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## **Change Rationale**

## Introduction

The College of Pharmacists of Manitoba (CPhM) is seeking feedback from registrants on proposed updates to new and existing Practice Directions and Guidelines. These updates reflect emerging pharmacy practices, regulatory changes, and efforts to improve clarity and patient safety.

## Key Changes and Rationale

Practice Direction /Guideline	Key Changes	Rationale
Informed Consent Practice     Direction and Informed     Consent Guideline	<ul> <li>Establishes a standalone Practice Direction outlining informed consent requirements.</li> <li>Introduces a Guideline to support pharmacy professionals in implementing best practices.</li> </ul>	Following a request from Council in 2023, a new Informed Consent Practice Direction and Guideline has been developed to set clear expectations for obtaining informed consent in pharmacy practice. These documents aim to standardize collection and documentation procedures for informed consent.
2. Drug Distribution and Storage Practice Direction	<ul> <li>New provisions permitting pick-up points outside of traditional pharmacy settings.</li> <li>Enhanced guidance on secure storage and tracking of medications.</li> <li>DPIN section revisions to improve clarity.</li> </ul>	The Drug Distribution and Storage Practice Direction has been updated to address concerns regarding pharmaceutical access in northern and remote communities.
3. Ensuring Patient Safety Practice Direction	<ul> <li>Revised Practice Direction for better alignment with other regulatory documents.</li> <li>DPIN section revisions to improve clarity and align with other Practice Directions.</li> </ul>	The Ensuring Patient Safety Practice Direction has been revised to clarify the DPIN section and remove the outdated definition of "Patient Safety". These updates streamline the document while maintaining its intent.

4. Controlled Substances Accountability Guideline	<ul> <li>Provide additional guidance for documenting inventory adjustments and sales reports.</li> <li>Clarifications on definitions and reporting procedures for controlled substance accountability.</li> </ul>	The Controlled Substances Accountability Guideline has been updated to address gaps in documentation and security requirements. These changes aim to reduce diversion risks and ensure compliance with federal regulations.
5. Compliance Packaging Practice Direction and Compliance Packaging Guidance Document	<ul> <li>Establishes a standalone Practice Direction to provide clear regulatory expectations.</li> <li>Introduces a supporting Guidance Document to help pharmacies implement compliance packaging best practices.</li> </ul>	To improve clarity, the Compliance Packaging Practice Direction has been separated from the Drug Distribution and Storage Practice Direction and paired with a new Guidance Document.
6. Administration of Drugs Including Vaccines Practice Direction	<ul> <li>Removal of "pre-filled syringe" requirement for epinephrine in anaphylaxis management kits</li> <li>Amend to include "applicable dosing charts" in anaphylaxis management kits</li> </ul>	The Administration of Drugs Including Vaccines Practice Direction has been revised to allow greater flexibility in how pharmacists meet their anaphylaxis management protocol.
7. Permanent and Temporary Pharmacy Closures Practice Direction	Removal of restrictions on transferring controlled substance prescriptions during permanent closures.	The Permanent and Temporary Pharmacy Closures Practice Direction has been revised to align with federal exemptions.