

## Comparison of policy levers for the safe handling of antineoplastic agents in Alberta, Manitoba, and British Columbia

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### Scope

This resource is part of a broader project conducted by CAREX Canada on reducing the occupational exposure to antineoplastic agents. The project analyzed the different dimensions that affect the safe handling of antineoplastic agents in health care settings. The outcomes of this project were four resources, including this report:

- 1. Compendium of policy levers regarding the safe handling of antineoplastic agents in occupational settings: This tool is a collection of policy levers for the safe handling of antineoplastic agents in different healthcare settings. It was designed to help policy makers create and update their own respective policies.
- 2. **Prevention framework for handling antineoplastic agents:** This tool was designed to help organizations assess and audit their own procedures and plans for the safe handling of antineoplastic agents. It was developed by applying internationally accepted approaches to auditing occupational health and safety management systems.
- 3. Comparison of policy levers for the safe handling of antineoplastic agents in Alberta, Manitoba, and British Columbia: This report details and compares the various statutes, regulations, policies, guidelines, and standards used in the safe handling of antineoplastic agents across three provinces. It outlines key similarities and differences that policy makers can use to create better-informed policies that protect the health and wellbeing of healthcare workers handling antineoplastic agents.
- 4. Webinar: Reducing occupational exposure to antineoplastic agents: This webinar presents the findings of our research on the barriers and facilitators that influence the safe handling of antineoplastic agents. It includes results from a literature review, environmental scan, and stakeholder interviews, and was designed to help decision makers and policy implementers create safer environments for workers handling antineoplastic agents.

The other resources developed as part of this project can be found at www.carexcanada.ca/special-topics/antineoplastic-agents/.

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## 1. Introduction

This document compares policy levers for the safe handling of antineoplastic agents in Alberta, Manitoba, and British Columbia. To synthesize the information, two lenses were applied. The first examines the policy levers through the lens of the levers' scope of application (e.g., province-wide vs. region-specific) and presents the findings by jurisdiction. The second examines the policy levers through the lens of profession and/or work setting (e.g., pharmacies vs. nursing) and presents the findings across jurisdictions.

The report is organized into the following sections:

**Section 1** introduces the report and describes how the information is organized.

**Section 2** defines key terms and provides background on occupational exposure to antineoplastic agents in Canada (i.e., routes of exposure, occupations exposed, numbers of workers exposed).

**Section 3** describes the legislative and regulatory landscape for prevention in Canada, with a specific focus on workplace exposure to antineoplastic agents. It also briefly describes the accreditation process for healthcare organizations in Canada, whereby they are assessed against standards developed by the <u>Health Standards Organization (HSO)</u>.

**Section 4** compares key features of the relevant policy levers in each jurisdiction. Information is organized into three subsections, defined by the policy levers' scope of application (i.e., do they apply at all organizations in the province? do they apply to organizations only at the regional level? do they apply only in the institution in which they were developed?). In each subsection, jurisdiction-specific summaries of the policy levers are provided.

**Section 5** concludes with a cross-cutting summary of policy levers developed by particular professional groups and/or for particular work settings. Information in this subsection is organized into four broad categories (nursing, pharmacies, veterinary clinics, and home care facilities) and compared across jurisdictions.

## 2. Background

#### 2.1 Definition of antineoplastic agents

Antineoplastic agents, also referred to as chemotherapy drugs or cytotoxic drugs, are the most common type of systemic drug therapy used to treat cancer (1). These drugs interfere with the ability of cancer cells to grow and spread. As of 2016, the National Institute for Occupational Safety and Health (NIOSH) had classified over 100 antineoplastic agents as "hazardous" (2). The International Agency for Research on Cancer (IARC) has evaluated different antineoplastic



agents for evidence of carcinogenicity (3-5). Based on animal and human evidence, as well as mechanistic considerations, IARC has classified a number of antineoplastic agents as known, probable or possible human carcinogens (5).

#### 2.2 Occupational exposure to antineoplastic agents in Canada

Occupational exposure to antineoplastic agents can occur directly via dermal contact, inhalation, ingestion, accidental injection, or indirectly via contact with contaminated surfaces, fluids, and objects (6, 7). Exposure can occur in hospitals, where antineoplastic agents are handled in shipping and receiving areas, prepared in pharmacies, administered to patients in wards, and contacted through sanitary services such as laundry, cleaning, and waste handling (8, 9). It can also occur outside of hospitals in workplaces such as community pharmacies, veterinary care facilities, and home care settings (2).

In 2016, CAREX Canada estimated that approximately 75,000 Canadians are exposed to antineoplastic agents at work (10, 11). Most exposures occur in the moderate category (low contact frequency with low exposure control or high contact frequency with high exposure control) (12). Over 75% of exposed workers are female (10, 11). Important jobs in terms of number of workers exposed include pharmacy technicians and nurses (12).

#### 2.3 Definition of "policy levers"

In the context of this report, the term "policy levers" is used to refer to the range of tools that government and healthcare agencies have at their disposal to direct, manage, and shape change to protect workers from exposure to antineoplastic agents (13, 14). The two principal categories of policy levers included in this toolkit are governing instruments and policy/guidance documents.

**Governing instruments:** These are policy levers that can only be made by government and are legally enforceable. They include occupational health and safety statutes and any regulations made pursuant to them. These instruments are either prescriptive or performance-based (i.e., outcomes based). Prescriptive instruments are inflexible — they set out the standard that must be met, as well as the method by which it must be met. In contrast, outcomes- or performance-based instruments are more flexible. They set out the standard that must be met but allow the organization(s) being regulated to choose how they will meet the standard. Compliance with both prescriptive and outcomes-based instruments is mandatory and is enforced through inspections and statutory reporting requirements. However, outcomes-based instruments allow enforcement officers to exercise their discretionary powers.

**Policy/guidance documents:** These are instruments that provide cues to action by those who manage and deliver services within the affected sector. In the case of antineoplastic agents, they include policies, guidelines, standards, protocols, standard operating



procedures (SOPs), etc. Because these types of policy levers are often developed by professional bodies and/or individual organizations/institutions, compliance may be voluntary or mandatory. However, unlike governing instruments, compliance is not enforceable by law.

The government, organization, or institution with responsibility and oversight for worker protection may use an individual lever or a combination of levers to achieve a particular prevention outcome.

# 3. The context for prevention of exposure to antineoplastic agents in Canada

#### 3.1 Legislation and regulations

In Canada, responsibility for occupational health and safety (OHS) is laid out in labour legislation, which falls under provincial authority. Generally, this legislation includes the *Occupational Health and Safety Act*<sup>1</sup> and the *Workers' Compensation Act*<sup>2</sup>, along with their related subordinate regulations. In most jurisdictions, responsibility for OHS is either held by a single branch of government (typically the Ministry of Labour) or by the agency responsible for the delivery of the workers' compensation system. In some jurisdictions, responsibility is shared between these two entities. Because labour legislation falls under provincial jurisdiction, responsibility for OHS and prevention varies by province (Table 1).

Jurisdiction	Prevention	Regulations	Enforcement	<b>Training &amp; Education</b>
Alberta	Ministry of Labour &		Ministry of Labour &	Ministry of Labour &
	Immigration –	Ministry of Labour &	Immigration –	Immigration –
	Occupational	Immigration	Occupational Health	Occupational Health
	Health & Safety		& Safety	& Safety
Manitoba	SAFE Work Manitoba	Labour and Regulatory	Labour and Regulatory	
		Services –	Services –	SAFE Work Manitoba
		Workplace Health &	Workplace Health &	
		Safety Branch	Safety Branch	
British Columbia	WorkSafeBC – Prevention Services	WorkSafeBC – Policy, Research & Regulation Division		WorkSafeBC –
			WorkSafeBC –	Prevention Services,
			Prevention Services	Worker & Employer
				Services

#### Table 1: Responsibility for prevention, by jurisdiction

Source: Jurisdictional websites and the Association of Workers Compensation Boards of Canada.

<sup>&</sup>lt;sup>1</sup> OHS legislation generally sets out the rights and duties of all workplace parties, as well as how workers are to be protected from health and safety hazards (i.e., prescriptive or performance-based procedures; education and training programs; inspection and monitoring requirements; and how laws and regulations are enforced in the absence of voluntary compliance).

<sup>&</sup>lt;sup>2</sup> Workers' compensation legislation delegates authority for the delivery of workers compensation programs and sets out responsibilities in the spheres of prevention, rehabilitation, and compensation.



#### 3.2 Accreditation by national bodies

In Canada, organizations and institutions in the healthcare sector can seek accreditation<sup>3</sup> from <u>Accreditation Canada</u>, which assesses organizations against standards developed by the <u>Health</u> <u>Standards Organization (HSO)</u>. Accreditation Canada has two standards that include elements relevant to the safe handling and management of antineoplastic agents: the <u>Cancer Care</u> <u>Standard</u> (15) and the <u>Medication Management Standard</u> (16). While Accreditation Canada has not categorized the recommendations for the safe handling of antineoplastic agents in these standards as "required organizational practice", they have categorized some as "high priority". There is no legal requirement for health care facilities to gain accreditation but many facilities in Canada do comply with Accreditation Canada standards.

## 4. Inter-jurisdictional comparison of policy levers

Across the three jurisdictions, the safe handling of antineoplastic agents is governed by a range of policy levers. As previously noted, most of the safe handling policy levers identified in the environmental scan fall into the second category defined above – namely, standards, policies, guidelines, protocols and procedures developed by either a professional body (e.g., the Alberta College of Pharmacists), an individual organization (e.g., the Winnipeg Regional Health Authority), or a specific institution (e.g., the BC Cancer Agency). Depending on the mandate of the organization that developed them, these policy levers may apply to certain occupations in all work settings in the province (e.g., nurses in hospitals, pharmacists in hospital or community pharmacies) or just to particular workplaces within a region, organization or institution (e.g., workers employed in companies delivering home care services).

This section of the document is organized into three subsections:

**Provincial-level policy levers:** This subsection summarizes the policy levers identified in the scan that were provincial in scope.

**Regional-level policy levers:** This subsection summarizes the policy levers identified in the scan that were regional in scope. Included are all levers created by organizations that operate at the regional level (e.g., a health authority) or at multiple locations throughout a jurisdiction (but that do not have a broad provincial mandate).

**Institution-level policy levers:** This subsection summarizes the policy levers identified in the scan that were developed by specific institutions and apply only to their particular work settings.

<sup>&</sup>lt;sup>3</sup> Defined by Accreditation Canada as "an ongoing process of assessing health and social services organizations against standards of excellence to identify what is being done well and what needs to be improved". Its purpose is to "provide health care and service organizations an independent, third-party assessment of their organization using standards built upon best practices used and validated by similar organizations around the world".



#### 4.1 Provincial-level policy levers

#### 4.1.1 Governing instruments

In all three jurisdictions, the occupational health and safety statutes and regulations include a general duty clause stipulating that all work must be carried out without undue risk of injury or occupational disease to any person. This clause applies whether or not hazard-specific requirements exist. Of the three jurisdictions, the only one with specific – and legally enforceable – requirements for antineoplastic agents is British Columbia.

• British Columbia: Sections 6.42 to 6.58 of the Occupational Health and Safety Regulation (OHSR) set out minimum requirements for hazardous drugs (17). Specific requirements include: the need for an exposure control plan, hazard communication (including labelling and signage), written policies and safe work procedures, training and education, supervision, recordkeeping, drug preparation and administration, equipment, engineering controls, personal protective equipment, personal hygiene, waste disposal and waste management, and spill control (17).

Guidelines are also available that interpret the following requirements and assist with compliance: the <u>definition of a cytotoxic drug</u>, required elements of an <u>exposure control</u> <u>plan</u>, information on <u>biological safety cabinets</u> (including key design features), and a list of practices that constitute <u>safe work procedures</u> for the administration of cytotoxic drugs (18). Sections 6.42 to 6.58 apply to all employers, workers and all other persons working in or contributing to the production of any industry within the scope of <u>Part 3 of the Workers Compensation Act</u>. As a result, all organizations using antineoplastic agents in British Columbia (i.e., hospitals, cancer agencies, pharmacies, veterinary clinics, and other healthcare facilities) must, at a minimum, comply with these regulations.

#### 4.1.2 Policy/guidance documents

This category includes all levers created by agencies and professional organizations in the healthcare sector with a provincial focus and/or mandate (e.g., cancer agencies, colleges of pharmacists). Examples of these types of provincial-level policy levers exist in all three jurisdictions. None of these policy levers are legally enforceable, although there may be an expectation of compliance across all organizations in the province.

British Columbia: Several organizations with a provincial mandate have developed their own policies and guidelines that meet or exceed the requirements mandated by the OHSR. Some are broader in focus, while others are specifically focused on a particular profession. Examples include: <u>BCCA Pharmacy Practice Standards for Hazardous Drugs</u> (19), <u>Hazardous Drugs Safe Handling Standards (Number V-10)</u> (20) and <u>Hazardous Drug Spill Management (Number V-30)</u> (21), all developed by BC Cancer.



- Alberta: Examples of levers developed and implemented by organizations with a
  provincial mandate include: <u>Hazardous Medication Personal Protective Equipment (PPE)</u>
  <u>Guide and List: Reducing Occupational Exposure to Hazardous Medication for All Staff</u>
  (22) and <u>Cytotoxic Drug Manual Administration and Handling Guidelines Version 3.5</u> (23),
  both of which were developed by Alberta Health Services, in collaboration with Covenant
  Health.
- **Manitoba:** Provincial-level policy levers have been developed for the safe handling of antineoplastic agents for all labs in the province (e.g., "Safe Handling of Cytotoxic and Non-Cytotoxic Waste and Specimens" (24), developed by Diagnostic Services Manitoba).

#### 4.2 Regional- or organization-level policy levers

#### 4.2.1 Governing instruments

No legislation or regulations exist at the regional level in any of the three jurisdictions.

#### 4.2.2 Policy/guidance documents

This category includes all levers created by organizations that operate at the regional level (e.g., a health authority) or at multiple locations throughout a jurisdiction (but that do not have a broad provincial mandate). Examples of these types of policy levers exist in all three provinces. None of these policy levers are legally enforceable, although there may be an expectation of compliance across all organizations in a particular region or institutions within an organization with multiple worksites.

- British Columbia: Some regional health authorities or organizations have created guidelines that are specific to their context (but which may not be consistent across the province as a whole). For example, some guidelines specify the use of closed system transfer devices (CSTD), while others do not.
- Alberta: No policies or guidelines have been developed and implemented by organizations with a regional mandate in Alberta.
- Manitoba: The Winnipeg Regional Health Authority (WRHA), in collaboration with the Cancer Care Manitoba (which has a provincial mandate), developed a policy entitled "Safe Handling of Hazardous Medications (Cytotoxic and Non-Cytotoxic) Policy" (25). While it applies specifically to organizations within the WRHA, it is also used by other health authorities in Manitoba.

One home care organization, which operates in all three jurisdictions, has developed internal policies and guidelines on the safe use of antineoplastic agents in all its facilities (see "<u>Home</u> <u>Care</u>" on page 9).

#### 4.3 Institution-specific policy levers



#### 4.3.1 Governing instruments

None of the three jurisdictions have created institution-specific legislation or regulations.

#### 4.3.2 Policy/guidance documents

This category includes all levers created by specific institutions for their particular work setting. Examples of these types of policy levers exist in Alberta and British Columbia, but not in Manitoba.

- British Columbia: Four examples were identified in British Columbia: <u>Hazardous Drugs:</u> <u>Handling Precautions (Policy # PTN.02.021)</u> (26) and <u>Medication Administration:</u> <u>Cytotoxic Chemotherapy and Biotherapy</u> (27), developed by BC Children's Hospital; and "Clinical Policies and Procedures: Chemotherapy, Biotherapy and other Hazardous Drug Administration" and "Clinical/Operations Policy and Procedure: Safe Drug Handling Decisions" (28, 29), developed by Bayshore Healthcare (which also has facilities in other jurisdictions).
- Alberta: The two identified in Alberta ("Personal Safety Precautions for Chemotherapy Patients Protocol" (30) and "Policy & Procedure for the Safe Handling of Hazardous Drugs" (31)) were developed for a veterinary clinic and a home care facility, respectively.
- **Manitoba:** No policy levers were identified that had been developed for specific hospitals or healthcare facilities.

## 5. Cross-cutting summary of policy levers, by selected professional settings

This section of the document provides a brief cross-cutting summary of the policy levers identified in the scan that were developed by particular professional groups and/or for particular work settings. Included are levers created for pharmacies, veterinary clinics and home care facilities, as well as levers created for nurses.

#### 5.1 Nursing

The Canadian Association of Nurses in Oncology (CANO/ACIO) has published guidelines on the safe chemotherapy work practice (<u>Standards and competencies for cancer chemotherapy</u> <u>nursing practice</u>) (32). In the absence of provincial-, regional-, and/or institution-specific guidelines, hospital and home care nurses in each of the three jurisdictions reported that they followed the CANO/ACIO guidelines.

• **British Columbia:** In addition to complying with the requirements of the *OHSR*, hospital and home care nurses follow the guidelines and policies of their respective facilities (where they exist). Examples include: <u>Hazardous Drug Safe Handling Standards (Number</u>



V-10) (20) and <u>Hazardous Drug Spill Management (Number V-30)</u> (21), both created by BC Cancer; and, "*Clinical Policies and Procedures: Chemotherapy, Biotherapy and other Hazardous Drug Administration*"(28) and "*Clinical/Operations Policy and Procedure: Safe Drug Handling Decisions*" (29), developed for home care nurses by Bayshore Healthcare.

- Alberta: Hospital and home care nurses follow the guidelines and policies of their respective facilities (where they exist). Examples include: <u>Hazardous Medication Personal</u> <u>Protective Equipment (PPE) Guide and List: Reducing Occupational Exposure to</u> <u>Hazardous Medication for All Staff</u> (22), published by Alberta Health Services, in collaboration with Covenant Health; and, "*Provincial Guide: Community Based Services Waste Disposal*" (33), created by Alberta Health Services.
- Manitoba: Hospital and home care nurses follow the guidelines and policies of their respective regional authorities or facilities (where they exist). Examples include: *"Cytotoxic and Non-Cytotoxic Hazardous Medications Home Care Guidelines"* (34) and <u>Safe Handling of Hazardous Medications (Cytotoxic and Non-Cytotoxic) Policy</u> (25), both created by the Winnipeg Regional Health Authority.

#### 5.2 Pharmacies

Provincial-level guidelines exist in all three jurisdictions for pharmacy compounding of hazardous sterile and non-sterile drugs. The College of Pharmacists in <u>British Columbia</u> and <u>Manitoba</u> have adopted the <u>National Association of Pharmacy Regulatory Authorities</u> (NAPRA) standards for both sterile and non-sterile preparations (35, 36). The <u>Alberta College of</u> <u>Pharmacy</u> uses the NAPRA model standards for sterile preparations but has developed its own standard for non-sterile preparations (37).

- **British Columbia:** All hospital and community pharmacies that compound hazardous drugs use the compounding guidelines noted above. All pharmacies also comply with the minimum requirements for safe handling and dispensing set out in the *OHSR*.
- Alberta: All hospital and community pharmacies in Alberta that compound hazardous drugs use the same compounding guidelines as the College of Pharmacy. Some, but not all, community pharmacies have an internal policy for handling and dispensing hazardous drugs. Hospital pharmacies comply with internal policies and guidelines for the preparation, handling, and dispensing of antineoplastic agents. One example is the guideline prepared by Alberta Health Services, in collaboration with Covenant Health (Hazardous Medication Personal Protective Equipment (PPE) Guide and List: Reducing Occupational Exposure to Hazardous Medication for all Staff (22)).
- **Manitoba:** All hospital and community pharmacies that compound hazardous drugs use the compounding guidelines noted above. No information was available on guidelines for dispensing or handling of hazardous drugs for community pharmacies in Manitoba. Hospital pharmacies either follow guidelines published by the Pharmaceutical



Association of Manitoba (*"Hospital Standards of Practice and Guidelines on Practice in Hospital Pharmacy"* (38)) or by the Winnipeg Regional Health Authority (<u>Safe Handling of Hazardous Medications (Cytotoxic and Non-Cytotoxic) Policy</u> (25)).

#### 5.3 Veterinary clinics

Provincial-level guidelines exist in Alberta and British Columbia. In Alberta, they were created by the <u>Alberta Veterinary Medical Association</u> and are not enforceable; in British Columbia, the requirements were created by <u>WorkSafeBC</u> and are enforceable. No provincial-level guidelines have been created by the <u>Manitoba Veterinary Medical Association</u>.

- **British Columbia:** All veterinary clinics comply with the requirements for safe handling and dispensing set out in the *OHSR*. In addition, some veterinary practices follow their own internal guidelines (e.g., VCA Canada).
- Alberta: Veterinary practices adhere to the following policies created by the Alberta Veterinary Medical Association: <u>Practice Inspection and Practice Standards Bylaw</u> (39) and "Safety Handbook for Alberta Veterinary Facilities" (40). In addition, some veterinary practices follow their own internal guidelines (e.g., Calgary Animal Referral & Emergency Centre, VCA Canada).
- Manitoba: Veterinary practices may have their own internal policies and/or guidelines.

#### 5.4 Home Care

Provincial-level guidelines for home care exist in Alberta and British Columbia, but not in Manitoba. They are similar to those described above for veterinary practices in that none are legally enforceable, except the requirements for antineoplastic agents set out in British Columbia's *OHSR*. Manitoba is the only jurisdiction that requires all medication for personal care homes be dispensed from one central pharmacy. The rationale is that centralized dispensing of medications leads to more consistency and better control of labelling and packaging.

British Columbia: Home care organizations comply with the requirements for safe handling and dispensing set out in the OHSR. In addition, home care workers follow their organization's internal policies and guidelines (where they exist) on the safe use of antineoplastic agents. Examples include: "Clinical Policies and Procedures: Chemotherapy, Biotherapy and other Hazardous Drug Administration" (28) or "Clinical/Operations Policy and Procedure: Safe Drug Handling Decisions" (29), developed by Bayshore Healthcare (for use in all of their facilities across the country). There is a provincial health and safety association dedicated to ensuring injury free, safe working conditions for continuing care workers in British Columbia (<u>SafeCareBC</u>); however, it does not publish guidelines on the safe handling of antineoplastic agents.



- Alberta: Home care workers follow their organization's internal policies and guidelines (where they exist) on the safe use of antineoplastic agents. One example is the waste disposal guideline prepared by Alberta Health Services ("Provincial Guide: Community Based Services Waste Disposal" (33)). Other examples include policies developed by Bayshore Healthcare for use in all of their facilities across the country. In Alberta, some home care workers expressed that they were often unaware whether a patient is taking hazardous drugs as not all pharmacies label oral antineoplastic agents as "hazardous".
- Manitoba: Home care workers follow their organization's internal policies and guidelines (where they exist) on the safe use of antineoplastic agents. Examples include: "Cytotoxic and Non-Cytotoxic Hazardous Medications Home Care Guidelines" (34), developed by the Winnipeg Regional Health Authority; and policies developed by Bayshore Healthcare for use in all of their facilities across the country.

### 6. Conclusion

There are numerous similarities and differences between the policy levers for the safe handling of antineoplastic agents in Alberta, Manitoba, and British Columbia. One significant difference found in the provinces is the way that occupational health and safety is managed. British Columbia was the only province with specific requirements pertaining to the safe handling of antineoplastic agents in the Occupational Health and Safety Regulations. Alberta and Manitoba did not have specific regulations for antineoplastic agents and instead covered them in the general occupational health and safety terminology. Similarly, provincial and regional health agencies had their own respective policies and did not refer to a single standard.

Nurses and pharmacists in all three provinces referred to a set of universal guidelines. This was not the same for health care workers in the homecare and veterinary practices. Another standard that was consistent across the provinces was Accreditation Canada's standards, despite being non-compulsory and not used by all healthcare facilities.

In summary, there is a lot of variation between the policy levers in the three provinces and creating pan-Canadian policy levers that can be adopted by all provinces is vital. Lessons can be learned from the National Association of Pharmacy Regulatory Authorities, which has created standards for compounding sterile products. These standards were adopted and/or adapted by the respective colleges of pharmacy for the three provinces.



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