



College of Pharmacists of Manitoba

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Practice Direction Alternate Verification Program: Drug Packaging and Drug Compounding

1. Scope and Objective:

1.1 Expected Outcome

This document is a practice direction by Council concerning the use of an Alternate Verification Program for drug packaging and/or drug compounding under the authority of *The Pharmaceutical Regulations* to *The Pharmaceutical Act* and *The Pharmaceutical Act*, as an alternative to a pharmacist doing the drug packaging and preparation.

1.2 Document Jurisdiction (Area of Practice)

Compliance is expected from all licensed pharmacies in Manitoba that use an Alternate Verification Program to repackage drugs and/or compounds in response to a prescription or medication order, or in anticipation of a prescription or medication order.

1.3 Regulatory Authority Reference

Sections 60(1)b, 65, 56(1)(6) and 56(1)(8) of *The Pharmaceutical Regulations* to the *Pharmaceutical Act* empowers the Council to create a practice direction for Alternate Verification Program.

2. Practice Direction:

2.1 Definitions

- 2.1.1 **Alternate verification program (AVP)** - a program to empower and authorize trained pharmacy personnel to perform some of the drug preparation duties and verification of the final drug preparation.
- 2.1.2 **Pharmacy assistant** – a person by the pharmacy who has received additional knowledge and/or training in drug preparation and drug distribution and are covered under Section 64 in the Regulations.
- 2.1.3 **Pharmacy assistant with Checker status** – a pharmacy assistant who:
 - 2.1.3.1 Has had a minimum of six months continuous full time employment in the respective pharmacy,

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- 2.1.3.2 Received further didactic information and supervised practical training, as required by the pharmacy manager, and
- 2.1.3.3 Has, without an error, checked the work of others by performing 200 consecutive drug preparation and packaging checks over a period of time as determined by the pharmacy manager.
- 2.1.3.4 Checker status for a pharmacy assistant can be transferred when the pharmacy assistant is moving to another pharmacy within the same health organization or company.

2.2 Requirements of an Alternate Verification Program

- 2.2.1 The AVP program can only be performed in response to a prescription or medication order, or in anticipation of a prescription or medication order.
- 2.2.2 All AVP programs must follow a prescribed, pharmacy manager approved, process that eliminates all likelihood of error.
- 2.2.3 The pharmacy manager must apply and receive prior approval from the Council, to the College of Pharmacists of Manitoba for a process whereby a pharmacy technician performs the final sign-off of the drug preparation in lieu of a pharmacist.
- 2.2.4 The pharmacy manager must ensure all pharmacy assistants and technicians are properly trained and have the required knowledge to perform the necessary tasks.
- 2.2.5 The pharmacy manager must conduct an accuracy test as described in 2.1.3.3 on a pharmacy assistant with Checker status once every two years.

2.3 Alternate Verification Program Options

- 2.3.1 **Drug repackaging process** - Repackaging drugs from a manufacturer's labelled container to a "unit of use" package or ward stock container, and either of the following:
 - 2.3.1.1 A second pharmacy assistant (with checker status) is required to verify the work has been done accurately. Once the work is completed and before the drugs are used, the second pharmacy assistant (with checker status) must sign-off that the task is done accurately. A pharmacist is required to sign-off within 72 hours on all drug repackaging.
 - 2.3.1.2 A pharmacy technician is required to verify the work has been done accurately. Once the work is completed and before the drugs are used, the pharmacy technician must sign-off that the task is done accurately. A pharmacist is not required to sign-off once the pharmacy manager has applied and received prior approval from the Council for the process.

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- 2.3.2 **Sterile and non-sterile compounding process** - Compounding/mixing of drugs and other ingredients pursuant to a prescription or medication order (or in anticipation of such) and places the end-product in a labelled container, and either of the following:
- 2.3.2.1 A second pharmacy assistant (with checker status) is required to verify the work has been done accurately and labelled appropriately. Once this work is completed and before the products are used, the second pharmacy assistant (with checker status) must sign-off that the task is done accurately. A pharmacist is required to sign-off within 24 hours on all compounding done under this program.
 - 2.3.2.2 A pharmacy technician is required to verify the work has been done accurately and labelled appropriately. Once this work is completed and before the products are used, the pharmacy technician must sign-off that the task is done accurately. A pharmacist is not required to sign-off once the pharmacy manager has applied and received prior approval from the Council for the process.
- 2.3.3 **Unit dose/Unit of use systems process** - Pharmacy assistant works from a list of medications ordered for a specific inpatient of the institution (pick list) and selects the right drug from the inventory of unit of use packaged drugs (either directly from the manufacturer or from the in-house unit of use repackaged medication), and, the selected medication is placed in a patient specific and labelled container (e.g. cassette), in addition to either 2.3.3.1 or 2.3.3.2.
- 2.3.3.1 A second pharmacy assistant (with checker status) is required to verify the work has been done accurately. Once the work is completed and before the drugs are used, the second pharmacy assistant (with checker status) must sign-off that the task is done accurately. A pharmacist is not required to sign-off on the prepared medication.
 - 2.3.3.2 A pharmacy technician is required to verify the work has been done accurately. Once the work is completed and before the drugs are used, the pharmacy technician must sign-off that the task is done accurately. A pharmacist is not required to sign-off on the prepared medication.
 - 2.3.3.3 If a pharmacy technician performs the task in 2.3.3, and does the sign-off that the task is done accurately, this program does not require a pharmacist, technician or a second pharmacy assistant to verify the work has been done accurately, once the program has received prior approval from the Council of the College of Pharmacists of Manitoba.
- 2.3.4 **Automated Dispensing Cabinet System** - Pharmacy assistant or pharmacy technician works from a list of medications for the restocking of a secured drug cabinet and selects the right drug from the inventory of packaged drugs (either

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directly from the manufacturer or from the in-house unit of use repackaged medication). This program must follow a prescribed, pharmacy manager approved, process that eliminates all likelihood of error and does not require a second person to verify the work has been done accurately if likelihood of errors can be eliminated through the use of technology.

3. Documentation

3.1 Documentation is to be recorded in a readily retrievable manner either electronically or in written form.

4. Compliance Adjudication

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

5. Appendices

5.1 Not applicable

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:

Standards of Practice Committee

Regulatory Reference:

Sections 60(1)b, 65, 56(1)(6) and 56(1)(8) of *The Pharmaceutical Regulations to the Pharmaceutical Act*

Consultation Close:

March 13, 2015

Authorized by Council:

April 17, 2015

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April 24, 2015

Revised:

Review Due:

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