provides for an acetaminophen dose limit of 3,600 mg/day (as single ingredient or in combination).

On March 4, 2015, to ensure the safety of clients, the NIHB Program lowered dose limits for opioids and benzodiazepines. NIHB is gradually reducing opioid dose limits to be in line with the *Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain*. This does not apply to clients who are taking opioids for cancer or palliative pain management. Since 2013, the NIHB Program has been gradually reducing the benzodiazepine dose limit. In some cases, clients may be exempt from these dose limits. On February 25, 2015, the NIHB Program set a new dose limit for stimulants to help ensure clients are using these drugs safely. Dose limits are the maximum quantity of these drugs that a client can receive per day.²¹³

Note: Manitoba and Yukon Territory do not cover Suboxone.

Source: Unless otherwise referenced, the information was gathered from the 2015 CADTH survey of public drug plans. Survey questions: “Which of the following medications or class of medications are listed or reimbursed *with criteria* (special authorization, exceptional access program, exception drug status, prior authorization, off-formulary, limited use, etc.)?” and “Which of the following medications or class of medications are listed or reimbursed with quantity limits as determined by the drug benefit plan (for example, dose limits, maximum day supply, maximum daily dose, quantity limits, annual quantity limits, limited number of prescriptions, weekly fills, etc.)?”

Table 11: Listing and Reimbursement Restrictions for High-Dose Opioids

| Public Drug Plans | Yes/No | Details |
|---------------------------|--------|--|
| British Columbia | No | |
| Alberta | No | |
| Saskatchewan | No | |
| Manitoba | No | |
| Ontario | No | |
| Quebec | No | |
| New Brunswick | No | |
| Nova Scotia | No | |
| Newfoundland and Labrador | Yes | All special authorization opioids are assessed using both the posted criteria, along with the manufacturer’s recommended dosing. Requests falling outside recommended dosing maximums or intervals are assessed on a case-by-case basis by our clinical pharmacists. |
| Yukon Territory | No | |
| NIHB | No | Note: NIHB clients who are over the NIHB opioid “watchful dose” (currently set at 450 mg of morphine equivalents) are required to provide rationale for the higher dose. |
| DND | No | |

DND = Department of National Defence Canadian Armed Forces drug benefit plan; NIHB = Health Canada Non-insured Health Benefits Program.

Source: Unless otherwise referenced, the information was gathered from the 2015 CADTH survey of public drug plans. Survey question: “Are there any specific listing restrictions and/or reimbursement criteria for high-dose opioids?”

Table 12: Filling and Refill Restrictions as Determined by the Drug Benefit Plan

| Public Drug Plans | Opioid Substitution Medications | | Naloxone | Class of Medications | | |
|---------------------------|---------------------------------|----------|----------|----------------------|------------|-----------------|
| | Methadone | Suboxone | | Opioids | Stimulants | Benzodiazepines |
| British Columbia | Yes | Yes | NA | Yes | Yes | Yes |
| Alberta | Yes | Yes | NA | Yes | Yes | Yes |
| Saskatchewan | No | No | NA | Yes | No | Yes |
| Manitoba | No | NA | NA | No | No | No |
| Ontario | No | No | NA | No | No | No |
| Quebec | Yes | No | NA | Yes | Yes | No |
| New Brunswick | Yes | Yes | NA | Yes | Yes | Yes |
| Nova Scotia | Yes | Yes | NA | Yes | Yes | Yes |
| Newfoundland and Labrador | Yes | Yes | NA | Yes | Yes | No |
| Yukon Territory | No | NA | NA | No | No | No |
| NIHB | Yes | Yes | NA | Yes | Yes | Yes |
| DND | No | No | No | No | No | No |

DND = Department of National Defence Canadian Armed Forces drug benefit plan; NA = not applicable; NIHB = Health Canada Non-insured Health Benefits Program.

Note: Manitoba and Yukon Territory do not cover Suboxone. None of the drug plans listed above covers naloxone, except for DND.

Source: Unless otherwise referenced, the information was gathered from the 2015 CADTH survey of public drug plans. Survey question: "Which of the following medications or class of medications are subject to refill restrictions as determined by the drug benefit plan (for example same-day refill, early refills, multiple fills, no repeats etc.)?"

Table 13: Specific Refill Restrictions as Determined by the Drug Benefit Plan

| Public Drug Plans (Canada) | Drug or Drug Class Subjected to Refill Restrictions | Details on Refill Restrictions |
|----------------------------|---|---|
| British Columbia | Opioids Stimulants Benzodiazepines Methadone Suboxone | Early Refill: Medication will not be refilled if more than a 14-day supply remains from the previous fill. Multiple fills of the same prescription for the same patient on the <i>same day</i> are not covered unless an intervention code is entered. |
| Alberta | Opioids Stimulants Benzodiazepines Methadone Suboxone | Early refill edit policy is applied to all drug claims with a supply of 90 days or more. Subsequent claims are accepted only after the use of 70% of the previous drug quantity. Multiple fills: Prescription claims for the same drug (DIN) for the same patient on the same day are not covered. |
| Saskatchewan | Opioids Benzodiazepines | For benzodiazepines and “other targeted substances,” repeats may be authorized on the original prescription, whether written or verbal, but authorization must be for a specific number of refills. Refills are permitted only if less than 1 year has elapsed since the date on which the prescription was issued. In the case of “narcotic drugs” (including codeine, Demerol, MS Contin, Novahistex DH, Percocet, Tussionex, Tylenol #4, Lomotil, Darvon-N, and Talwin), no repeats are allowed and all reorders must be new, written prescriptions (a prescription may be dispensed in divided portions [part-fill], subject to professional discretion). Adjudication rules limit the number of prescriptions that can be filled to 3 submissions in a 45-day period. If prescriptions are dispensed more frequently, pharmacists must contact the drug plan and provide a reason for the increase before payment is authorized. The prescriber may also be requested to provide clinical background information, documentation, or a letter regarding the need for increased prescription frequency. |
| Manitoba | No refill restriction as determined by the drug benefit plan (see Table 12) | |
| Ontario | No refill restriction as determined by the drug benefit plan (see Table 12) | |
| Quebec | Opioids Methadone Stimulants | Details not specified |
| New Brunswick | Opioids Stimulants Benzodiazepines Methadone Suboxone | Details not specified |
| Nova Scotia | Opioids Stimulants Benzodiazepines Methadone Suboxone | The adjudication system will not permit same-day refills for any drug covered under the Pharmacare Programs. Other monitoring activities are conducted by Nova Scotia’s Prescription Monitoring Program, such as multiple fills and double-doctoring. In addition, there are no “repeats” on straight narcotics under the deferral law, although part-fills are permitted. |

| Public Drug Plans (Canada) | Drug or Drug Class Subjected to Refill Restrictions | Details on Refill Restrictions |
|----------------------------|---|---|
| Newfoundland and Labrador | Opioids Stimulants Methadone Suboxone | Refill duration is controlled within the special authorization system. Benzodiazepine refills are controlled using CPhA 3 claim standards. |
| Yukon Territory | All drugs on formulary | Same restrictions as all items on the formulary. There are no special refill policies for opioids, stimulants, benzodiazepines, and opioid substitution therapies. |
| NIHB | Opioids Stimulants Benzodiazepines Methadone Suboxone | <p>The NIHB Program sends warning messages to pharmacies from the claim system to indicate, for example, that a client recently received the same drug at another pharmacy. The pharmacist may then be requested to provide a code to override the warning message. This will also be triggered if the client has used less than two-thirds of the medication based on the days' supply.</p> <p>In addition, more specifically to drugs of concern, warning messages will be sent to address situations of possible drug misuse, such as 3 or more active prescriptions for benzodiazepines; 3 or more active prescriptions for opioids; and a prescription for methadone in association with other opioid-based drugs.</p> |
| DND | | The rules for dispensing follow federal legislation. |

CPhA 3 = standard established by the Canadian Pharmacists Association for the transmission of electronic drug claims; DIN = drug identification number; DND = Department of National Defence Canadian Armed Forces drug benefit plan; NIHB = Health Canada Non-insured Health Benefits Program.

Note: In Prince Edward Island, some plans restrict early refills entirely (e.g., Financial Assistance Drug Program). Some plans require that at least 80% of the time duration has passed between refills before the system will pay for the next claim (e.g., PEI Seniors' Drug Cost Assistance Program).²

Source: Unless otherwise referenced, the information was gathered from the 2015 CADTH survey of public drug plans. Survey question: "Which of the following medication or class of medications are subject to refill restrictions as determined by the drug benefit plan (for example same-day refill, early refills, multiple fills, no repeats etc.)?"

Table 14: Delisting of Opioids, Stimulants, or Benzodiazepines

| Public Drug Plans | Yes/No | If Yes, Product or Drug Classes Delisted | Details |
|---------------------------|---------------|---|--|
| British Columbia | No | | |
| Alberta | No | | |
| Saskatchewan | Yes | Demerol and Talwin | Delisted due to poor safety profile and abuse potential, as per the advice of the Drug Advisory Committee of Saskatchewan. |
| Manitoba | No | | |
| Ontario | Not specified | | Note: When OxyContin was discontinued by the manufacturer and replaced by OxyNEO, long-acting oxycodone was moved from Limited Use to the more restricted EAP. A decision was made not to fund 60 mg and 80 mg OxyNEO through EAP. |
| Quebec | No | | Note: Nitrazepam was moved to Médicament d'exception with the following criterion: to control seizure disorder. This was due to the misuse problem associated with this drug. |
| New Brunswick | No | | |
| Nova Scotia | No | | |
| Newfoundland and Labrador | Yes | Oxycodone generics | Delisted as part of a review and recommendations from the Atlantic Common Drug Review. |
| Yukon Territory | Yes | Benzodiazepines | Benzodiazepines were removed from the Chronic Disease formulary because of reported abuse. |
| NIHB | Yes | Opioids: Tylenol #4 and generics, Meperidine, OxyContin, and Pentazocine. Benzodiazepines: Clorazepate dipotassium, chlordiazepoxide, and flurazepam | Opioids: Tylenol #4 and generics delisted to reduce risk associated with high codeine content. Meperidine delisted to promote use of more appropriate treatment options for pain. OxyContin delisted due to risks of inappropriate use and because other efficacious opioids are available. Pentazocine delisted to promote use of more appropriate treatment options for pain. Benzodiazepines: Clorazepate dipotassium, chlordiazepoxide, and flurazepam delisted to promote use of more appropriate treatment options. |
| DND | No | | |

DND = Department of National Defence Canadian Armed Forces drug benefit plan; EAP = Exceptional Access Program; NIHB = Health Canada Non-insured Health Benefits Program.

Source: Unless otherwise referenced, the information was gathered from the 2015 CADTH survey of public drug plans. Survey question: "In the past, was there a decision made to delist opioids (including high-dose formulations of opioids, such as transdermal fentanyl 100 mcg patches), stimulants, or benzodiazepines from your drug benefit plan?"

Table 15: Incentives for Pharmacists

| Public Drug Plans | Yes/No | Details of the incentive |
|---------------------------|--------|--|
| British Columbia | Yes | <p>BC PharmaCare pays an “interaction fee” to pharmacists for witnessing the ingestion of methadone, but does not pay a fee for buprenorphine plus naloxone. This is based on the reduced risk of drug diversion and the formulation of the product (in British Columbia, buprenorphine plus naloxone is supplied as sublingual tablets that require up to 10 minutes for dissolution).</p> <p>In British Columbia, pharmacists are compensated for interception of prescriptions that result in cost savings to PharmaCare (only if the patient’s deductible had been paid). Valid reasons for refusal include significant drug–drug interaction; previous adverse reaction; therapeutic duplication; subtherapeutic dose; dangerously high dose; treatment failure; overuse; suspicion of polypharmacy or double-doctoring; and falsified prescription.</p> |
| Alberta | Yes | Under the Compensation Plan for Pharmacy Services, Alberta pharmacists may claim for an Assessment for Refusal to Fill a Prescription fee based on one of the following: potential overuse and/or abuse, or a falsified or altered prescription. |
| Saskatchewan | Yes | Saskatchewan’s Ministry of Health reimburses pharmacies for refusing to fill certain medications when misuse and/or abuse is suspected, including when a pharmacist determines that the prescription has been altered or falsified, or if multiple pharmacy or double-doctoring are suspected. Methadone for harm reduction is dispensed daily, or weekly with carries. |
| Manitoba | No | |
| Ontario | Yes | The Pharmaceutical Opinion Program includes remuneration for pharmacist interventions, including when a prescription is not filled because of a confirmed forged or falsified prescription. |
| Quebec | No | |
| New Brunswick | No | Upcoming system changes will no longer allow for this. |
| Nova Scotia | Yes | <p>Nova Scotia’s Basic Medication Review Service (approximately 20 to 30 minutes to complete), Advanced Medication Review Service (approximately 1 to 1.5 hours to complete), and Medication Review Follow-up are insured services funded by the Nova Scotia Seniors’ Pharmacare Program, and are provided to patients who meet certain criteria in community pharmacies. For Basic Reviews, eligible patients must be taking 3 or more prescription medications that are covered by Pharmacare Programs for the treatment of a chronic condition. For an Advanced Review, the eligible patient must be taking 4 or more medications, or 1 of a list of medications including 3 benzodiazepines.</p> <p>“Refusal to Fill” is an insured service that applies to drugs monitored by the Prescription Monitoring Program (opioids, stimulants). This applies under circumstances such as suspicion of falsified prescription and double-doctoring – but not for early part-fills, if that is the only issue.</p> |
| Newfoundland and Labrador | Yes | The Newfoundland and Labrador Prescription Drug Program currently pays a professional fee to pharmacists when there is a refusal to fill a narcotic prescription due to suspected abuse or misuse. |
| Yukon Territory | No | Note: A daily dispensing fee is paid for methadone maintenance. |
| NIHB | Yes | Witnessing fee for ingestion of methadone or Suboxone. |
| DND | No | |

DND = Department of National Defence Canadian Armed Forces drug benefit plan; NIHB = Health Canada Non-insured Health Benefits Program.

Source: Unless otherwise referenced, the information was gathered from the 2015 CADTH survey of public drug plans. Survey question: “Do you provide incentives for pharmacist interventions specifically related to opioids, stimulants, or benzodiazepines, or opioid substitution therapy? (For example, refusal fees such as a prescription not filled because of suspicion of falsified prescription, suspicion of double-doctoring, drug interactions, therapeutic duplication, witnessing the ingestion of methadone, etc.)”

Table 16: Single-Pharmacy Designation

| Public Drug Plans | Yes/No |
|---------------------------|--------|
| British Columbia | Yes |
| Alberta | Yes |
| Saskatchewan | No |
| Manitoba | Yes |
| Ontario | No |
| Quebec | Yes |
| New Brunswick | Yes |
| Nova Scotia | Yes |
| Newfoundland and Labrador | Yes |
| Yukon Territory | No |
| NIHB | No |
| DND | No |

DND = Department of National Defence Canadian Armed Forces drug benefit plan; NIHB = Health Canada Non-insured Health Benefits Program.

Note: See Table 18 for details.

Source: Unless otherwise referenced, the information was gathered from the 2015 CADTH survey of public drug plans. Survey question: "Do you have a program to restrict to a single *pharmacy* for accessing opioids, stimulants, or benzodiazepines, or opioid substitution therapy?"

Table 17: Single Prescriber Designation

| Public Drug Plans | Yes/No |
|---------------------------|--------|
| British Columbia | Yes |
| Alberta | No |
| Saskatchewan | No |
| Manitoba | No |
| Ontario | No |
| Quebec | Yes |
| New Brunswick | Yes |
| Nova Scotia | No |
| Newfoundland and Labrador | No |
| Yukon Territory | No |
| NIHB | Yes |
| DND | Yes |

DND = Department of National Defence Canadian Armed Forces drug benefit plan; NIHB = Health Canada Non-insured Health Benefits Program.

Note: See Table 18 for details.

Source: Unless otherwise referenced, the information was gathered from the 2015 CADTH survey of public drug plans. Survey question: "Do you have a program to restrict a patient to a single *prescriber* for accessing opioids, stimulants, or benzodiazepines, or opioid substitution therapy?"

Table 18: Details of Single Prescriber or Pharmacy Designation Program

| Public Drug Plans | If Yes, for What Type of Program? |
|-------------------------|--|
| British Columbia | <p>British Columbia runs a Restricted Claimant Program to reduce problematic medication use. The program limits coverage for patients with identified histories of misuse and/or abuse to medications prescribed by a single practitioner, or dispensed by a single pharmacy. Physicians and pharmacists must communicate this information to the patient.</p> <p>The program applies only to prescriptions paid for by PharmaCare, and patients may avoid adherence by paying for their own drugs. However, a new dispensing pharmacist would be able to view the patient’s information through the PharmaNet system. The new pharmacist could then ask patients about their reasons for infringing upon the restriction, and engage the beneficiary in a dialogue to encourage compliance.</p> <p>Pharmacists are not mandated to alert the new physician with whom the patient is double-doctoring. But if the pharmacist chooses to do so, the new doctor could then limit the prescribing of the drug in question or cancel the prescription.</p> |
| Alberta | <p>The Alberta Works Income Support and AISH Health Benefits programs (transferred from Human Services to Alberta Health) that cover persons with disabilities and low-income and unemployed citizens or permanent residents have a restriction policy in place. If clients are identified as high-volume users, their case workers can restrict prescription drug coverage to one pharmacy by having restrictions applied to their Health Benefits Card.</p> <p>Prescribers working with other beneficiaries are encouraged to develop agreements with the patient, and sometimes the pharmacy, whereby the patient assents to limit his or her treatment to one doctor and one pharmacy. Because information regarding dispensing is available to both physicians and pharmacists on Netcare (via the Pharmaceutical Information Network), non-adherence can be checked through the system.</p> |
| Saskatchewan | <p>Note: Although there is no program restricting patients to a single pharmacy, pharmacists and physicians have access to the Pharmaceutical Information Program, which captures prescription information from Saskatchewan pharmacies.</p> |
| Manitoba | <p>Manitoba’s MH is able to use its Drug Programs Information Network to restrict a patient to filling prescriptions at a particular pharmacy. This restriction is initiated at the request of the physician and with the agreement of the patient.</p> <p>Where the MH is the sole payer for the cost of the prescribed medication for a patient, it has the authority to limit reimbursement to only one pharmacy, with or without the consent of the patient. The pharmacy filling the prescriptions must contact the drug program to “open” the patient’s file before it can begin dispensing for that individual.</p> |
| Ontario | <p><i>No prescriber or pharmacy designation policies (see Tables 16 and 17)</i></p> |
| Quebec | <p>In 1985, Programme Alerté was created by OPQ to encourage the appropriate use of drugs. This program identifies patients who are misusing substances that are known to be habit-forming (mainly benzodiazepines and opioids), based on such criteria as visits to multiple pharmacies and multiple physicians, or when habit-forming drug therapy overlaps are found. When a patient has been identified, a warning is sent by a designated OPQ staff member to the pharmacist and neighbouring pharmacies about that patient. When patients visit a pharmacy, they are invited to select one physician and one pharmacy for their drug therapy needs.</p> <p>Note: The program was created by OPQ and not by the government.</p> |

| | |
|----------------------------------|---|
| New Brunswick | <p>As part of the New Brunswick Prescription Drug Program, a report is generated once a month that identifies beneficiaries who have met one or both of the following criteria: used 2 or more physicians or used 2 or more pharmacies. In cases where further investigation is warranted, a 6-month profile is obtained and reviewed on an individual basis. The physician(s) and pharmacies related to each individual case will be contacted if a patient's profile includes one or more of the following criteria: multiple physicians or pharmacies; duplication of therapy; excess daily dosage; long-term or escalating use; multiple narcotics, controlled drugs, or benzodiazepines; or high-prescription volumes, dollars, and/or quantities external alerts or requests (pharmacy alerts; individual physician or pharmacy requests).</p> <p>Under the New Brunswick Prescription Drug Program Drug Utilization Review process, limitations to the access of narcotics, controlled drugs, and benzodiazepines are occasionally placed upon some beneficiaries. When this is necessary, the beneficiary will be restricted to accessing 1 physician and 1 pharmacy in the province. The decision to enact restrictions on a patient is based on reviews and recommendations received from prescribers.</p> <p>Once the province's PMP is operational, prescribers will be able to register a Patient Monitoring Agreement within the PMP system. Registration establishes that the patient has agreed to be limited to 1 prescriber and 1 pharmacy. If the individual attempts to fill a prescription from a different prescriber or use a different pharmacy, the system will generate an alert to warn the patient's care team.</p> |
| Nova Scotia | <p>The decision to designate a single pharmacy to dispense a patient's medications is determined by physicians in consultation with their patients and, in some cases, with input from the Department of Community Services. In some cases, the NSPMP may offer this as a suggestion to a physician as a strategy to limit misuse, abuse, or diversion. The NSPMP then monitors patient agreements and reports on a weekly basis any patient who receives controlled drugs from a pharmacy or physician outside of the patient's appointed care team.</p> |
| Newfoundland and Labrador | <p>Beneficiaries restricted to a maximum of 2 pharmacies.</p> |
| Yukon Territory | <p><i>No prescriber or pharmacy designation polices (see Tables 16 and 17)</i></p> |
| NIHB | <p>A methodology (via the PMP) identifies NIHB clients who are misusing or are at greater risks of misusing drugs of concern and places the clients under certain restrictions with a view to prevent double-doctoring, by requesting the client to find a sole prescriber for the 4 categories of drugs. If clients or their health care providers cannot follow the PMP process to support the continuation of the drug therapy in question, the NIHB Program reserves the right to refuse coverage.</p> |
| DND | <p>On rare occasions, if a specific patient demonstrates a behaviour that could be associated with abuse potential, a specific prescriber may be assigned. This decision is made with the involvement of the Senior Medical Authority, the patient's primary care provider, the pharmacist, and the patient.</p> |

AISH = Alberta Assured Income for the Severely Handicapped; DND = Department of National Defence Canadian Armed Forces drug benefit plan; MH = Ministry of Health; NIHB = Health Canada Non-insured Health Benefits Program; NSPMP = Nova Scotia Prescription Monitoring Program; OPQ = L'Ordre des pharmaciens du Québec; PMP = Prescription Monitoring Program.

Source: Unless otherwise referenced, the information was gathered from the 2015 CADTH survey of public drug plans. Survey question: "If you have a program to restrict a patient to a single *prescriber* or *dispenser* for accessing opioids, stimulants, or benzodiazepines, or opioid substitution therapy, please describe the program."

Table 19: Reimbursement of Tamper-Resistant Products

| Public Drug Plans | Yes/No | If Yes, What Products? | Details |
|---------------------------|--------|------------------------|--|
| British Columbia | Yes | OxyNEO | Through palliative care program only. |
| Alberta | Yes | OxyNEO | Listed as a regular benefit. |
| Saskatchewan | Yes | OxyNEO and Concerta | OxyNEO is covered under the Exceptional Drug Status program for patients who meet set criteria (i.e., clinical criteria – for the treatment of pain in palliative and cancer patients) Concerta changed from restricted to full formulary benefit, as it was determined to be more difficult to abuse or tamper with. |
| Manitoba | Yes | OxyNEO | OxyNEO is listed under the Exception Drug Status Program. |
| Ontario | Yes | OxyNEO | Funded through the Exceptional Access Program (but 60 mg and 80 mg tablets not funded). OxyNEO 80 mg tablets funded under the Palliative Care Drugs mechanism. |
| Quebec | Yes | OxyNEO | OxyNEO covered according to eligibility criteria under the Médicament d'exception mechanism. |
| New Brunswick | Yes | Concerta | Concerta is covered for the treatment of ADHD in patients aged 6 to 25 years who demonstrate significant symptoms and who have tried immediate or slow-release methylphenidate with unsatisfactory results. Note: OxyNEO covered only for beneficiaries who had received OxyContin coverage in the 3 months prior to February 2012. |
| Nova Scotia | No | | Note: OxyNEO is not a benefit under the Pharmacare Programs. However, when OxyNEO was introduced in February 2012, patients who had received OxyContin in the 3 months prior to that date were grandfathered to receive coverage for OxyNEO. |
| Newfoundland and Labrador | Yes | Concerta | Special authorization. |
| Yukon Territory | No | | |
| NIHB | No | | Note: OxyNEO is available only to clients who had received coverage for OxyContin in the 3 months prior to Feb 2012. ²¹⁴ |
| DND | Yes | OxyNEO | |

ADHD = attention-deficit/hyperactivity disorder; DND = Department of National Defence Canadian Armed Forces drug benefit plan; NIHB = Health Canada Non-insured Health Benefits Program.

Source: Unless otherwise referenced, the information was gathered from the 2015 CADTH survey of public drug plans. Survey question: "Are tamper-resistant products (i.e., drugs that resist crushing, cutting, chewing, dissolution, or other forms of tampering) currently listed under your drug benefit plan?"

Table 20: Listing and Reimbursement Actions for OxyNEO by Public Drug Plans in Canada^{214,215}

| Jurisdictions | Drug Plan | Listing Actions for OxyNEO | Reimbursement Actions for OxyNEO |
|---------------------------|------------------------------|----------------------------|---|
| Health Canada | NIHB | Listed | Clients who had received coverage for OxyContin in the 3 months prior to February 2012 legible for coverage of OxyNeo |
| British Columbia | PharmaCare | Listed | Special Authority required |
| Alberta | Alberta Blue Cross | Listed | |
| Saskatchewan | Saskatchewan Drug Plan | Listed | Exceptional Drug Status with no reimbursement unless patients meet set criteria |
| Manitoba | PharmaCare | Listed | Exceptional Drug Status with no reimbursement unless patients meet set criteria |
| Ontario | Ontario Drug Benefit Plan | Listed | Exceptional Access Approval required after February 2013 |
| Quebec | RAMQ | Listed | Covered according to eligibility criteria established by the RAMQ, Medicament d'Exception mechanism. |
| New Brunswick | Prescription Drug Program | Listed | Only beneficiaries who had received OxyContin coverage in 3 months prior to Feb. 2012 would be covered for OxyNEO. |
| Nova Scotia | Nova Scotia PharmaCare | Listed | Only beneficiaries who had received OxyContin coverage in 3 months prior to Feb. 2012 would be covered for OxyNEO. |
| Prince Edward Island | Health PEI | NOT Listed | Only beneficiaries who had received OxyContin coverage in 3 months prior to Feb. 2012 would be covered for OxyNEO. |
| Newfoundland and Labrador | NL Prescription Drug Program | NOT Listed | OxyNEO not reimbursable. |
| Yukon Territory | | NOT Listed | OxyNEO not reimbursable. |

NIHB = Health Canada Non-insured Health Benefits Program; NL = Newfoundland and Labrador; RAMQ = Régie de l'Assurance Maladie du Québec

Source: Information as reported by the Patented Medicine Prices Review Board²¹⁴ and DrugCoverage.ca, a proprietary Web portal operated by Plasmid Biocommunications Inc. Plasmid is a wholly owned subsidiary of Shoppers Drug Mart Corporation (Shoppers Drug Mart; Pharmaprix in Quebec), which is owned by Shoppers Drug Mart Canada.²¹⁵

Table 21: Requirement to Show Identification to Prescriber or Pharmacist, and/or Requirement for Pharmacist to Keep a Record of Patient's Identification When Dispensing

| Public Drug Plans | Patient Must Show Proof of Identity to Prescriber | | | | | | Patient Must Show Proof of Identity to Pharmacist | | | | | | Pharmacist Must Keep a Record of the Patient's Identification | | | | | |
|-------------------|---|-----------|----------------|-----------|----------|--------------|---|-----------|----------------|-----------|----------|--------------|---|-----------|----------------|-----------|----------|----------|
| | Opioid | Stimulant | Benzodiazepine | Methadone | Suboxone | Naloxone | Opioid | Stimulant | Benzodiazepine | Methadone | Suboxone | Naloxone | Opioid | Stimulant | Benzodiazepine | Methadone | Suboxone | Naloxone |
| BC ^a | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| AB ^b | No | No | No | No | No | No | No | No | No | No | No | No | No | No | No | No | No | No |
| SK ^c | See footnote ^c | | | | | | See footnote ^c | | | | | | See footnote ^c | | | | | |
| MB | No | No | No | No | No | No | Yes | Yes | Yes | Yes | Yes | Yes | No | No | No | No | No | No |
| ON ^d | Yes | Yes | Yes | Yes | Yes | No | Yes | Yes | Yes | Yes | Yes | No | Yes | Yes | Yes | Yes | Yes | No |
| QC | No | No | No | No | No | No | No | No | No | No | No | No | No | No | No | No | No | No |
| NB | No | No | No | No | No | No | No | No | No | No | No | No | No | No | No | No | No | No |
| NS ^e | Yes | Yes | Yes | Yes | Yes | ^f | Yes | Yes | Yes | Yes | Yes | ^f | See footnote ^e | | | | | |
| NL | See footnote ^f | | | | | | See footnote ^f | | | | | | See footnote ^f | | | | | |
| YT | No | No | No | No | No | No | No | No | No | No | No | No | No | No | No | No | No | No |
| NIHB | Follow provincial rules | | | | | | Follow provincial rules; client required to present status card | | | | | | Follow provincial rules | | | | | |
| DND | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | No | No | No | No | No | No |

AB = Alberta; BC = British Columbia; DND = Department of National Defence Canadian Armed Forces drug benefit plan; MB = Manitoba; NB = New Brunswick; NIHB = Health Canada Non-insured Health Benefits Program; NL = Newfoundland and Labrador; NS = Nova Scotia; ON = Ontario; QC = Quebec; SK = Saskatchewan; YK = Yukon Territory.

^a At the time of release of a methadone prescription, the patient and pharmacist must acknowledge receipt by signing a patient- or prescription-specific part-fill accountability log.

^b When a patient seeks medical services — e.g., at a physician's office — presentation of the Alberta Health Plan Insurance Card is requested.

^c This is not regulated or determined by drug plans.

^d The *Narcotics Safety and Awareness Act* requires the prescriber to record on a prescription for a monitored drug the patient's identification number and the type of identification provided by the patient. The dispenser is required to keep a record of this information, as well as the prescriber's College registration number.

^e Legislation requires pharmacists to confirm the identity of individuals receiving a prescription for monitored drugs by having them sign on the Prescription Monitoring Program prescription pad. Pharmacists are also given the authority to confirm the identity of the person picking up the prescription. Presentation of a valid Nova Scotia health care card is required to access all insured services, including physician visits and filling prescriptions under the Pharmacare Programs. In practice, however, patients may not be asked to present their health cards each time they access services, including filling a prescription or consulting their physician, if this information is already on the patient's record. Standards of practice require that the patient record contain identifying information that includes name, contact information, date of birth, gender, health card number (when applicable), and any applicable medical information. The *Prescription Monitoring Regulations* also require these details to be included on the patient record. However, there is no requirement for copies of identification to be retained on the record; e.g., a photocopy of the driver's licence.

^f Not specified.

Source: Unless otherwise referenced, the information was gathered from the 2015 CADTH survey of public drug plans. Survey question: "Must a patient show proof of identity to a prescriber to receive a prescription for the following medication or class of medications? Must a patient show proof of identity to a pharmacist when filling a prescription for the following medication or class of medications? Is a pharmacist required to keep a record of a patient's identification when filling a prescription for the following medication or class of medications? Are there other requirements on the part of the prescriber or dispenser regarding confirmation of a patient's identification?"

Table 22: Length of Prescription Validity

| Public Drug Plans | Drug Class | Prescription Considered Expired BEFORE it is Filled | | Prescription Considered Expired AFTER it is Filled | |
|----------------------------|-------------------------|---|--|--|--|
| | | 1 Year | Other | 1 Year | Other |
| British Columbia | Opioids | | 5 days ^a | X | |
| | Stimulants | X | | X | |
| | Benzodiazepines | X | | X | |
| Alberta ^b | Opioids | X (non-TPP) | 3 days for TPP | X | |
| | Stimulants ^c | | 3 days for TPP | X | |
| | Benzodiazepines | X | | X | |
| Saskatchewan | Opioids | X | | X | |
| | Stimulants | X | | X | |
| | Benzodiazepines | X | | X | |
| Manitoba | Opioids | | 3 days for DPP | X | |
| | Stimulants | | 3 days for DPP | X | |
| | Benzodiazepines | | | X | |
| Ontario | Opioids | | | | X |
| | Stimulants | | | | X |
| | Benzodiazepines | X | | | X |
| Quebec ^d | Opioids | X | | X | |
| | Stimulants | X | | X | |
| | Benzodiazepines | X | | X | |
| New Brunswick ^e | Opioids | X | | X (from date on Rx) | |
| | Stimulants | X | | X (from date on Rx) | |
| | Benzodiazepines | X | | X (from date on Rx) | |
| Nova Scotia ^f | Opioids | X | | X | |
| | Stimulants | X | | X | |
| | Benzodiazepines | X | | X | |
| Newfoundland and Labrador | Opioids | X | | X | |
| | Stimulants | X | | X | |
| | Benzodiazepines | X | | X | |
| Yukon Territory | Opioids | | Determined by dispensaries | | Determined by dispensaries |
| | Stimulants | | | | |
| | Benzodiazepines | | | | |
| NIHB | Opioids | | NIHB follow provincial rules, typically 1 year | | NIHB follow provincial rules, typically 1 year |
| | Stimulants | | | | |
| | Benzodiazepines | | | | |
| DND ^d | Opioids | X | | X | |
| | Stimulants | X | | X | |
| | Benzodiazepines | X | | X | |

DND = Department of National Defence Canadian Armed Forces drug benefit plan; DPP = duplicate prescription pad; NIHB = Health Canada Non-insured Health Benefits Program, Rx = prescription; TPP = triplicate prescription pad.

^a Except for methadone

^b As per Standard 6.5 of the Alberta College of Pharmacists *Standards of Practice for Pharmacists and Pharmacy Technicians*: "Neither a pharmacist nor a pharmacy technician may refill a prescription for: A benzodiazepine or other targeted substance, as defined in the regulations to the *Controlled*

Drugs and Substances Act, for a period of greater than 12 months after the prescription was written; or A Schedule 1 drug for a period greater than 18 months after the prescription was first filled.”

^c Included in the regulations to the *Controlled Drugs and Substances Act*.

^d Following federal legislation, which is 1 year for all medications.

^e The *New Brunswick Pharmacy Act and Regulations* govern these requirements. There are no drug plan-specific policies. Prescriptions expire 1 year from the original date on the prescription, and *not* 1 year from the date of first dispense.

^f Prescription is considered expired or invalid 1 year after it was written.

Source: Unless otherwise referenced, the information was gathered from the 2015 CADTH survey of public drug plans. Survey questions: “After what length of time is a prescription considered expired before it is filled (i.e., the patient has made a decision not to fill the prescription right away)? After what length of time is a prescription considered expired after it is filled (i.e., a patient can no longer get repeats)?”

Table 23: Paper-Based (Tamper-Resistant Prescription Drug Pad Program) or Electronic (Prescription Drug Monitoring Program) Program to Monitor the Use of Opioids, Stimulants, and/or Benzodiazepines

| Jurisdiction | Type of Program (Paper-Based or Electronic) | Details |
|------------------|---|--|
| British Columbia | Paper-based program | DPP required for selected opioids, stimulants, and benzodiazepines under BC's Controlled Prescription Drug Program, and for all drugs listed as Schedule 1A in the Drug Schedules Regulation for the Pharmacy Operations and Drug Scheduling Act (including buprenorphine, butalbital, butorphanol, codeine, fentanyl, hydrocodone [dihydrocodeinone], hydromorphone, meperidine [pethidine], methadone, morphine, normethadone, oxycodone, pentazocine, propoxyphene, and tapentadol). Written prescriptions are required on an approved 2-part form available from the College of Physicians and Surgeons of BC. Fax transmission is not allowed in community pharmacies (exception: licensed facilities). More than 1 medication or strength of medication can be included on 1 Controlled Prescription Program form, provided the orders are legible. The prescription expires after midnight of the 5th day following the date of issuance by the prescriber, unless the prescription is for methadone. |

| Jurisdiction | Type of Program (Paper-Based or Electronic) | Details |
|--------------|---|---|
| Alberta | Both: paper-based and electronic program | <p>TPP required for selected opioids, stimulants, and benzodiazepines. The CPSA administers the TPP for all program participants. Prescribers must register with the TPP in order to prescribe medications on the TPP list (including listed opioids, stimulants, and benzodiazepines). To prescribe any of these medications, it is mandatory that prescribers use TPP prescription forms. TPP forms are 3-part prescription forms. The prescriber retains the practitioner copy. The top 2 parts of the form are to be used by the pharmacist or veterinary clinic to dispense the medication. The pharmacist or veterinary clinic retains the pharmacy copy and forwards the CPSA copy to the CPSA. TPP forms are personalized and must not be shared. The prescriber's name, business address, and a unique prescriber identification number are imprinted on the pads. Prescriptions written on a TPP are valid for 72 hours after the date prescribed.</p> <p>In addition to receipt of the CPSA copy of the triplicate prescription, TPP drug claims information from PIN is forwarded electronically to the CPSA.</p> |
| Saskatchewan | Electronic program | <p>TPP no longer required, with some exceptions. The Government of Saskatchewan's Drug Plan reports: "Use of special multiple prescription pads is no longer necessary since the data required to operate this program is now captured electronically. However, pharmacists must continue to mail to the College of Physicians and Surgeons a copy of any prescriptions for drugs monitored under the Prescription Review Program that are not successfully "adjudicated" or "captured" by the drug plan system. Upon receipt of the prescription copy, the College of Physicians and Surgeons will enter the information into their computer system".²¹⁶</p> |

| Jurisdiction | Type of Program (Paper-Based or Electronic) | Details |
|---------------|---|--|
| Manitoba | Paper-based program | DPP required for all opioids, stimulants, and benzodiazepines included in monitoring program. The original copy of the Manitoba Prescribing Practices Program (M3P) form must be presented by the patient in order to receive a drug covered under the program. The pharmacist must ensure that the prescription is still valid. The order is valid for only 3 days once it is written (i.e., the written order is valid on the day it is written, plus 3 additional days). The prescription must be placed in the narcotic prescription file in the pharmacy. A duplicate copy of the prescription remains in the prescriber's office for their record. |
| Ontario | Electronic program | No TPP or DPP requirements. Ontario has a prescription monitoring system, the Narcotics Monitoring System. Monitored drugs include all drugs listed in the federal Controlled Drugs and Substances Act and other opioid drugs not listed in the Act (e.g., tramadol and tapentadol). |
| Quebec | No tamper-resistant prescription drug pad program. | |
| New Brunswick | No tamper-resistant prescription drug pad program. Prescription Monitoring Program under development. | |

| Jurisdiction | Type of Program (Paper-Based or Electronic) | Details |
|--------------|---|---|
| Nova Scotia | Both: paper-based and electronic program | <p>DPPs required for selected drugs (benzodiazepines are excluded from the requirement). Section 5 of the Prescription Monitoring Regulations requires that all prescribers who prescribe monitored drugs, and all pharmacists and pharmacies that dispense monitored drugs, register with the Nova Scotia PMP. Section 13 of the Regulations also requires prescribers to use a specific program prescription pad (a DPP) to write prescriptions for monitored drugs, and Section 21 of the Regulations requires pharmacists to only dispense monitored drugs when they are prescribed on the specific program prescription pad. These pads are provided to physicians and dentists at no charge when they register with the program. However, there is no requirement for prescriptions for drugs that were exempted in the past (benzodiazepines and compounded topical testosterone) to be written on a DPP, with the following exceptions: Prescriptions for monitored drugs for patients in long-term-care facilities, as defined by the Homes for Special Care Act, are not required to be written on a DPP; and prescriptions for federal inmates are not required to be written on a DPP.</p> <p>There is also an electronic PMP that captures and actively monitors all prescriptions for monitored drugs that are dispensed in community pharmacies in Nova Scotia. Data are “real-time”; i.e., available when input by the pharmacist. In addition, effective April 1, 2012, the PMP introduced eAccess, a new secure Web application that allows prescribers and pharmacists to access patient profiles regardless of time of day.</p> |

| Jurisdiction | Type of Program (Paper-Based or Electronic) | Details |
|---------------------------|---|---|
| Newfoundland and Labrador | Paper-based program | <p>Special prescription pads must be used for selected opioids and stimulants under the province's Tamper-Resistant Prescription Drug Pad program. Benzodiazepines are not included in this schedule of drugs and, therefore, are not required to be written on the tamper-resistant prescription pads.</p> <p>The government of Newfoundland and Labrador has stated: "It is important to note that the tamper-resistant drug pad program is not a monitoring program. It is in response to the issue of prescription drug abuse and concerns regarding the diversion of certain prescription drugs, some of which is the result of prescription forgeries and alterations."²¹⁷</p> |
| Yukon Territory | Paper-based program | Uses Alberta's TPP program for the same drugs. |
| NIHB | Electronic program | <p>PMP for opioids, benzodiazepines, stimulants, and gabapentin: A methodology identifies NIHB clients who are misusing or are at greater risk of misusing drugs of concern and places the clients under certain restrictions with a view to preventing double-doctoring, by requesting that the client find a sole prescriber for the 4 categories of drugs. If clients or their health care providers cannot follow the PMP process to support the continuation of the drug therapy in question, the NIHB Program reserves the right to refuse coverage.</p> |
| DND | No tamper-resistant prescription drug pad program | |

CPSA = College of Physicians and Surgeons of Alberta; DND = Department of National Defence Canadian Armed Forces drug benefit plan; DPP = duplicate prescription pad; NIHB = Health Canada Non-insured Health Benefits Program; PIN = Pharmaceutical Information Network; PMP = Prescription Monitoring Program; TPP = triplicate prescription pad.

Source: Unless otherwise referenced, the information was gathered from the 2015 CADTH survey of public drug plans. Survey question: "Does your jurisdiction have a program to monitor the use of opioids, stimulants, or benzodiazepines, or opioid substitution therapy?"

Table 24: System in Place for Reporting Forged or Illegal Prescriptions

| Public Drug Plans | Yes/No | If Yes, for What Type of Program? |
|-------------------|--------|--|
| British Columbia | Yes | The College of Pharmacists and Prescription Review Program have a telephone fan-out system to alert pharmacies of forgeries and stolen prescription pads. Fan-out communications rely on reports from College of Pharmacists and 3rd parties, such as individual physicians or law enforcement. |
| Alberta | Yes | <p>As part of the Alberta Netcare Electronic Health Record, PIN gives health care providers access to the list of patients' active and previous medication(s). PIN is the central repository of patients' medication profiles and includes a list of prescriptions, dispensing history, and known allergies and intolerances. Information is currently supplied by community and outpatient pharmacies; however, eventually PIN will include information from all other prescribers as well. The system allows pharmacies, physician offices, primary care sites, and other health facilities to exchange real-time information and can be used before prescribing or dispensing medication.</p> <p>"Duplicate drug" messaging also occurs through adjudication processes.</p> <p>Prescribers are asked to report stolen or lost triplicate prescription pads or single prescriptions to the ACP, and a subsequent notification is sent out to pharmacies and pharmacists. Although the patient is not identified, a description that may include their sex and age is released. ACP also maintains a list of lost or stolen triplicate prescription pads on their website.</p> |
| Saskatchewan | Yes | The Saskatchewan Drug Plan does not have a specific program in place, but it utilizes the Pharmaceutical Information Program to assist prescribers and pharmacists. |
| Manitoba | Yes | <p>The College of Pharmacists of Manitoba coordinates a forgery alert system in the province.</p> <p>When a forged prescription is identified by either the pharmacist or the prescriber, or if a prescriber has identified that Manitoba Prescribing Practices Program prescriptions have gone missing and are presumed stolen, the College details this information in a "forgery alert" that is distributed by fax and email to all pharmacy managers in the province. Pharmacy managers are required to maintain a system within their pharmacy to ensure that this information is communicated to all pharmacy staff.</p> <p>When pharmacists identify a forged prescription, they are required to report this forgery to the Ministry of Health, the College, and their local law-enforcement agency. An individual prescriber may contact law enforcement directly, or report the forgery to the College of Physicians and Surgeons Manitoba, or the College of Pharmacists of Manitoba.</p> <p>Additionally, the Ministry of Health Provincial Drug Program sends notifications to pharmacists regarding the use of fraudulent Personal Health Identification Numbers.</p> |
| Ontario | Yes | Ontario's Narcotics Monitoring System issues alerts to pharmacy staff in real time if double-doctoring or multiple pharmacy use is detected. Information regarding individual patients or prescribing patterns is not provided to physicians. Prescribers may notify the Ministry of Health and Long-Term Care's Ontario Public Drug Programs of forged, illegitimate, or lost prescriptions. The Ministry sends an email notification to all pharmacies to alert them to the forged prescriptions or lost prescription pads. |
| Quebec | Yes | Programme Alerte (<i>see Table 18 for details</i>) |
| New Brunswick | No | Note: There are upcoming system changes with the implementation of the new Prescription Monitoring Program, which will address this issue. |

| | | |
|----------------------------------|---|---|
| Nova Scotia | Yes | <p>NSPMP prescription pads allow for centralized voiding of prescriptions, and the capability of tracking individual prescribers through the program's electronic system. The NSPMP system can also issue alerts regarding criminal or concerning activities, and is able to share information with law enforcement when necessary.</p> <p>All pharmacists are required to register with the NSPMP. All monitored drugs dispensed are to be reported by pharmacists to the NSPMP at the time of dispensing if there is an issue with the submission, such as a system-based error. This allows the NSPMP to provide real-time data to prescribers and pharmacists. The program completes audits of pharmacies to confirm submission and data integrity.</p> <p>The program also issues alerts to pharmacies regarding double-doctoring or stolen prescription pads. Before dispensing, pharmacists also receive electronic notifications on the patient's file, which indicates multiple pharmacy use, or double-doctoring.</p> |
| Newfoundland and Labrador | Yes | The Pharmacy Board in Newfoundland and Labrador has a process to notify all pharmacies where there has been a report of a forged or illegal prescription. |
| Yukon Territory | No | |
| NIHB | Yes | NIHB Program sends warning messages, as appropriate, to pharmacies during the assessment of drug claims for payment; for example, when a client has recently received the same drug at another pharmacy. The pharmacist may then be requested to provide a code to override the warning message. |
| DND | <i>Not applicable to DND base pharmacies.</i> | |

ACP = Alberta College of Pharmacists; DND = Department of National Defence Canadian Armed Forces drug benefit plan; NIHB = Health Canada Non-insured Health Benefits Program; NSPMP = Nova Scotia Prescription Monitoring Program; PIN = Pharmaceutical Information Network.

Source: Unless otherwise specified, the information was gathered from the 2015 CADTH survey of public drug plans. Survey question: "Do you have a system in place for reporting forged or illegal prescriptions?"

APPENDIX 2: Survey Findings: Criteria and Approval Processes for Opioids, Stimulants, Benzodiazepines, and Opioid Substitution Therapies

Table 25: Reimbursement Criteria for Opioids, Stimulants, Benzodiazepines, and Opioid Substitution Therapies

| Public Drug Plans | Reimbursement Criteria for Opioids, Stimulants, Benzodiazepines, and Opioid Substitution Therapies |
|-------------------|---|
| Opioids | |
| British Columbia | <ul style="list-style-type: none"> • Special authorization required for most SR opioids, based on clinical criteria. • Coverage of some products may be restricted to specific programs. For example, OxyNEO coverage is restricted to the Palliative Care program. |
| Alberta | <p>Fentanyl patches and injection are the only narcotic drug products that require completion of a Drug Special Authorization Request form (when prescribed for non-palliative patients).</p> <ul style="list-style-type: none"> • Fentanyl patches: Special authorization. <ul style="list-style-type: none"> ◦ For the treatment of persistent, severe chronic pain in those patients who require continuous around-the-clock analgesia for an extended period of time in those patients who cannot swallow. ◦ For the treatment of persistent, severe chronic pain in those patients who require continuous around-the-clock analgesia for an extended period of time in those patients who require opioid therapy at a total daily dose of at least 60 mg/day oral morphine equivalents. Patients must have tried and not been able to tolerate at least 2 discrete (separate) courses of therapy with 2 of the following drugs: morphine, hydromorphone, and oxycodone, if not contraindicated. <p>Special authorization may be granted for 6 months. Information is required regarding previous medications utilized and the patient’s response to therapy. In addition, information regarding the number of discrete (separate) courses of these medications is required. A discrete course is defined as a separate treatment course, which may involve more than 1 drug, used at one time to manage the patient’s condition.</p> <ul style="list-style-type: none"> • Fentanyl Citrate injection 0.05 mg/mL: Special authorization. <ul style="list-style-type: none"> ◦ For the treatment of persistent, severe chronic pain in those patients who cannot swallow, or who are intolerant of morphine and/or hydromorphone, if not contraindicated. Special authorization may be granted for 6 months. |
| Manitoba | <ul style="list-style-type: none"> • OxyNEO: EDS <ul style="list-style-type: none"> ◦ For cancer-related pain, <i>plus</i> patients who are unable to tolerate or receive an adequate response to either the regular release dosage forms of oxycodone or the SR preparations of morphine or hydromorphone. <i>or</i> ◦ For pain management in a specified chronic pain diagnosis (details regarding patient’s condition and previous medication history are required), <i>plus</i> patients who are unable to tolerate or receive an adequate response to either the regular release dosage forms of oxycodone or the SR preparations of morphine or hydromorphone. • OXY IR: EDS. <ul style="list-style-type: none"> ◦ For patients who have tried the combination products (Percodan, Percocet) and have maximized the acetaminophen dose or have contraindications to acetaminophen. • Fentanyl Injection: EDC. <ul style="list-style-type: none"> ◦ For the management of acute cancer-related breakthrough pain. • Fentanyl patches: Limited Use. <ul style="list-style-type: none"> ◦ For the treatment of pain in patients unable to tolerate analgesics or when there is a failure to adequately control pain with oral analgesics or in patients for whom oral analgesics are deemed inappropriate. |

| | |
|---------------|---|
| Saskatchewan | <ul style="list-style-type: none"> • Some opioids have EDS and are reimbursed according to published criteria.²¹⁸ • Fentanyl may also be adjudicated through the online adjudication system. Approval is automatic if there are SR opioids on the patient's profile. |
| Ontario | <ul style="list-style-type: none"> • OxyNEO: EAP. <ul style="list-style-type: none"> ◦ For chronic pain. OxyNEO 60 mg and 80 mg tablets not funded under EAP. • OxyNEO: Facilitated Access for Palliative Care Drugs mechanism. <ul style="list-style-type: none"> ◦ For the treatment of cancer-related pain, or pain in patients receiving end-of-life palliative care. OxyNEO 80 mg tablets funded under the Palliative Care Drugs mechanism. |
| Quebec | <ul style="list-style-type: none"> • Codeine phosphate, syrup: <ul style="list-style-type: none"> ◦ For treatment of pain in persons unable to take tablets. • Oxycodone, LA tablets: <ul style="list-style-type: none"> ◦ When two other opiates are not tolerated, contraindicated, or ineffective. |
| New Brunswick | <ul style="list-style-type: none"> • Codeine (Codeine Contin): 50 mg, 100 mg, 150 mg, and 200 mg tablets (CR). <ul style="list-style-type: none"> ◦ For the treatment of mild to moderate cancer-related or chronic non-cancer pain. • Oxycodone (OXY IR and generic and Supeudol): 5 mg, 10 mg, and 20 mg tablets (IR). <ul style="list-style-type: none"> ◦ For the treatment of moderate to severe cancer-related or chronic non-malignant pain. • Fentanyl (Duragesic MAT and generic brands): Transdermal system 12 mcg/hr, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr, and 100 mcg/hr. <ul style="list-style-type: none"> ◦ For the management of malignant or chronic non-malignant pain in adult patients who were previously receiving continuous opioid administration (i.e., not opioid naive), or who are unable to take oral therapy. |
| Nova Scotia | <ul style="list-style-type: none"> • Fentanyl (Fentanyl 12 mcg/hr, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr, 100 mcg/hr Transdermal System and generic brands): EDS. <ul style="list-style-type: none"> ◦ For the treatment of malignant or chronic non-malignant pain in adult patients who were previously receiving continuous opioid administration (i.e., not opioid naive), or who are unable to take oral therapy • Butorphanol (10 mg/mL nasal spray and generic brands): EDS. <ul style="list-style-type: none"> ◦ For the treatment of migraine, upon the request of a neurologist, prescriber with a specialty in neurology or a specialist in pain management, when conventional forms of therapy are ineffective or inappropriate |

| | |
|--------------------------------|---|
| <p>DND</p> | <p>Some opioids that are reimbursed under Special Authorization</p> <ul style="list-style-type: none"> • Hydromorph Contin (hydromorphone hydrochloride): Requests considered for members who are on regular-release hydromorphone but require an SR product. • OxyNEO (oxycodone hydrochloride): Requests considered for members requiring treatment of chronic non-cancer pain, cancer pain, or palliative pain, who have tried and failed on or proven intolerant to one of the LA opioids on the benefit list. • Demerol 50 mg tab (meperidine hydrochloride): Requests considered for a maximum 14 days' supply. • Duragesic patch and generics (fentanyl): <ul style="list-style-type: none"> ◦ Transdermal: Requests for special authorization are considered for the treatment of malignant or chronic non-malignant pain in patients who are unresponsive or intolerant of at least 2 LA oral SR products such as codeine, morphine, hydrocodone, and hydromorphone, despite appropriate dose titration and adjunctive therapies. ◦ Transmucosal (fentanyl citrate oral transmucosal 800 mcg (SG) PIN#00903759 ONLY): Transfer supply list medication for Regional Mission Kits. • Ultram, Zytram XL, Tridural, Durela, Ralivia (tramadol and tramadol LA): <ul style="list-style-type: none"> ◦ Ultram and generics: Requests considered for members for post-op pain control or neuropathic pain. ◦ Zytram XL, Tridural, Durela, Ralivia: Requests considered for patients with neuropathic pain stabilized on short-acting tramadol. ◦ Tramacet and generics (tramacet/acetaminophen): Requests considered for members for post-operative pain control or neuropathic pain. |
| <p>Stimulants</p> | |
| <p>British Columbia</p> | <ul style="list-style-type: none"> • Methylphenidate ER (Concerta): Special authorization required for coverage and based on predefined criteria. <p>No coverage is provided for other ER stimulants (Biphentin, Adderall XR)</p> |
| <p>Manitoba</p> | <ul style="list-style-type: none"> • Dexedrine: Limited Use. <ul style="list-style-type: none"> ◦ For treatment of attention-deficit disorder and narcolepsy. • Ritalin: Limited Use. <ul style="list-style-type: none"> ◦ For treatment of attention-deficit disorder and narcolepsy. |
| <p>Saskatchewan</p> | <ul style="list-style-type: none"> • Some stimulants have EDS and are reimbursed according to published criteria.²¹⁸ |
| <p>Quebec</p> | <ul style="list-style-type: none"> • Amphetamine mixed salts: <ul style="list-style-type: none"> ◦ For treatment of persons suffering from attention-deficit disorder and in whom the use of short-acting methylphenidate or of dexamphetamine has not properly controlled the symptoms of the disease. • Lisdexamfetamine dimesylate: <ul style="list-style-type: none"> ◦ For treatment of persons suffering from attention-deficit disorder and in whom the use of short-acting methylphenidate or of dexamphetamine has not properly controlled the symptoms of the disease. • Methylphenidate hydrochloride, LA caps: <ul style="list-style-type: none"> ◦ For treatment of children and adolescents suffering from attention-deficit disorder and in whom the use of short-acting methylphenidate or of dexamphetamine has not properly controlled the symptoms of the disease. • Methylphenidate hydrochloride, LA tab. (12 h): <ul style="list-style-type: none"> ◦ For treatment of persons suffering from attention-deficit disorder and in whom the use of short-acting methylphenidate or of dexamphetamine has not properly controlled the symptoms of the disease. <p>Before it can be concluded that these treatments are ineffective, the stimulant must have been titrated optimally, unless there is proper justification.</p> |

| | |
|------------------------|--|
| New Brunswick | <ul style="list-style-type: none"> • Methylphenidate (Biphentin) 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, and 80 mg CR capsules; and Methylphenidate ER (Concerta and generic brands) 18 mg, 27 mg, 36 mg, and 54 mg ER tablets. <ul style="list-style-type: none"> ◦ For the treatment of ADHD in children aged 6 to 25 years who demonstrate significant symptoms and who have tried immediate- or slow-release methylphenidate with unsatisfactory results. Requests will be considered from specialists in pediatric psychiatry, pediatricians, or general practitioners with expertise in ADHD. • Dexamphetamine (Dexedrine) 5 mg, 10 mg, and 15 mg tablets: Listed as regular benefit but <i>only</i> for patients aged 18 years and younger. |
| Nova Scotia | <ul style="list-style-type: none"> • Methylphenidate: EDS <ul style="list-style-type: none"> ◦ Methylphenidate (Biphentin) 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, and 80 mg capsule); and Methylphenidate ER (Novo-Methylphenidate ER-C) 18 mg, 27 mg, 36 mg, and 54 mg tablets). For patients aged 6 to 25 years, diagnosed with ADHD who require 12-hour continuous coverage due to academic and/or psychosocial needs, and who meet the following: <ul style="list-style-type: none"> ▪ patients who demonstrate significant and problematic disruptive behaviour or who have problems with inattention that interfere with learning <i>and</i> ▪ prescribed by or in consultation with a specialist in pediatric psychiatry, pediatrics, general practitioners, or other prescribers with expertise in ADHD <i>and</i> ▪ have been tried on immediate- or slow-release methylphenidate with unsatisfactory results. |
| Yukon Territory | <ul style="list-style-type: none"> • For the treatment of psychiatric disorders on recommendation of psychiatrist or pediatrician. Specialist's consult to be provided. |
| DND | <ul style="list-style-type: none"> • Strattera and generics (atomoxetine): Requests for use are considered for members requiring treatment of attention-deficit disorder, with or without hyperactivity, where the member has either failed to respond to or has developed intolerable side effects using stimulant medications or in which cases where psychostimulant medication is not appropriate, not tolerated or is ineffective. • Adderall (amphetamine [mixed salt]): Requests for special authorization are considered for members for use in treating attention-deficit disorder, with or without hyperactivity. • Dexedrine, Dexedrine Spansules (dextroamphetamine sulfate): Requests for special authorization are considered for members who suffer from narcolepsy; attention-deficit disorder, with or without hyperactivity; or IR formulation for short-term use in airsickness, when used in combination with promethazine and prescribed by a flight surgeon. • Ritalin IR and Ritalin SR (methylphenidate hydrochloride): Requests for special authorization are considered for members who suffer from narcolepsy or attention-deficit disorder, with or without hyperactivity. • Concerta and Biphentin (methylphenidate hydrochloride): Requests for special authorization are considered for members for use in treating attention-deficit disorder, with or without hyperactivity. • Vyvanse (lisdexamfetamine dimesylate): Requests for special authorization are considered for members for use in treating attention-deficit disorder, with or without hyperactivity, <i>and</i> prescribed by a psychiatrist. • Alertec (modafinil): Requests for Special Authorization are considered for members experiencing excessive sleepiness with narcolepsy, as adjunctive treatment in obstructive sleep apnea, for circadian rhythm sleep disorder and shift work type (shift work disorder), which has been confirmed by sleep studies. |
| Benzodiazepines | |
| Quebec | <ul style="list-style-type: none"> • Benzodiazepines: Covered without criteria. • Nitrazepam to control seizure disorders. However, nitrazepam tablets will remain covered under the basic prescription drug insurance plan until 31 May 2016 for insured persons who have used this drug in the 90 days preceding 1 June 2015. |

| | |
|---------------------------|--|
| DND | <p>Some Benzodiazepines</p> <p>Frisium (clobazam): Requests for special authorization are considered for members who are not adequately stabilized with their current anticonvulsant therapy and who require adjunctive therapy for the treatment of epilepsy.</p> <p>Triazolam (triazolam): Restricted to dental practitioners for use in members undergoing dental surgery (up to 3 doses).</p> <p>Sublinox (zolpidem tartrate): Requests for special authorization are considered for aircrew for treatment of jet lag disorder in accordance with Flight Surgeon Guidelines.</p> |
| Methadone | |
| British Columbia | <ul style="list-style-type: none"> • Effective February 1, 2014, methadone must be dispensed only as the commercially available 10 mg/mL methadone oral preparation Methadose. • All prescriptions for methadone for opioid dependence must be written on a methadone duplicate prescription pad for methadone maintenance. Only prescriptions for methadone for analgesia may be written on the usual duplicate prescription pad. • Prescriptions may only be written by prescribers approved by the College of Physicians and Surgeons. |
| Manitoba | <ul style="list-style-type: none"> • Changes to the <i>Specified Drugs Regulation</i> under the <i>Prescription Drugs Cost Assistance Act</i> will indicate that Methadose (for opioid dependence) and Metadol (for pain management) will be covered benefits. Capsules compounded from methadone powder are not an eligible benefit through provincial drug programs and will not be covered under Part 3 EDS.²¹⁹ |
| Ontario | <ul style="list-style-type: none"> • General Benefit Listing. <ul style="list-style-type: none"> ◦ For methadone maintenance treatment for addiction • Methadone extemporaneous compounded solution for methadone maintenance treatment will no longer be a benefit. |
| Quebec | <ul style="list-style-type: none"> • Magistral solutions, tablets of 1 mg, 5 mg, 10 mg et 25 mg, oral solution of 1 mg/mL, 10 mg/mL (Metadol) are covered without criteria. |
| New Brunswick | <ul style="list-style-type: none"> • Methadone HCL (Metadol) 1 mg/mL oral solution and 10 mg/mL oral concentrate: Requests from New Brunswick physicians authorized to prescribe methadone will be considered: <ul style="list-style-type: none"> ◦ For the treatment of severe cancer-related or chronic non-malignant pain as an alternative to other opioids ◦ For the treatment of opioid dependence. • All requests must meet requirements set out by the New Brunswick Drug Plans. Claims submitted by pharmacies must be billed using the applicable PIN. • Methadone HCL (Metadol) 1 mg, 5 mg, 10 mg, and 25 mg tablets <ul style="list-style-type: none"> ◦ Requests from New Brunswick physicians authorized to prescribe methadone will be considered for the treatment of severe cancer-related or chronic non-malignant pain as an alternative to other opioids ◦ Requests will <i>not</i> be considered for the treatment of opioid dependence. ◦ Preparations compounded using Metadol tablets will <i>not</i> be considered. |
| Newfoundland and Labrador | <ul style="list-style-type: none"> • Compounded methadone capsules and liquids are not a covered benefit. |

| | |
|----------------------------|---|
| Nova Scotia | <ul style="list-style-type: none"> • EDS <ul style="list-style-type: none"> ◦ Metadol 1 mg, 5 mg, 10 mg, 25 mg tablet: <ul style="list-style-type: none"> ▪ For the management of severe chronic or malignant pain as an alternative to other opiates. Written request of a physician authorized to prescribe methadone. • Methadone, oral liquid (methadone oral liquid compound): <ul style="list-style-type: none"> ◦ For the management of severe chronic or malignant pain as an alternative to other opiates ◦ For the management of patients undergoing therapy for drug dependence ◦ Written request of a physician authorized to prescribe methadone. • Compounded methadone capsules are <i>not</i> a covered benefit. |
| DND | <ul style="list-style-type: none"> • Requests for special authorization are considered for members when methadone is prescribed in conjunction with a treatment program. |
| NIHB | <ul style="list-style-type: none"> • Limited Use Benefit. <ul style="list-style-type: none"> ◦ Prescriber is registered with Health Canada and is eligible to prescribe methadone for the management of pain <i>and</i> <ul style="list-style-type: none"> ▪ For the management of moderate to severe cancer pain or chronic non-cancer pain, as an alternative to other opioids or for the management of pain for palliative care patients. • Methadone pseudo DINs listed for the treatment of pain should not be used for methadone maintenance therapy. • Methadone for the treatment of opioid dependency is an open benefit covered under the NIHB Program. • Prescription monitoring Program restrictions concerning benzodiazepines, stimulants, and gabapentin also apply to Suboxone and methadone. A justification from the prescriber for each opioid prescription is requested by the NIHB Program for a client on Suboxone. |
| Suboxone | |
| British Columbia | <ul style="list-style-type: none"> • Buprenorphine 2 mg + naloxone 0.5 mg combination tablet and buprenorphine 8 mg + naloxone 2 mg combination tablet: Limited coverage drug. Covered for patients for whom methadone is contraindicated or who have an inadequate response or intolerance to methadone and whose prescription has been written by a methadone maintenance prescriber who is approved by the College of Physicians and Surgeons and who has entered into a Collaborative Prescribing Agreement. |
| Ontario | <ul style="list-style-type: none"> • Limited Use Benefit <ul style="list-style-type: none"> ◦ For the treatment of opioid dependence in patients who have failed, have significant intolerance to, have a contraindication to, or who are at high risk for toxicity with methadone. High risk for toxicity with methadone is defined as use of benzodiazepines; alcohol abuse or dependence; elderly patients; patients who are dependent on codeine or abuse opioids on a less-than-daily basis, who are on medications that interfere with methadone metabolism, who are at high risk for prolonged QT interval. ◦ For the treatment of opioid dependence when a methadone maintenance program is not available or accessible (i.e., no methadone maintenance programs available in the area, or waiting list is 3 months or longer). <p>Physicians should complete an accredited course on opioid addiction and buprenorphine treatment before prescribing Suboxone or its generics. Limited use authorization period is 1 year.</p> |
| Quebec | <ul style="list-style-type: none"> • Buprenorphine/naloxone: For replacement treatment of opioid dependency, where methadone has failed, is not tolerated or is contraindicated; or where a methadone maintenance program is not available or not accessible. |
| New Brunswick ^a | <ul style="list-style-type: none"> • Buprenorphine/naloxone (Suboxone and generic brands) 2 mg/0.5 mg and 8 mg/2 mg sublingual tablets: <ul style="list-style-type: none"> ◦ For the treatment of opioid dependence for patients in whom methadone is contraindicated (e.g., patients at high risk of or with QT prolongation, or hypersensitivity to methadone). Commonly reported adverse effects associated with methadone therapy (e.g., sweating, constipation, insomnia, etc.) will not be considered to be hypersensitivity. Requests from New Brunswick physicians authorized to prescribe methadone or physicians with experience in the treatment of opioid dependence will be considered. |

| | |
|-------------|---|
| Nova Scotia | <ul style="list-style-type: none"> • EDS (2 mg/0.5 mg, 8 mg/2 mg sublingual tablet): <ul style="list-style-type: none"> ◦ For the treatment of opioid dependence for patients in whom methadone is contraindicated (e.g., patients at high risk of or with QT prolongation, or hypersensitivity to methadone) ◦ For the treatment of opioid dependence for appropriate patients aged 18 to 24 years. ◦ Must be prescribed by a physician licensed to prescribe methadone for opioid dependence |
| DND | <ul style="list-style-type: none"> • Requests for special authorization are considered for members for the treatment of opioid dependence in whom methadone is contraindicated (e.g., members at high risk of or with QT prolongation, or hypersensitivity to methadone). Prescribing of Suboxone is limited to physicians with a license to prescribe methadone in treating opioid dependence. |
| NIHB | <ul style="list-style-type: none"> • Limited Use benefit. A rationale for using Suboxone instead of the alternative (i.e., methadone). In cases where the client lives in a remote or isolated location, confirmation is required that the community has the ability to support Suboxone administration. These supports include the safe daily witnessing, storage, and handling of the Suboxone doses. The client must be 16 years or older. |

ADHD = attention-deficit/hyperactivity disorder; CR = controlled-release; DIN = drug identification number; DND = Department of National Defence Canadian Armed Forces drug benefit plan; EAP = Exceptional Access Program; EDS = Exception Drug Status; ER = extended-release; hr = hour; IR = immediate-release; LA = long-acting; NIHB = Health Canada Non-insured Health Benefits Program; PIN = Pharmaceutical Information Network; SR = sustained-release.

^aNew Brunswick also covers Naltrexone (REVIA) 50 mg tablet for the maintenance of an opioid-free state in individuals who were previously opioid dependent but have successfully completed detoxification. Treatment should not be attempted until the patient has remained opioid free for 7 to 10 days. Requests will be considered only when used as an adjunct to psychosocial intervention. In the event that a patient participates in a program other than those offered by New Brunswick Addiction Services, details on the type of counselling or supportive program the patient will be involved in will be requested. Continued coverage will require information on the outcome of therapy as well as the patient's compliance with treatment programs. Coverage will be approved initially for 12 weeks.

Source: Unless otherwise referenced, the information was gathered from the 2015 CADTH survey of federal, provincial, and territorial public drug plan authorities. Survey question: "Please specify the listing restrictions and/or reimbursement criteria for the medication or class of medications are listed or reimbursed *with criteria* (Special Authorization, Exceptional Access Program, Exception Drug Status, Prior Authorization, Off-formulary, Limited Use, etc.)?"

Table 26: Approval Process (Manual Prior Approval, Use of Prescription Codes or Electronic) for Drugs Listed With Criteria

| Public Drug Plan | Approval Process (Manual Prior Approval, Use of Prescription Codes or Electronic) for Drugs Listed With Criteria |
|---------------------------|--|
| British Columbia | <ul style="list-style-type: none"> Prescribers must complete and submit a Special Authority Request form by fax or mail. |
| Alberta | <ul style="list-style-type: none"> All of the applicable fentanyl products require manual completion of a Special Authorization Request Form. Prior authorization must be received before coverage will be granted. |
| Manitoba | <ul style="list-style-type: none"> OxyNEO, OXY IR, and Fentanyl Injection require prior approval process. Fentanyl patches, Dexedrine, and Ritalin can be approved for benefit coverage using a code. |
| Saskatchewan | <ul style="list-style-type: none"> EDS – published criteria; prescribers or pharmacists submit a request (written or verbal) on behalf of their patients. Palliative benefits – some products are automatic benefits for palliative patients. Fentanyl may also be adjudicated through the online adjudication system. Automatic approval if there are sustained-release opioids on the patient’s profile. |
| Ontario | <ul style="list-style-type: none"> OxyNEO requires a manual, prior approval process (Exceptional Access) when not used under the Palliative Care Drugs mechanism. Suboxone requires a Limited Use code assigned by the prescriber, based on the patient meeting specific clinical criteria or conditions, and entered into the system by the pharmacist. |
| Quebec | <ul style="list-style-type: none"> For non-codified drugs, the prescriber has to fill a formulary and send it to Régie de l’assurance maladie du Québec. The formularies have special authorization forms specific to each drug. Some drugs are codified (e.g., amphetamine mixed salts, buprenorphine/naloxone, codeine syrup, lisdexamfetamine, methylphenidate caps long-acting, methylphenidate). In these cases, prescribers have to identify the reason for the prescription with a code on the prescription. The authorization is granted directly in pharmacies. |
| New Brunswick | <ul style="list-style-type: none"> Written special authorization must be submitted for review by the drug plan. |
| Newfoundland and Labrador | <ul style="list-style-type: none"> All special authorization drugs considered under the Newfoundland and Labrador Prescription Drug Program are facilitated using manual forms submitted by health care providers and assessed by the clinical pharmacists within the Division. |
| Nova Scotia | <ul style="list-style-type: none"> Through a prior approval process using special authorization forms that are reviewed by the administrator for compliance with clinical criteria. The special authorization forms must be completed (in writing) by the prescriber. |
| Yukon Territory | <ul style="list-style-type: none"> Manual prior approval process. |
| DND | <ul style="list-style-type: none"> These drugs are reviewed by the Canadian Armed Forces Pharmacy and Therapeutics Committee for consideration of inclusion on the Canadian Armed Forces Drug Benefit List. Special authorization criteria are established by the Committee. Medication with special authorization criteria can be adjudicated at the base pharmacy and entered into the claims adjudication system by the pharmacist. |
| NIHB | <ul style="list-style-type: none"> Prior approval process |

DND = Department of National Defence Canadian Armed Forces drug benefit plan; EDS = exception drug status; NIHB = Health Canada Non-insured Health Benefits Program.

Source: Unless otherwise referenced, the information was gathered from the 2015 CADTH survey of federal, provincial, and territorial public drug plan authorities. Survey question: “For drugs that are listed or reimbursed with criteria, please provide *details of the approval process*. Is this a manual, prior approval process (i.e., use of special authorization forms that are reviewed by the drug plans prior to coverage approval) or the use of prescription codes that are assigned by the prescriber (based on the patient meeting specific clinical criteria/conditions), and entered into the system by the pharmacist?”

APPENDIX 3: Survey Questionnaire – 2015 CADTH Survey of Public Drug Plans

A. Formulary and Reimbursement Strategies

The following questions are specific to policies related to your government-sponsored drug benefit plan and strategies for formulary management.

Drug listing and reimbursement requirements

1. Which of the following medications are currently listed under your drug benefit plan?

- Methadone Suboxone Naloxone

2. a) Which of the following medication or class of medications are listed or reimbursed with criteria (Special Authorization, Exceptional Access Program, Exception Drug Status, prior authorization, off-formulary, Limited Use)?

- Opioids Stimulants Benzodiazepines

- Methadone Suboxone Naloxone

For those selected above, please specify the listing restrictions and/or reimbursement criteria.

b) If any of the above-mentioned drugs are listed or reimbursed with criteria, please provide details of the approval process.

Is this a manual, prior approval process (i.e., use of special authorization forms that are reviewed by the drug plans prior to coverage approval) or the use of prescription codes that are assigned by the prescriber (based on the patient meeting specific clinical criteria/conditions), and entered into the system by the pharmacist?

3. Are there any specific listing restrictions and/or reimbursement criteria for high-dose opioids?

- Yes No

If yes, please specify the listing restrictions and/or reimbursement criteria and the approval process. For example, requiring physicians to apply for approval when prescribing doses above a certain threshold, such as 120 mg morphine equivalent per day, etc.)

4. Which of the following medication or class of medications are listed or reimbursed with quantity limits as determined by the drug benefit plan (for example, dose limits, maximum day supply, maximum daily dose, quantity limits, annual quantity limits, limited number of prescriptions, weekly fills, etc.)?

- Opioids
 Stimulants
 Benzodiazepines
 Methadone
 Suboxone
 Naloxone

For those selected above, please specify the details of the limits:

5. Which of the following medications or class of medications are subject to refill restrictions as determined by the drug benefit plan (for example, same-day refill, early refills, multiple fills, no repeats, etc.)?

- Opioids Stimulants Benzodiazepines
 Methadone Suboxone Naloxone

For those selected above, please specify the details of the refill restrictions:

Tamper-resistant products

6. a) Are tamper-resistant products (i.e., drugs that resist crushing, cutting, chewing, dissolution, or other forms of tampering) currently listed under your drug benefit plan?

- Yes No

If yes, please specify which ones and the listing restriction and/or reimbursement criteria.

b) When adding a tamper-resistant product to your drug benefit plan, do you delist its equivalent non-tamper resistant product (for example, a listing of OxyNEO would mean a subsequent delisting of OxyContin)?

Yes No

If Yes, please providing specific reasons for delisting. Please add if grandfathering of patients who were previously treated with a delisted agent is considered.

If No, please specify why a decision is made not to delist and whether or not criteria for listing or reimbursement are changed.

Delisting of drugs from the drug benefit list

7. In the past, was there a decision made to delist opioids (including high-dose formulations of opioids, such as transdermal fentanyl 100 mcg patches), stimulants, or benzodiazepines from your drug benefit plan?

Yes No

If yes, please specify which drug class and the reasons behind the policy decision.

8. Do you have policy and procedures for delisting opioids, stimulants, or benzodiazepines from your drug benefit plan?

- Yes No

If yes, please specify what these are.

Incentives for pharmacists

9. Do you provide incentives for pharmacist interventions specifically related to opioids, stimulants, or benzodiazepines, or opioid substitution therapy? (For example, refusal fees such as a prescription not filled because of suspicion of falsified prescription, suspicion of double-doctoring, drug interactions, therapeutic duplication, witnessing the ingestion of methadone, etc.)

- Yes No

If yes, please specify what types of interventions would be remunerated.

Patient restricted to single prescriber and/or pharmacy

10. a) Do you have a program to restrict a patient to a single prescriber for accessing opioids, stimulants, or benzodiazepines or opioid substitution therapy?

- Yes No

If yes, please describe the program.

b) Do you have a program to restrict a patient to a single pharmacy for accessing opioids, stimulants, or benzodiazepines or opioid substitution therapy?

Yes No

If yes, please describe the program.

B. Prescription-Writing and -Dispensing Strategies

Prescription validity

11. After what length of time is a prescription considered expired before it is filled (i.e., the patient has made a decision not to fill the prescription right away)? If applicable only to a specific drug, please specify the drug name below the drug category.

| | 3 days | 1 month | 3 months | 1 year | More than 1 year | Not applicable | Other, please specify |
|-----------------|--------|---------|----------|--------|------------------|----------------|--------------------------|
| Opioids | | | | | | | |
| | | | | | | | |
| Stimulants | | | | | | | |
| | | | | | | | |
| Benzodiazepines | | | | | | | |
| | | | | | | | |

Comments:

12. After what length of time is a prescription considered expired after it is filled (i.e., a patient can no longer get repeats)? If applicable only to a specific drug, please specify the drug name below the drug category.

| | 3 days | 1 month | 3 months | 1 year | More than 1 year | Not applicable | Other, please specify |
|------------------------|--------|---------|----------|--------|------------------|----------------|--------------------------|
| Opioids | | | | | | | |
| | | | | | | | |
| Stimulants | | | | | | | |
| | | | | | | | |
| Benzodiazepines | | | | | | | |
| | | | | | | | |
| Comments: | | | | | | | |
| | | | | | | | |

Personal identification

13. a) Must a patient show proof of identity to a prescriber to receive a prescription for the following medication or class of medications?

- Opioids Yes No
- Stimulants Yes No
- Benzodiazepines Yes No
- Methadone Yes No
- Suboxone Yes No
- Naloxone Yes No

b) Must a patient show proof of identity to a pharmacist when filling a prescription for the following medication or class of medications?

- Opioids Yes No
- Stimulants Yes No
- Benzodiazepines Yes No
- Methadone Yes No
- Suboxone Yes No
- Naloxone Yes No

c) Is a pharmacist required to keep record of a patient's identification when filling a prescription for the following medication or class of medications?

- Opioids Yes No
- Stimulants Yes No
- Benzodiazepines Yes No
- Methadone Yes No
- Suboxone Yes No
- Naloxone Yes No

d) Are there other requirements on the part of the prescriber or dispenser regarding confirmation of a patient's identification? Please specify:

Tamper-resistant prescription drug pad programs

14. Does your jurisdiction have a program to monitor the use of opioids, stimulants, or benzodiazepines, or opioid substitution therapy (for example, Triplicate Prescription Program, Duplicate Prescription Program, Prescription Drug Monitoring Program, or other form of electronic program)?

- Yes, paper-based program Yes, electronic program No, we don't have a program at this time

If Yes, please describe the program and specify which medications or class of medications would be included.

Forged or illegal prescriptions

15. Do you have a system in place for reporting forged or illegal prescriptions (for example, fan-out email to area pharmacies, reporting to licensing bodies, etc.)?

- Yes No

If Yes, please describe.

Authors: Ian Currie, Sirjana Pant and Monika Mierzwinski-Urban.

Contributors: Kristen Chelak, Janet Crain and Christine Perras.

Cite as: Prescribing and dispensing policies to address harms associated with prescription drug abuse. Ottawa: CADTH; 2015 Oct. (Environmental Scan; Issue 52).

CADTH takes sole responsibility for the final form and content of this environmental scan. The statements and conclusions in this environmental scan are those of CADTH.

Production of this report is made possible by financial contributions from Health Canada and the governments of Alberta, British Columbia, Manitoba, New Brunswick, Newfoundland and Labrador, Northwest Territories, Nova Scotia, Nunavut, Prince Edward Island, Saskatchewan, and Yukon. The Canadian Agency for Drugs and Technologies in Health takes sole responsibility for the final form and content of this report. The views expressed herein do not necessarily represent the views of Health Canada or any provincial or territorial government.

Disclaimer: The Environmental Scanning Service is an information service for those involved in planning and providing health care in Canada. Environmental Scanning Service responses are based on a limited literature search and are not comprehensive, systematic reviews. The intent is to provide information on a topic that CADTH could identify using all reasonable efforts within the time allowed. Environmental Scanning Service responses should be considered along with other types of information and health care considerations. The information included in this response is not intended to replace professional medical advice nor should it be construed as a recommendation for or against the use of a particular health technology. Readers are also cautioned that a lack of good quality evidence does not necessarily mean a lack of effectiveness, particularly in the case of new and emerging health technologies for which little information can be found but that may in future prove to be effective. While CADTH has taken care in the preparation of the report to ensure that its contents are accurate, complete, and up to date, CADTH does not make any guarantee to that effect. CADTH is not liable for any loss or damages resulting from use of the information in the report. Copyright: This report contains CADTH copyright material. It may be copied and used for non-commercial purposes, provided that attribution is given to CADTH. Links: This report may contain links to other information available on the websites of third parties on the Internet.

Canadian Agency for Drugs and Technologies in Health (CADTH)
600-865 Carling Avenue,
Ottawa, Ontario K1S 5S8