

Policy Title POLICY ON OUTSOURCING AND ADMIXING PHARMACEUTICAL PRODUCTS FOR USE IN MANITOBA Branch/Division Provincial Drug Programs/Provincial Policy and Programs Responsible Authority Executive Director, Provincial Drug Programs	POLICY CATEGORY/NUMBER HCS 200.23
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	Applicable to Health, SeniorSeniors and Active Living and all Regional Health Authorities
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1.0 POLICY STATEMENT

Manitoba Health, Seniors and Active Living provides policy direction regarding Outsourcing procurement of Admixed and Compounded pharmaceuticals for those who deliver pharmaceutical services in Manitoba.

2.0 BACKGROUND

Commercially Available Products are regulated by Health Canada and are manufactured without a specific prescriber/patient identified at the time of manufacture. For pharmaceutical products not commercially available in a form required, preparation can include Compounding and/or Admixing carried out by provincially regulated health care professionals within Facilities and is often prescriber/patient specific. This activity is overseen by the College of Pharmacists of Manitoba, the regulatory authority for pharmacists in Manitoba.

Some Compounding and Admixing of larger quantities of like pharmaceutical products has been outsourced to Commercial Compounding Manufacturers as human resource, quality assurance and equipment costs made it difficult to sustain services in Facilities. Health Canada has recently made an interim statement that Admixing and/or Compounding activities must be carried out under one of the following conditions:

1. They are done within a hospital, meeting provincial regulatory requirements;
2. They are done outside a hospital as a service under the supervision of a provincially licensed pharmacist; or
3. They are done in a manner that meets the licensing and manufacturing requirements of the federal Food and Drugs Act.

Following an incident in the spring of 2013 where a number of cancer patients were under-dosed with chemotherapy drugs, Ontario commissioned a report from Dr. Jake Thiessen. This report was released August 7, 2013 and contained recommendations to help prevent future incidents. Also, as a result of nation-wide consultation following the incident, a new category of pharmaceutical preparation was identified and described as "Commercial Compounding Manufacturing". This new category is only

permitted in federally regulated facilities and is carried out by regulated health care professionals or under the supervision of regulated health care professionals.

3.0 PURPOSE

To identify requirements when Admixing and/or Compounding of pharmaceuticals is outsourced from a Facility.

4.0 DEFINITIONS

Admixing: For pharmaceutical products, the addition of one product to another. (This does not include reconstitution – the “bedside” preparation of a product for administration.)

Compounding: The preparation, mixing, assembling, altering, packaging and labelling of a drug by a pharmacist in a licensed pharmacy in accordance with a Practitioner’s prescription or order for a specific patient based on a direct patient-Practitioner-pharmacist relationship in the course of professional practice.

Commercial Compounding Manufacturing: The preparation, mixing, assembling, altering, packaging and labelling of a drug prior to or without obtaining a Practitioner’s prescription or order.

Commercially Available Products: Pharmaceutical products authorized by Health Canada for use and sale in Canada and assigned a Drug Identification Number (DIN) for marketing in Canada after having received a Notice of Compliance.

Establishment License: A license issued by Health Canada to a person in Canada allowing them to conduct licensable activities in a building which has been inspected and assessed as being in compliance with the requirements of Divisions 2 to 4 of federal *Food and Drug Regulations*.

Facility: A hospital, personal care home, psychiatric facility, medical clinic, laboratory, CancerCare Manitoba, community health centre, community pharmacy, or other facility in which health care is provided.

Manufacturer or Distributer: A person including an association or partnership who under their own name, under a trade name, design or word mark, or other name controlled by them, sells a food or drug.

Outsourcing: When a product or service is procured from outside a pharmacy or facility with an Establishment License.

Pharmacy License: A license issued under the authority of *The Pharmaceutical Act* (Manitoba) by the College of Pharmacists of Manitoba for the purpose of operating a pharmacy.

Practitioner: A person who is entitled under the laws of a province to issue a prescription for a drug and is practicing their profession in that province.

5.0 POLICY

When a Manitoba Regional Health Authority or Manitoba Facility outsources the Compounding or Admixing of pharmaceutical products, the Manitoba Regional Health Authority or Facility must enter into a contract with the Manufacturer or Distributor who provides Commercial Compounding Manufacturing service, that shows that the Manufacturer or Distributor:

- 5.1 Has their production facilities located within Canada;
- 5.2 Demonstrates to the Manitoba Regional Health Authority or Facility that the service provider is licensed and providing the contracted service under the authority of either an Establishment License or Pharmacy License and meets the appropriate provincial or federal licensure requirements.

6.0 CORE SUPPORTING DOCUMENTS: Standards, Procedures, Guidelines

6.1 Guidelines for Compounding Products

Compounded products must:

- be compounded either for immediate dispensing or administration pursuant to a prescription or order; or in anticipation of a prescription or order based on routine, regularly observed prescribing patterns; and
- not duplicate a commercially available, Health Canada-approved product; and
- be compounded using only Health Canada-approved products or products that comply with appropriate standards; and
- when not performed in a licensed pharmacy, be compounded by a regulated healthcare professional, or under the supervision of a regulated healthcare professional, with the appropriate authority and relevant knowledge, technical ability and resources to conduct the activity; and
- be compounded in a pharmacy or in an establishment in accordance with applicable standards under the oversight and/or authority of a provincial or territorial government.

6.2 Guidelines for Commercial Compounded Manufactured Products

Commercially compounded manufactured products must:

- not be sold by an entity other than the Commercial Compounding Manufacturer that compounded the product; and
- not be sold to an entity other than a healthcare entity that provides medical services through regulated healthcare professionals directly to patients; and
- not duplicate a commercially available, Health Canada-approved product; and
- be compounded using only Health Canada-approved products or products that comply with appropriate standards; and
- be compounded by a regulated healthcare professional, or under the supervision of a regulated healthcare professional, with the appropriate authority and relevant knowledge, technical ability and resources to conduct the activity; and
- not include claims or promotion, except as permitted by the Health Canada-approved Product Monograph, as applicable; and
- be compounded in a location with an establishment licence, in accordance with federal standards, issued by Health Canada.

7.0 Reference Documents

- Final Report to the Ad Hoc FPT Working Group on Admixing and Compounding From the Sub-Working Group, November 2013.
- The Food and Drugs Act (Canada)

- Health Canada Policy POL-0051 Manufacturing and Compounding Drug Products in Canada; January 26, 2009.
- Managing Overfill during Preparation and Delivery of Intravenous Medications; ISMP Canada Safety Bulletin Volume 13; Issue 7; August 15, 2013.
- *The Pharmaceutical Act* (Manitoba)
- Thiessen, Jake J.; A Review of the Oncology Under-Dosing Incident: A Report to the Ontario Minister of Health and Long-Term Care; July 12, 2013.