Panacea Pharmacy

3-620 Dakota Street, Winnipeg

Policies and Procedures Manual

Compiled / updated by Management of Panacea Pharmacy

May 6, 2019

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1 Introduction

The policy and procedure manual of "**Panacea Pharmacy**" will provide the pharmacy staff with clear direction on the scope and limitations of their functions and responsibilities. The manual will ensure safe and effective pharmacy practice and will help identify, mitigate and avoid situations that may expose patients and staff to hazardous risks.

Contacting the College of Pharmacists of Manitoba: The following contact information can be used for contacting the College of Pharmacists of Manitoba. Detailed information can be obtained by visiting the website: [https://www.cphm.ca/]. This manual is digitally available to download from the website following the link [https://panaceaclinic.ca/pharmacy]

College of Pharmacists of Manitoba 200 Taché Avenue Winnipeg, Manitoba R2H 1A7

Ph: 204.233.1411, Fax: 204.237.3468

Email: info@cphm.ca

2 General Practice

2.1 Pharmacy information

Details of the pharmacy information given below:

Name: O/A Panacea Pharmacy, Legal name: 10008554 Manitoba Ltd.

Address: 3-620 Dakota Street, Winnipeg, Manitoba, R2M 3K1

Telephone: +1 (204)256-5726

Fax: +1 (204)256-5963

Email: panacea.pharmacy.wpg@gmail.com

Hours of operation: Mon to Fri - 9:00 am to 5:00 pm

2.2 Staff Information

Pharmacists:

1. Olaide Alafia,

Address: 3 Donald Street, Winnipeg, MB. R3L 2P6.

Phone: +1 (204) 962-2031

2.

Pharmacy Technicians:

1. Presently vacant

2.

Pharmacy Assistants:

1. Presently vacant

2.

Other Staff:

1. Presently no support staff is necessary.

2.

2.3 Position descriptions:

2.3.1 Pharmacy manager

Pharmacy manager is required to lead staff members within the pharmacy by assigning tasks, supervising technicians and assistants as well as other staffs. Pharmacy manager must be able to fill and be able to check prescriptions filled by pharmacy techs to ensure proper procedures have been followed according to the standard of Manitoba guidelines.

2.3.2 Pharmacist

Pharmacist are required to prepare medications according to the Manitoba provincial guideline by reviewing and interpreting physicians orders. At the Panacea Pharmacy the role of pharmacy manager will be performed by the Pharmacist.

2.3.3 Pharmacy technicians / Assistant

Pharmacy Technicians / Assistants are required to work with pharmacists to aide in administrative duties. This aide can include the preparation and handling of prescription medications, also to take prescriptions over the phone and in person, work with health professionals and customers, help mixing medicines, count pills, measure medication, label and give instructions for medicine, and help take payments.

2.3.4 Other staff

Assist Pharmacy Manager and to perform daily routine pharmacy activities.

2.4 Security:

The security alarm system is installed by the Canadian National Security (CNS) Ltd. at the 335 Henderson Hwy, Winnipeg, Manitoba, R2L 1M7, Canada. The contact person at CNS is Mr. Eric Melsted, Sr. Security Technician. Mr. Melsted can be reach over phone at +1 (204) 654 0000 or via email at erikmelsted@cnat.ca. More details of the alarm system can be found in Section 2.4.4.

2.4.1 Opening and closing procedure

The daily opening and closing of the pharmacy will be done by the Pharmacy Manager or Manager-in-charge (in the absence of Pharmacy Manager). The opening and closing will require starting / closing in the software, update log and sales including the sales terminal and POS. The Pharmacy owner may also open and close the pharmacy.

Pharmacy Hours:

Monday to Friday - 9:00 am to 4:30 pm Saturday - 10:00 am to 12:00 pm

2.4.2 Individuals with Key(s) to Pharmacy:

The owner of the pharmacy will have access to the pharmacy's keys. In addition to the owner a set of keys will be given to the pharmacy manager / pharmacist. In case of absence of the pharmacy manager, the relief pharmacist will be given temporary access to the key for a certain period of time.

2.4.3 Lock and leave

No lock and Leave component at the Panacea Pharmacy.

2.4.4 Alarm

A security alarm is in place at the Pharmacy (including the clinic) to detect intrusion – unauthorized entry - fire protection – within the clinic and Pharmacy area. The clinic is assigned as Zone 1, and the pharmacy is assigned as Zone 2 inside Zone 1. The combined alarm system installed at the Panacea Pharmacy / Clinic is for the protection against fire, burglary (theft) or property damage, and personal protection against intruders. There is no closed-circuit television surveillance (CCTV) in place at the Pharmacy / Clinic. In the event of alarm system break, two-way voice monitoring will be activated which allows communication between the panel and Monitoring station. The Monitoring station will communicate with the owner or designated person.

Arming / Disarming: Therefore in order to arm: step 1 - arm zone 2 (pharmacy) and Step 2 - arm Zone 1 (Clinic) and exit from the back door. In order to disarm: Enter from the back door - Step 1 - disarm Zone 1 (Clinic) and Step 2 - Disarm Zone 2 (Pharmacy).

Contact Alarm service provider: Canadian National Security (CNS) Ltd. is the alarm system monitoring professional for Panacea Pharmacy. The address of CNS Ltd. is given below:

Address: 335 Henderson Hwy, Winnipeg, Manitoba, R2L 1M7, Canada

Phone: +1 (204) 654 0000 Fax: +1 (204) 654 0004

To contact **monitoring station, please call 1-800-561-5433**, if alarm system breaks - An audible warning will be activated show that an event has occurred.

2.5 Storage of Electronic Records:

The "Paper Less" concept provided by KROLL will be practiced at the Panacea Pharmacy. The software provider will train and update the paper less system concept from time to time. At present we will keep the paper copies for 5 Year until we successfully practice "Paper Less". The digital copy of documents from the "KROLL" software will be backed-up every night at 3:00 am in a hard drive as well as an external USB hard drive.

2.6 Storage of Prescription Hard Copies

The pharmacy Manager / pharmacist / Manger-in-charge shall document and keep all required records according to the legislation and any other applicable practice directions. All paper will be kept in a file cabinet locked inside the alarm zone. All paper copies will be kept stored for a period of 5 Years.

2.7 Hardware and Software Security

KROLL: As a hardware supplier / vendor Telus / KROLL will provide the hardware security and warranty. The IT company software security in the system as well as data within the software.

KROLL Contact: For account services, please contact Lyle Gulash, Account Director, Pharmacy Services, Telus Health, Phone: +1 (250)769-1850, Email: lyle.gulash@telus.com

For technical Service, please contact Paul Persaud, Technical Services Supervisor-THPS, TELUS Health, Phone: + 1 800 263 5876, +1 647 837 7331 (D), Fax: +1 833 343 0001, Email: Paul.Persaud@telus.com.

Firewall: All computers used in the pharmacy will be behind the FortiNet firewall. The firewall security and upgrade will be done automatically once an upgrade is available. Remote maintenance will be done by the firewall company. The contact is given below in this section. Local support of the firewall is provided by local IT company. Hardware and software upgrade and maintenance in the pharmacy will be supported by an IT company. Presently In and Out Technology is providing the IT support for Panacea Pharmacy. The IT company contact is given below in this section.

Firewall Contact: Sean Scarbrough, Renewal Operations, Fortinet, 899 Kifer Road, Sunnyvale, CA 94086, Phone: +1 (408) 331-4569, Email: sscarbrough@fortinet.com, The firewall unit number (**FWF50E3U17001188**) is required for communicating with FortiNet

IT Contact: One of the following IT personnel could be contacted in case of hardware and software issues.

(1) David Boissonneault, In and Out technologies inc.,

Ph: 204-899-5057 (mobile), 204-272-5057 (main line),

Email: david@inandouttech.com,

(2) Derrick Litovitch, In and Out technologies inc.,

Ph: 204-890-5124 (mobile), 204-272-5057 (main line),

Email: derrick@inandouttech.com,

(3) Reuben Ilagan, In and Out technologies inc.,

Ph: 204-998-2911 (mobile) 204-272-5057 (main line),

Email: reuben@inandouttech.com,

2.8 Patient Data Security

Digital data is kept secured in the pharmacy behind a secure firewall 24/7. Pharmacy Manager / Pharmacists/ Manager-in-charge will be responsible and accountable for dealing with data relating to patients' health in the pharmacy and are responsible for ensuring that the principles of data protection are met. Pharmacy owner will facilitate pharmacy manager / pharmacist in ensuring and supervising that the professional responsibilities are fulfilled.

All staff who process data should be made aware of the importance of patient confidentiality and of legal requirements that are professionally obligated of pharmacy owners, manager, pharmacists and pharmacy technicians. All users will be in-house trained and will be aware of the penalties for data breaches.

2.9 Non-prescription medication:

2.9.1 Stock layout

Pharmacy manager / Pharmacist with the help of owner will secure (place in a location) the Schedule II drugs is appropriate location ensuring that there is no opportunity for self selection by the patient.

2.9.2 Sales

All non-prescription medication will follow practice direction concerning the sale of NAPRA "Schedule 2 and 3 of the Manual" Drugs through the authority of the Pharmaceutical Regulations to The Pharmaceutical Act and The Pharmaceutical Act.

2.9.3 NAPRA Schedule II and III drugs

Schedule III drugs shall be placed in an area where self selection by the patient is possible. Pharmcy Manger will ensure the opportunity for patient-pharmacist consultation.

If necessary, Pharmacist will document the patient interaction and any recommendation(s) in the patient's health record and may refuse the sale of a Schedule III Drug.

2.10 Delivery / Mail Policy and Procedures:

Panacea pharmacy will provide a delivery service within the city for delivery of prescription and non-prescription drugs. For all deliveries of prescription drugs, the pharmacist shall ensure that the standards of practice for patient counseling are met.

Panacea pharmacy shall arrange a delivery when the patient or an agent will be present to accept the delivery and receipts should be signed by the patient or agent to confirm receipt of drugs. If delivery fails, the drugs will be returned to the pharmacy within 24 hours or sooner if possible. A courier company will be used to deliver in-town deliveries.

Medical couriers or Canada post will be used for deliveries / mails. Couriers will mostly be used in-town delivery.

2.11 Dress code:

General dress code applys for support stuffs (tunic tops and trousers). Pharmacy manager / Pharmacist are not required to wear a uniform. If pharmacy manager / pharmacists wish, he/she can wear clothes similar to the support staff/ assistants / technicians. In general, dress code will prohibit shorts, flip-flops.

2.12 Excused absences:

An excused absence is unpaid, such as medical appointments, jury duty, funerals and must be scheduled and pre-approved by the pharmacy management / owner in advance. Excused or unexcused absence will follow the guideline provided in the employment standard of Manitoba.

2.12.1 Sick leave

Sick leave are unpaid family leave for health-related reasons and allowed three days with a doctors note.

2.12.2 Vacation requests

Vacation request need to be approved by the pharmacy owner / management-incharge well ahead of time. A substitute is required before leaving for vacation. If a substitute is not found, the pharmacy management may change the vacation request.

2.12.3 Leaves of absence

Any absence needs to be approved by the pharmacy management / owner.

3 Dispensary

3.1 Computers/Software

Panacea pharmacy will use KROLL provided by Telus. Computer hardware and KROLL software will be under maintenance and warranty through authorized organizations. Contact information of Tulus (KROLL), IT support, and Firewall organizations are given in Section 2.7.

3.2 Reference Library

Panacea Pharmacy will use an electronic library which will be available through "iPharmacist", a tabled based operating system. The "iPharmacist" will include the following:

- 1. College of Pharmacists of Manitoba Manual containing current Federal and Provincial pharmacy related statutes and information;
- 2. Policy and procedures Manual that includes minimum content as required by Council;
- 3. Interaction and information references for drugs, herbs, nutraceuticals and food;
- 4. Counseling references for drugs, and

5. All other reference material consistent with the standards of practice and pharmacy practice and type of practice (e.g. geriatric, pediatric, pre-natal and maternal, medical dictionary, etc.)

3.3 Stock Layout

Schedule I drug will all be inside the pharmacy / dispensary. Schedule II drugs will also be inside the dispensary separately while schedule III (OTC) will be available outside the dispensary.

Stocks will be arranged in alphabetic order. Branded drugs will be separated from generics. Stocking will also follow the pattern of the dosage from medications come in: Tablets and capsules together, creams, suspension and syrups all in different designated areas.

3.4 Work Flow Text

The work flow will follow the order given below:

- 1. Pharmacy may receive fax or in-person prescription / refill orders;
- 2. In both cases (fax or in-person) patient identity will be validated first.
- 3. Check dosage, confirm appropriateness based on regulations;
- 4. Process prescription;
- 5. Counseling before pick-up. Phone counseling in case of delivery.
- 6. Signature for pharmacy record; for pick-up as well as delivery.

3.5 Work Flow Diagram

Need input

3.6 Narcotics

The pharmacy manager / pharmacist must complete and record a physical count of narcotics drugs at least once every three months. Pharmacist will update inventory records of expired and returned narcotics and controlled drugs stock which shall include the date of entry into the expired narcotic inventory and quantity of the drug. In case of discrepancies, pharmacist will investigate and send an "incident report" to the appropriate authorities keeping one copy for the pharmacy. Pharmacist will return expired narcotics for disposal.

3.7 Outdated Stock

Pharmacist shall remove all outdated drugs from stock at the first available time. Pharmacist shall check expiry date of medication offered for sale as often as necessary to allow optimum time of usage of drug by the patient before expiration.

3.8 Child Resistant Containers

Pharmacy owner and Pharmacist will jointly ensure that requested packaging ordered is in child resistant containers. In the event that packaging is not in a child resistant containers, Pharmacist will adequately advise patients and caregivers to take precaution with the usage and storage of drugs.

3.9 Suppliers

Primary supplier of Panacea Pharmacy is the **Kohl and Frisch**, Canada's leading national distributor in the healthcare industry. Local Contact: Ken Mayers, Business Development Representative, Kohl and Frisch, Canada, Ph. 204.590.7913.

Secondary supplier of of Panacea Pharmacy is **McKessen**, a leading health-care company for wholesale medical supplies and equipment, pharmaceutical distribution, and healthcare technology solutions.

For generics, Apotex Generics. Local Contact: Tony Duma, Phone: 204.955.4933

3.10 Ordering

Panacea pharmacy will order most medication from the suppliers mentioned in the Section 3.9.

3.11 Inventory

Apart from narcotics inventory mentioned in Section 3.6, pharmacist / pharmacy manager will keep inventory of medication in the Pharmacy. The software KROLL is supported with pharmaceutical / medication inventory and report module.

3.12 Return policies

Pharmacy Manager /Pharmacist shall not accept or return to inventory any drug that has been previously dispensed to a patient according to the *Pharmaceutical*

Act: Manitoba Pharmaceutical Regulations section 85(1), December 2006.

3.13 Complaints

All complains should be in writing along with the contact information (name, address and phone/fax/email). Anonymous complaints are not be accepted. Written complaints can be mailed / forwarded to the College of Pharmacists of Manitoba at the address given in Section 1.

3.14 Counseling

If required, pharmacy manager / pharmacists will provide individualized counseling for all prescription medication in an area designated for counseling.

3.15 Expanded Scope of Practice

Expanded Scope of Practice for a Pharmacist in Manitoba covers the following

- Administering Drugs and Vaccinations. Pharmacist licensed to administer vaccines and injections will be required to follow standard of practice as described by the College of Pharmacist of Manitoba. (See appendix A). The guideline for administration of Drugs including Vaccines can be downloaded following the link. [https://mpha.in1touch.org/uploaded/web/Legislation/Standard%205%20-%20Administration%20of%20Drugs%20&%20Vaccines%20(updated%20June%2023,%202014)2.pdf]
- Prescribing for Self-Limiting Conditions (not including for smoking cessation)
- Prescribe a Drug for Smoking Cessation
- Lab Test Ordering
- Application for Registration as an Extended Practice Pharmacist

Under the Workplace Safety and Health Act (section 45.1 - Needles in Medical Workplaces) needle stick injury must be addressed following guideline. The needle stick injury guideline can be downloaded from the following the link. [https://mpha.inltouch.org/uploaded/web/Guidelines/Needle%20Stick%20Guidelines% 20(June%202015)%20FINAL.pdf]

3.16 Error Standard

Pharmacist shall document all medication error / incidents at the first available time and duly reported to the College. In the event of an error/ discrepancy, the pharmacy manager / pharmacist shall follow the *Medication Incidents and Discrepancies or Near-Miss Events* guideline which can be seen on appendix C. The guideline of Medication Incidents and Discrepancies or Near-Miss Events can be downloaded following the link. [https://www.cphm.ca/uploaded/web/Legislation/Incidents%20and%20Discrepancies%20Practice%20Direction%20-%20FINAL.pdf]

All incidents error and discrepancies must be reported by filling a prescribed form which is available on the College of Pharmacist of Manitoba website. The medication incident and discrepancy report form is attached in the appendix D. Medication incident and discrepancy report form can be downloaded following the link. [https://www.cphm.ca/uploaded/web/Legislation/MPhA%20Forms/Medication%20Incident%20and%20Discrepancy%20Report%20Form%20(July% 202013).pdf]

3.17 Confidentiality Agreements

Pharmacy Manager / Pharmacist or any person working at the Panacea Pharmacy must preserve secrecy about all information that comes to his or her knowledge in the course of his or her duties, and must not communicate any information to any other person and must abide by *Manitoba Pharmaceutical Act* (December 2006, confidentiality of information 94(2) Subject to section 95).

3.18 Prescribing

No prescriptions will be issued by the Pharmacist at the Panacea Pharmacy unless a verbal order is receiver from a license physician.

3.19 Fax Standards Compliance

Facsimile transmissions may be accepted from a practitioner registered to practice in any province of Canada and in compliance with the Food and Drug Act and regulations and, the Controlled Drugs and Substances Act and regulations, except for medications on the M3P program. All faxed prescriptions must meet the requirements of the *Joint Statement on Facsimile Transmission of Prescriptions*.

The standard faxed prescription must include: the prescriber's signature (the actual signature or an electronic image), the time and date of transmission, name of the intended pharmacy and signed certification that the prescription represents the original prescription order and the addressee is the intended recipient. The original hard copy prescription that is sent by fax from the prescriber's office must be invalidated, securely filed and not transmitted elsewhere.

3.20 Documentation Guideline Compliance

3.20.1 Documentation Loss or theft:

Panacea pharmacy will follow guideline procedures and documentations (including reporting) in case of any theft or loss. Pharmacy Manger / Pharmacist shall take all reasonable steps in order to protect narcotics on his/her premises, or under his/her control against loss or theft. Pharmacy Manger / Pharmacist will complete narcotics count quarterly as well as prepare narcotic sales reports monthly. Pharmacy Manger / Pharmacist is responsible to report to the concerned authorities (the College of Pharmacists, and the police) with in 10 days of discovery of theft or loss of narcotics.

3.20.2 Prescription forgeries:

Panacea pharmacy will follow guideline procedures in case of any forgery. Once forgery is discovered, the Pharmacy manger / Pharmacist will report to Health Canada, the College of Pharmacists, and the police. Pharmacist will report a forgery even if the forged prescription was not filled.

3.21 Waste management:

Sharps disposal at the Panacea Pharmacy will be done through authorized organization using approved containers. All drugs/ pharmacy devices for disposal shall be done in accordance with provincial laws, and regulations relating to hazardous waste materials.

In case **needle stick injury** the protocol prescribed by the *Integrated Post-exposure for HIV, HBV and HCV Guidelines for Managing Exposures to Blood and Body Fluids* from the Communicable Disease Control branch of Manitoba Health and Healthy Living will be observed / followed.

4 International Practice

Panacea pharmacy will not provide any international service.

5 Additional Recommended Content

This section will be developed by the owner as purchase, manage accounts and finance will be dealt by the owner.

- **5.1** Charge Accounts
- 5.2 Cheques
- **5.3** Staff Purchases
- **5.4** Telephones
- 5.5 Accounts Receivable
- **5.6** Accounts Payable
- 5.7 Counselling Audit Trail
- 5.8 Banking

A Administration of Drugs including Vaccines



200 Tache Avenue, Winnipeg, Manitoba R2H 1A7
Phone (204) 233-1411 | Fax: (204) 237-3468
E-mail: info@cphm.ca | Website: www.cphm.ca

Practice Direction Standard of Practice # 5: Administration of Drugs including Vaccines

1.0 Scope and Objective:

1.1 Expected Outcome

This document is a practice direction by Council concerning the implementation of the principle of Administration of Drugs including Vaccines through the authority of *The Pharmaceutical Regulations* to *The Pharmaceutical Act* and *The Pharmaceutical Act*

1.2 Document Jurisdiction (Area of Practice)

Administration of drugs, including vaccines, can be done by all licensed pharmacists under section 108(1) of the regulations and by certified pharmacists under section 109(1).

1.3 Regulatory Authority Reference

Section 56(1) and 56(2) of regulations to the *Act* allows Council to create this practice direction.

2.0 Practice Direction

- **2.1** A pharmacist administering a drug, using an advanced method, or a vaccine regardless of the route of administration, must:
 - 2.1.1 Collaborate with the patient and receive permission;
 - 2.1.2 Be satisfied there has been compliance with Standard of Practice #5 of 56(1) of the regulations;
 - 2.1.3 Take appropriate steps to ensure the patient is given the right drug including a vaccine, for the right reason, in the right dose, at the right time and using the right route;
 - 2.1.3.1 Review relevant and applicable immunization guidelines, such as those set out by Manitoba Health and the National Advisory Committee on Immunization (NACI) when administering a vaccine;
 - 2.1.4 Possess current certification in emergency first aid and "CPR Level C";
 - 2.1.5 Ensure the pharmacy creates and maintains a policy and procedure manual that includes administration of drugs, including vaccines, and



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- emergency response protocols;
- 2.1.6 Ensure the pharmacy maintains a readily accessible supply of epinephrine syringes ("pens") for emergency use, diphenydramine, cold compresses and non-latex gloves;
- 2.1.7 Be certified under section 114(1) when administering a drug, including a vaccine, under section 109(1) and has received informed written consent from the patient.
- 2.1.8 Comply with Sections 57 to 59 of the *Public Health Act* and its regulations when administering an immunizing agent.

2.2 Non Vaccine or Advanced Method Administration

- 2.2.1 When administering a drug as permitted under section 108(1) of the regulation and the drug is not a vaccine, the pharmacist may apply the requirements of section 2.3 and 2.4 as appropriate for the drug being administered.
- 2.2.2 The administration of the drug described in section 2.2.1 does require the authorization of the patient and the documentation thereof.

2.3 Before Administration:

- 2.3.1 The pharmacist must perform basic assessment of the patient proportional to the complexity of administration, that includes:
 - 2.3.1.1 History,
 - 2.3.1.2 Overall condition, e.g., vital statistics,
 - 2.3.1.3 Appropriate information if administering a drug by injection, including appropriate immunization information when administering a vaccine, e.g. reviewing immunization records, and
 - 2.3.1.4 Condition of the administration site.
- 2.3.2 The pharmacist must assess the appropriateness of the drug, including a vaccine, for the specific patient, including but not limited to:
 - 2.3.2.1 Indication
 - 2.3.2.1.1 For a publicly funded vaccine, the patient's eligibility for that program, as set out by Manitoba Health
 - 2.3.2.2 Dose
 - 2.3.2.3 Allergy status
 - 2.3.2.4 Risk factors and contraindication
 - 2.3.2.5 Route of administration including:
 - 2.3.2.5.1 Appropriateness for the patient

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- 2.3.2.5.2 Appropriateness of the drug, including a vaccine2.3.2.5.3 Drug and route follows established protocols, if applicable
- 2.3.3 The pharmacist must obtain consent from the patient or from the person authorized to consent on the patient's behalf to administer the drug, including consent for administration of a vaccine in accordance with *The Public Health Act* and the Immunization Regulation made under the *Act*.
- 2.3.4 The pharmacist must wash hands before (and after) caring for the patient.
- 2.3.5 In addition to the above, and before administering a drug under section 109(1), the pharmacist certified under section 114(1) must:
 - 2.3.5.1 Provide the patient the following information:
 - 2.3.5.1.1 Name of the drug, including a vaccine, to be administered,
 - 2.3.5.1.2 Indication for the drug, including a vaccine,
 - 2.3.5.1.3 Expected benefits and material risks of the administration and drug,
 - 2.3.5.1.4 Expected reaction,
 - 2.3.5.1.5 Usual and rare side effects,
 - 2.3.5.1.6 Rationale for the 15-30 minute wait following the administration,
 - 2.3.5.1.7 Importance of immediately consulting with the pharmacist if a reportable event occurs,
 - 2.3.5.1.8 Contacts for follow-up or emergency, and
 - 2.3.5.1.9 Any other information that a reasonable person in the same circumstances would require in order to make a decision about the drugs to be administered.
 - 2.3.5.2 ensure the pharmacy creates and maintains a clean, safe, appropriately private and comfortable environment within which the injection is to be administered.
 - 2.3.5.3 be satisfied the drug, including a vaccine, to be injected is stable, has been prepared for administration using aseptic technique, has been stored properly and is clearly labeled.
 - 2.3.5.4 ensure the route of administration and the site has been appropriately prepared for the administration.

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2.4 After Administration:

- 2.4.6 The pharmacist must:
 - 2.4.1.1 Ensure the patient is appropriately monitored;
 - 2.4.1.2 Respond to complications of therapy, if they arise;
 - 2.4.1.3 Ensure devices, equipment and any remaining drug, including a vaccine, is disposed of safely and appropriately;
 - 2.4.1.4 Document the administration of the drug, including a vaccine, as required by the regulations;
 - 2.4.1.4.1 In the case of an immunizing agent, record the information on the patient's health record as stated in Section 5 of the Immunization Regulation to the Public Health Act
 - 2.4.1.5 Report any reportable events to the applicable agency or organization;
 - 2.4.1.5.1 In the case of an immunizing agent, within seven days after becoming aware of a reportable event, a health professional must report it in accordance with the Immunization Regulation to the *Public Health Act*
 - 2.4.1.6 Provide relevant information to other regulated health professionals and provincial health agencies as appropriate, including reporting patient names and vaccine doses to the provincial vaccine registry (Manitoba Immunization Monitoring System).

2.5 Restrictions:

- 2.5.1 A pharmacist must not administer an injection to a person under five years of age.
- 2.5.2 A pharmacist must not administer a vaccine to a person under seven years of age.
- 2.5.3 A pharmacist must not administer a drug, including a vaccine, to a family member unless there is no other alternative.

2.6 Infection Control:

- 2.6.1 The pharmacist must use precautions for infection control, which includes:
 - 2.6.1.1 Handling all body fluids and tissues as if they were infectious, regardless of the patient's diagnosis,



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- 2.6.1.2 Washing hands before and after caring for the patient, and after removing gloves; and wearing gloves to prevent contact with body fluids excretions or contaminated surfaces or object;
- 2.6.1.3 Proper disposal of waste materials
- 2.6.1.4 Maintaining a setting for administration that is clean, safe, comfortable and appropriately private and furnished for the patient
- 2.6.1.5 Management of needle stick injuries.

3.0 Compliance Adjudication

All documentation must be readily accessible and open to regulatory review. All references to patient would include a person who is authorized to make decisions on behalf of the patient.

4.0 Appendices

Not applicable

A Practice Direction is a written statement of a regulatory position made by Council for the purposes of giving direction to members and owners about the conduct of their practice or pharmacy operations.

A Practice Direction carries similar legal weight to a Regulation under the Act and compliance by all Manitoba pharmacists and pharmacy license holders is expected.

The process for development, consultation, implementation, appeal and review is been published on the College website.

Development Source: Regulatory Reference: Consultation Close: Authorized by Council: Effective Date: Revised: Review Due: Standards of Practice Committee
Sec 108(1), 109(1), The Pharmaceutical Regulations
November 15, 2013
December 9, 2013
January 1, 2014
June 23, 2014

B Needle Stick Injury Guidelines

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NEEDLE STICK INJURY GUIDELINES

This reference document will outline information on prevention of needle stick injuries in the workplace and the procedures to follow in the event of an injury.

Hepatitis B, Hepatitis C and Human Immunodeficiency Virus (HIV) are the diseases of concern for needle stick injuries with the highest risk of transmission occurring with Hepatitis B. Under <u>The</u> <u>Workplace Safety and Health Amendment Act</u>, Section 45.1(3), the employer must develop procedures to be followed in a medical workplace when a worker suffers a needle stick injury, including instructions for the worker suffering the injury.

Post exposure to a patient's blood via a needle stick injury is a serious health concern for pharmacists providing injections therefore it is required that pharmacy managers ensure all employees at risk of injury are educated in needle stick prevention and the protocol to follow should an injury occur.

Prevention

Needle stick injuries are often associated with these activities:

- Recapping needles
- Failing to dispose of used needles properly in a puncture-resistant sharps container
- Trying to do several things at the same time, especially when disassembling or disposing of needles
- Difficult patient situations such as an immediate patient reaction to injection whether it be a patient experiencing an anaphylactic reaction, fainting or a child refusing injection

Reduce your risk by:

- Not recapping needles. If necessary, use the single-handed scoop technique
- Keeping handling of sharps to a minimum
- Only using safety-engineered needles (See <u>The Workplace Safety and Health Amendment Act</u> (Needles in Medical Workplaces) for more information)
- Placing sharps containers at eye level and within arms' reach
- Disposing of sharps immediately after use in designated sharps containers
- Sealing and discarding sharps containers when they are three-quarters full
- **Before** the beginning of a procedure, establishing means for the safe handling and disposal of sharps devices
- Ensuring patient is prepared for the procedure
- Ensuring your sharps handling policies and procedures are up to date and reviewed regularly by all affected staff
- Ensuring Hepatitis B vaccinations for pharmacy personnel are current. Pharmacist should have post immunization titre testing done to confirm immunity to Hepatitis B
- See Section 39 "Health Care Facilities" of the Workplace Safety and Health Regulation to the <u>Workplace Safety and Health Act</u> focusing on the areas of infectious materials and sharps containers



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Review the pharmacy setting's environment, workflow, policies and procedures and make adjustments as needed to mitigate as many of these risks as possible.

(Adapted from Alberta College of Pharmacists, The Link, September 10, 2013)

Manitoba Post Exposure Protocol

Definitions and Introduction

Exposed: Individual who comes into contact with the potentially infected blood/body fluid. Source: Individual from whose body the potentially infected blood/body fluid originated from.

The Integrated Post-exposure Protocol for HIV, HBV and HCV: Guidelines for Managing Exposures to Blood and Body Fluids from the Communicable Disease Control branch of Manitoba Health and Healthy Living is the protocol followed for a needle stick injury in Manitoba. A risk assessment of the exposure incident is conducted evaluating body fluid involved, type of exposure and evaluation of the Source (patient) if consent given. The Exposed (pharmacist) may have baseline testing done for Hepatitis B (HBV), Hepatitis C (HCV) and HIV. If the Source (patient) has given consent then they also may have testing done. Post Exposure Prophylaxis (PEP) will be implemented weighing the risk and benefits of PEP based on the risk assessment of the exposure incident and evaluation of the Exposed (pharmacist). Post Exposure Prophylaxis may include Hepatitis B vaccine, Hepatitis B immunoglobulin and/or HIV regimens. There is no known effective chemoprophylaxis or immunoprophylaxis for individuals exposed to an HCV-positive source. However, post-exposure testing, information sharing and medical follow-up may be indicated. Please see The Integrated Post-Exposure Protocol for HIV, HBV and HCV: Guidelines for Managing Exposures to Blood and Body Fluids for more information.

Post Exposure Action

- 1. Remove gloves or clothing to determine the injury area.
- **2.** Encourage the wound to bleed.
- 3. Immediately wash the area well with soap and water but do not scrub.
- **4.** Report the incident to your pharmacy manager.
- **5.** Seek medical treatment promptly.

Option 1 - Proceed to local emergency department within 2 to 4 hours of exposure and not longer than 72 hours. Post exposure treatment to prevent infection is most effective if given promptly. Attend the nearest Urgent Care. The medical staff should be informed that the pharmacist will be filing a Workers Compensation claim as a medical report of the injury will need to be submitted to Workers Compensation. If being seen at Urgent Care during an Occupational Health nurse's off hours, pharmacists can call the Occupational Health nurse closest to them for advice and the Nurse will follow up on the next working day. Please see the contact list of Occupational Health nurses in Winnipeg for the appropriate contact information. Those outside of Winnipeg should call the Occupational Health nurse in the Regional Health Authority at the site closest to them. The Exposed pharmacist must then see their family physician for all follow up treatment.



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Option 2 - The Occupational Health section of Winnipeg Regional Health Authority (WRHA) has set up contracts with some organizations to provide Post Exposure treatment services to their employees. **If** the community pharmacy has a contract with Occupational Health of the WRHA (see information below) or if the pharmacist works for the WRHA, then the Exposed pharmacist would contact the Occupational Health nurse at the site closest to them – Concordia, Victoria, Grace, Seven Oaks or Health Sciences. (St. Boniface Hospital is not a participant). Please see the contact list of Occupational Health nurses in Winnipeg for the appropriate contact information. Regional Health Authority workers can also call the Occupational Health nurse at the site closest to them and will be assisted. The Occupational Health nurse would assess the risk, determine the baseline for HBV, HCV and HIV and provide the necessary treatment. Once consent has been obtained from the Source, the nurse would also contact the Source for the necessary blood work. The Occupational nurse will provide follow-up care for the Exposed pharmacist at 3 and 6 months as well as counselling as needed.

For information on setting up a contract with WRHA Occupational Health, please contact Bernice Irvine, Manager WRHA Occupational Health and Disability Case Management at 204-926-1041 or BIrvine@wrha.mb.ca.

- **6.** The Exposed pharmacist and pharmacy manager must fill out an injury report and the pharmacist must submit a claim to Workers Compensation (or phone in the claim at 204.954.4100). Post exposure treatment may include vaccinations, immune globulin and/or HIV post exposure prophylaxis and if required post exposure counselling.
 - An injury report should include the following information:
 - Date, time and location of the exposure.
 - Job duty being performed at the time of exposure.
 - Details of exposure incident (e.g. needle used, severity of exposure, Source).
 - Precautions taken while performing the job.
 - Witnesses.
 - Factors that may have contributed to the exposure incident.
 - If pharmacist was previously vaccinated against HBV.
 - Action taken after exposure.

Obtaining Consent of Source for testing

All testing is voluntary unless a court order has been issued. Both the Exposed and the Source have the right to refuse testing for HBV, HCV and HIV. In most cases the Exposed (pharmacist) should not be involved in obtaining consent of the Source (patient). The pharmacy manager or delegate should have a discussion with the Source to obtain their consent either verbally or in writing but the consent should be documented. Consent from the Source is also required to provide the results of the testing to the Exposed.

It is recommended to obtain consent of the patient for testing, should a needle stick injury occur, before an injection is even administered.



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Filing with Workers Compensation Board

A needle stick injury requires immediate and possible short/long term medical treatment and in some cases post exposure counselling. If a pharmacist is injured at work he/she must file a Workers Compensation Board report. It is important for the Exposed pharmacist and pharmacy manager/employer to submit the necessary claims to the Workers Compensation Board. Please view the Workers Compensation Board of Manitoba website for complete information and applicable forms.

References

Alberta College of Pharmacists, The Link, September 10, 2013

Saskatchewan College of Pharmacists – Guidelines for Post-Exposure to Blood, September 21, 2010 Manitoba Health, Communicable Disease Control Branch - Integrated Post-exposure Protocol for HIV, HBV and HCV: Guidelines for Managing Exposures to Blood and Body Fluids, March 2009 The Workplace Safety and Health Act – Manitoba

World Health Organization – Best practices for injections and related procedures toolkit, March 2010 Manitoba Health Fact Sheet - *Exposure to Infected Blood or Other Body Fluids Information for Occupational Settings, September 2009*

Workers Compensation Board website - http://www.wcb.mb.ca/how-to-file-a-claim-workers

C Medication Incidents and Discrepancies or Near-Miss Events



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Practice Direction – Standards of Practice #9: Medication Incidents and Discrepancies or Near-Miss Events

1.0 Scope and Objective:

1.1 Expected Outcome

This document is a practice direction by Council concerning medication incidents and discrepancies or near-miss events through the authority of the *Pharmaceutical Regulations* to *The Pharmaceutical Act* and *The Pharmaceutical Act*.

1.2 Document Jurisdiction (Area of Practice)

Compliance is expected from all licensed pharmacists in Manitoba practice.

1.3 Regulatory Authority Reference

Sections 56(1) and 56(2) of *The Pharmaceutical Regulations* to the *Pharmaceutical Act* empowers the Council to create a practice direction for medication incidents and discrepancies or near-miss events.

2.0 Definitions:

- 2.1 Medication incident a preventable occurrence or circumstance that may cause or lead to inappropriate medication use or patient harm. Medication incidents may be related to professional practice, drug products, procedures, and systems, and include prescribing, order communication, product labelling/ packaging/nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.
- **2.2** Discrepancy or Near-Miss Event an event or circumstance that took place, and could have resulted in an unintended or undesired outcome(s), but was discovered before reaching the patient.

3.0 Practice Direction

3.1 Policies and Procedures for medication incidents

The Pharmacy Manager will ensure that:

3.1.1 The pharmacy has written policies and procedures for addressing, reporting, investigating, documenting, disclosing and learning from medication incidents. In the case of a pharmacy owned by a Regional Health Authority, the



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manager/director of the pharmacy will collaborate with the regional health authority to ensure that there are written policies and procedures for addressing, reporting, investigating, documenting, disclosing and learning from medication incidents.

3.1.2 Licensed pharmacists, pharmacy technicians, pharmacy assistants and employees of the pharmacy are trained and are required to comply with systems, policies and procedures related to medication incidents, discrepancies or near misses.

3.2 Community Pharmacies

- **3.2.1** Upon discovery of a medication incident, the pharmacist made aware of the incident must:
 - **3.2.1.1** Determine if the patient has experienced harm or is at risk of possible harm
 - **3.2.1.2** Provide care for the patient to the best of their ability to protect their health and safety
 - **3.2.1.3** Ensure the patient receives the right medication in a timely manner
 - **3.2.1.4** Acknowledge that something has happened and the distress the incident has caused the patient and express empathy and concern. Listen to the patient.
 - **3.2.1.5** Take reasonable steps to ensure that the incorrect medication is quarantined and/or returned to the pharmacy to avoid risk of harm or further harm, if relevant.
 - **3.2.1.6** Inform the patient that the medication incident will be reported to pharmacy manager, investigated transparently and steps taken to reduce the likelihood of the medication incident happening to others
 - **3.2.1.7** Notify the prescriber about the medication incident and any other personnel deemed necessary.
 - **3.2.1.8** Notify the pharmacy manager of the medication incident.

3.2.2 The Investigation

Upon discovery of a medication incident, the pharmacy manager must ensure that:

- **3.2.2.1** The staff member(s) involved in the incident are made aware of the incident.
- **3.2.2.2** The investigation of the factors associated with the medication incident is done in a transparent and timely manner.
- **3.2.2.3** Changes in processes or systems that may have led to the medication incident are identified, and a plan is developed and implemented to reduce the risk of the incident recurring.

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3.2.2.4 Findings and changes to be implemented are shared with pharmacy staff and changes reflected in the policies and procedures manual if deemed necessary

3.2.3 Documentation

The Pharmacy manager must ensure that:

- **3.2.3.1** The pharmacist who discovered the incident initiates documentation of the medication incident, including information obtained in section **3.2.1** of this document
- **3.2.3.2** All medication incidents are documented promptly on a pharmacy incident report form (a sample template of a report is provided in the appendices of this practice direction).
- **3.2.3.3** The pharmacy incident report form shall include, at minimum, the date, prescription number, incident number and a brief summary of the incident.
- **3.2.3.4** Corrective action taken to mitigate the risk of the incident recurring is documented.
- **3.2.3.5** The documentation is collated internally and periodically assessed to determine if other changes must be made to pharmacy systems or processes as a result of the incident.

3.3 Hospital pharmacy, personal care home, and long term care facility

3.3.1 When the pharmacist discovers a medication incident, they must notify the pharmacy manager, the prescriber, as well as other healthcare providers as specified in the organization's policies and procedures.

As part of the healthcare team, pharmacists must:

- **3.3.2** Determine if the patient has experienced or is at risk of experiencing harm. Participate in providing care for the patient as appropriate that is required to protect their health and safety.
- **3.3.3** Adhere to the organizations/pharmacy's policies and procedures for patient disclosure, reporting, investigating, documenting, and sharing lessons learned.
- **3.3.4** Participate in a process to review medication incidents with a multidisciplinary team.

3.4 Incidents involving a breach of personal health information

3.4.1 Refer to Practice Direction # 12 Records and Information, section 2.7

3.5 Discrepancies or Near-Miss Events

3.5.1 Whether in community, hospital, personal care home, or long-term care facility the documentation of near-miss events should be considered since it can initiate



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changes to improve safety and reduce risk of future medication incidents and patient harm.

3.6 System-wide learning

- **3.6.1** Pharmacists can help prevent recurrences of near misses and medication incidents in other practice sites in Manitoba and Canada by confidentially and anonymously reporting to the Institute for Safe Medication Practices Canada (ISMP). Go to http://www.ismp-canada.org/
- **3.6.2** Sharing information on system changes being proposed should be considered, including to colleagues outside of the pharmacy, to promote wider shared learning and improvement while maintaining confidentiality (PHIA) principles.

4.0 Compliance Adjudication

4.1 All documentation must be readily accessible and open to regulatory review.

5.0 Appendices

5.1 Medication Incident and Discrepancy or Near-Miss Event Report Form

A Practice Direction is a written statement made by Council for the purposes of giving direction to members and owners about the conduct of their practice or pharmacy operations. Compliance with practice directions is required under the Pharmaceutical Act.

The process for development, consultation, implementation, appeal and review is been published on the College website.

Development Source: Regulatory Reference: Consultation Close: Authorized by Council: Effective Date: Revised: Review Due: Standards of Practice Committee Section 56(9) of *The Pharmaceutical Regulations* March 13, 2015 June 20, 2016 July 8, 2016

D Medication Incident and Discrepancy Report F	?orm
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MEDICATION INCIDENT AND DISCREPANCY REPORT FORM

Incident Report #:

Use for all medibe reported at p The pharmacist Notify physicial INCIDENTS the	N INCIDENT AND DISCE ication incidents. Medi harmacist's discretion. discovering the error i n and pharmacy manag hat could affect the hea	PATIENT INFORMATION Name: Address: Phone: Sex: DOB: Rx #: PHIN		
Error Date:	Hour Date Month	n Year	Pharmacist initiating report:	
Discovery Date:	Hour Date Month	ı Year		
Drug ordered: (State: drug/dose/form	m/route/directions for u	use)		
		us medication commission on the medication commission of the medication commission com		
	NT– Patient received	drug:		
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TYPE OF INCIDE	NT OR DISCREPAN	ICY – Patient did not rece	oive drug:	
□ Dispensing	(specify)			
☐ Documentat	ion (specify)			
☐ Other (speci	fy)			
INCIDENT/DISCR State facts as known attached to this doc		ΓΙΟΝ . Additional details abou	t the error by the pharm	macist involved may be
DATE: Ho	our Date Month	Year Signature o	f Pharmacist:	

1			
CONTRIBUTING FACTORS			
(To be completed by pharmacist responsible)			
	 ☐ Improper patient identification ☐ Incorrect transcription ☐ Lack of patient counselling 	 ☐ Misread/misinterpreted drug order (include verbal orders) ☐ Drug unavailable ☐ Other 	
DATE:			
	Hour Date Month Year	Signature	
NOTIF	TICATION – Complete the following informati	on according to Standards of Practice.	
1.	Patient notified:		
		Hour Date Month Year	
2.	Physician notified:		
2.	Yes/No	Hour Date Month Year	
SEVER	RITY		
	None	□ No change in patient's condition: no medical intervention	
	Minor	required	
	Major	☐ Produces a temporary systemic or localized response: does	
	. J	not cause ongoing complications	
		☐ Requires immediate medical intervention	
OUTC	OME OF INVESTIGATION		
	OW-UP:		
	Problem Identification	Action	
	Lack of knowledge	☐ Education provided	
	Performance problem	□ Policy/procedure changed	
	Administration problem	☐ System changed	
	Other	☐ Individual awareness	
		☐ Group awareness	
		□ Other	
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	acist filling out the form)	Oate: Signature: Date: (Pharmacy Manager)	
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PHARMACY USE ONLY