A Guide to Pharmacy Practice in Manitoba

December 2013
(Updated January 2015, January 2018 & January 2022)

Forward

All pharmacists in Manitoba have a professional obligation to be aware of all statutory requirements under *The Pharmaceutical Act* (SM 2006, c.37), its accompanying Pharmaceutical Regulation, which includes the standards of practice, and the Code of Ethics, as they may be amended from time to time.

Disclaimer

This guide focuses on key points in the legislation and standards that govern the pharmacy profession in Manitoba. As a professional health practitioner in a self-regulated profession, each pharmacist is responsible for understanding and practising according to all related requirements and laws. It remains the pharmacist's responsibility as a professional to interpret and apply this information within the context of their own practice.

Acknowledgement

The College would like to acknowledge the Alberta College of Pharmacists (ACP) for granting permission to use and adapt the ACP's Orientation to the New Practice Framework home study program in development of this Manitoba specific guide.

Feedback

Comments and suggestions on this resource are welcome and should be sent to info@cphm.ca.

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Welcome

1.1 *Guide to Pharmacy Practice in Manitoba Manual Overview*

The Pharmaceutical Act, Regulation, Standards of Practice and Code of Ethics provide a framework for pharmacy practice. This framework is designed to enable continued high quality patient care by all pharmacists and pharmacy technicians, and to serve as a foundation for expanded scopes of practice. The standards of practice and practice directions shape and guide professional practice within the framework.

A Guide to Pharmacy Practice in Manitoba will help new pharmacists, pharmacy students, pharmacy technicians, as well as already practicing professionals understand and apply the legislative framework to their patient care services. This manual highlights key themes in *The Pharmaceutical Act*, Regulations and standards of practice that frame your practice.

1.2 *Guide objectives*

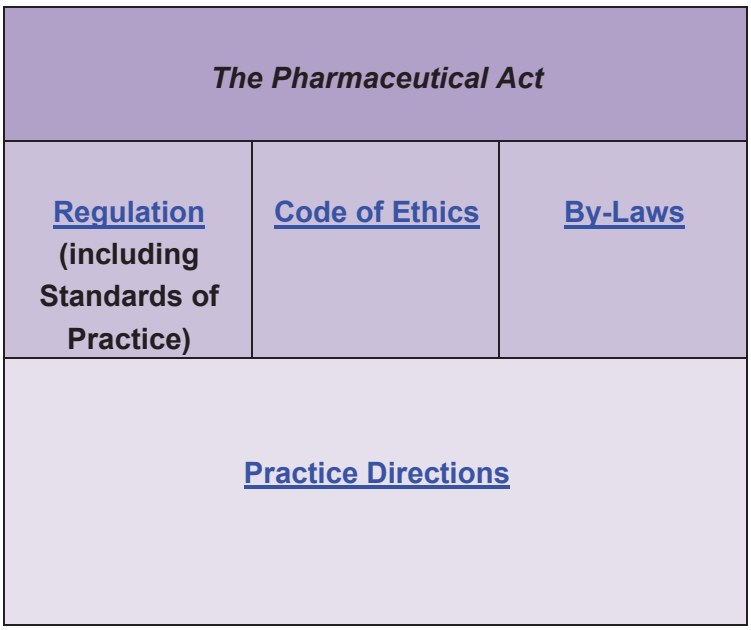
After studying this guide, you will be able to:

1. Describe the role of the College and its committees
2. describe the registration requirements for pharmacists,
3. describe the different components possible for community and hospital pharmacy,
4. identify practice requirements for all pharmacists,
5. differentiate among the types of pharmacist prescribing,
6. identify the limitations of adapting a prescription,
7. identify additional requirements for pharmacists who will administer drugs by injection,
8. identify additional registration requirements for pharmacists to obtain authority to prescribe drugs for Self-limiting Conditions and uncomplicated cystitis,
9. identify additional registration requirements for an Extended Practice pharmacist and explain their expanded authority for prescribing and ordering of lab tests, and
10. understand the additional documentation requirements outlined in the Regulation and Practice Directions and the communication a pharmacist must have with other health professionals.

1.3 *Introduction to your practice framework*

The Pharmaceutical Act (The Act) and the Pharmaceutical Regulation to The Act grant to pharmacists the privilege of self-regulation. This legislation establishes standards for pharmacy practice as well as standards for operating licensed pharmacies. Under this legislation, the College is granted the authority to create by-laws and practice directions for the standards of practice of pharmacy. The Code of Ethics is created by Manitoba pharmacists and was updated and passed in 2012. Together, these documents create a framework for pharmacy practice in Manitoba. It is important to note that provincial legislation can only STRENGTHEN federal legislation, but it cannot weaken it.

The Practice Framework



***The Pharmaceutical Act*:**
The current Manitoba *Pharmaceutical Act* came into effect on January 1, 2014. The Act governs, among other things, the registration, education, licensing, standards of practice, and complaints and discipline process for pharmacists and pharmacies in Manitoba.

The Pharmaceutical Regulation to *The Pharmaceutical Act*:
The Regulation, also enforced on January 1, 2014, outlines the intricacies of the practice of the profession including scope of practice.

By-Laws to *The Pharmaceutical Act*:
The By-laws are developed and upheld by the College's Council, and it regulates the College's internal affairs such as Council elections, annual general meetings, voting processes, etc.

Practice Directions (formerly referred to as Standards of Practice) and Descriptors:
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 and pharmacy operations. Compliance with approved practice directions is required under The Act. Please refer to section 1.4.4 for more information.

Code of Ethics:
The Code of Ethics governs the conduct of members, students, interns and owners. It contains ten general statements describing the key principles to follow in the practice of pharmacy. Please refer to the section, "Maintaining Professionalism", for more information on the Code of Ethics.

1.4 *How to use this manual*

Remember that this manual is a supplement to, not a substitute for, the practice rules. The *Guide to Pharmacy Practice in Manitoba* refers to but does not duplicate the standards, practice directions, Code of Ethics and legislation. **A review of these documents in addition to this manual is strongly recommended.** These documents need to be within reach as they are frequently referenced, and a review of the actual standards and practice directions will help understand each of the concepts discussed.

1.4.1 Reading and interpreting the standards and practice directions

- The standards of practice in the Regulation are one part of the framework that governs pharmacist practice. They must be read or considered in the context of the overall legislative scheme and practice framework which includes the relevant acts, regulations, the Code of Ethics and practice directions.
- The intention of the standards of practice is to set out the minimum acceptable standard of practice for pharmacists. For each standard, a practice direction can be developed to provide detailed rules of application of practice.

Compliance with both the standard and the practice direction is mandatory in daily practice.

- This manual, the standards of practice and practice directions use the legal writing style for lists. Often only the second-last item in a list will end with "or" or "and."
    - When a list of items is shown, if the second-last item ends with "or," it means each item in the list ends with or. In other words, the list is giving several alternatives from which a person may choose one or more.
    - If the second-last item in a list ends with "and," it means each item in the list ends with "and". In other words, the list is giving a group of items, all of which apply.

1.4.2 Icon legend

This manual incorporates a side bar with icons to emphasize special sections. In some cases, the icon will refer to a standard, practice direction, regulation or act for further details on the topic. Other icons may indicate to exercise caution in pharmacy practice, or points which require particular attention.

This icon signals a reference to another document for full details.

REG 30(1)

Below this icon will be a reference. The reference includes the initials of the document title, followed by the relevant section of the document. For example, REG 30(1) refers to the Pharmaceutical Regulation to *The Pharmaceutical Act*, Section 30, and item 1. Documents referenced in this guide include:

- REG = Pharmaceutical Regulation to *The Pharmaceutical Act*
- ACT = *The Pharmaceutical Act (Dec 2006)*
- PD = Practice Direction

This icon signals that the topic deals with matters that require particular attention in your practice.

This icon signals that a practice direction is available for this subject.

1.4.3 Important Notes

Practise within the limits of your own competencies

Authorization should never be interpreted as **obligation**. Just because the legislation or standards authorize an activity does not mean that a pharmacy professional must undertake that activity. If a pharmacy professional does not have the competencies or appropriate information required for the activity, or is not willing to take responsibility/liability for their decisions, they should not undertake the activity.

The Pharmaceutical Regulation and The Act grant authority to pharmacists to undertake the following included practices:

- dispense, compound, sell a drug by retail (a Schedule I, Schedule II or Schedule III drug),
- administer drugs through an "advanced method" upon completion of additional training. Advanced methods include administration through intradermal, subcutaneous, or intramuscular injection, intravenously through an established central or peripheral venous access device and rectally,
- prescribe Schedule II and III drugs and medical devices. Upon completion of additional training, pharmacists can prescribe from a limited list of Schedule I drugs for self-limiting conditions, and for uncomplicated cystitis. Extended Practice pharmacists have independent prescribing authority within their specialty area,
- provide a continued care prescription for a Schedule I drug if it is not reasonably possible for the patient to see a health professional to obtain a prescription and there is an immediate need for drug therapy,
- order from a limited list of tests for monitoring patient's therapy. Extended Practice pharmacists are permitted to order lab tests within their scope of practice and in relation to any medications they prescribed; and
- interpret patient-administered automated tests.

1.4.4 Understanding your practice framework

The remainder of this manual describes the implications and applications of the legislation, standards of practice and practice directions. These are only highlights and pharmacists are expected to read the Regulation including the standards of practice in their entirety.

REG Part 7

The standards of practice included in the Regulation state the minimum requirements for seventeen aspects of pharmacy practice as follows:

1. Patient counselling
2. Referring a patient
3. Collaborative care
4. Prescribing and dispensing drugs
5. Administration of drugs
6. Drug distribution
7. Test interpretation
8. Extemporaneous compounding
9. Incidents and discrepancies
10. Transfer of patient care
11. Termination of relationship with patient
12. Records and information
13. Policies and procedures
14. Pharmacist to staff ratio
15. Pharmacy facilities
16. Technology
17. Drug product acquisition and handling

Practice Direction

For most standards of practice, a practice direction is available and has been drafted by a Standards of Practice committee and approved by members. Members and stakeholders are consulted prior to the approval of practice directions by council, and with every amendment made.

> *Definition: 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 and pharmacy operations. Compliance with approved practice directions is required under The Pharmaceutical Act*.

A practice direction must:

1. have clearly defined and specific objectives that are directly linked to clear and verifiable outcomes,
2. be of the level necessary to achieve stated objectives,

3. serve the public interest consistent with the mandate of the College
4. allow for periodic assessment of its effectiveness and be subject to regular reviews,
5. be published by Council in a standard form.

Practice directions approved by Council can be reviewed on the College website under the "Resource Library" or by linking: https://cphm.ca/resource-library/?_sft_resource_category=practice-directions-and-standards

Other practice directions are in development or may be available for member feedback. Members are encouraged to visit the website regularly and review the bi-weekly Friday Fives sent out to all Registrants for new practice directions.

2 The College of Pharmacists of Manitoba

The pharmacy regulatory and licensing authority in Manitoba was established in 1878 and was known as the Manitoba Pharmaceutical Association (MPhA). On January 1, 2014, the current *Pharmaceutical Act* and regulations came into effect, and MPhA became the College of Pharmacists of Manitoba (College).

The College administers *The Pharmaceutical Act* of Manitoba (December 2006) and is responsible for licensing of pharmacists and pharmacies, establishing practice directions and Code of Ethics, complaint investigations and discipline, monitoring of continuing education of pharmacists and setting qualifications for pharmacy technicians.

The College is a not-for-profit organization with a principal mandate of protection of the health and safety of the public. The purpose statement and guiding principles of the College are as follows:

Purpose Statement

Our purpose is to regulate the pharmacy profession with a commitment to excellence in person-centred, evidence-informed, and timely pharmacy care for all people. We serve the public interest by ensuring all pharmacy professionals are qualified to provide safe, ethical, and culturally sensitive care, free from all forms of racism, including Indigenous-specific racism. Through inclusivity, collaboration, and a dedication to integrity and accountability in our regulatory practices, we create an equitable environment that protects and prioritizes the public's best interests.

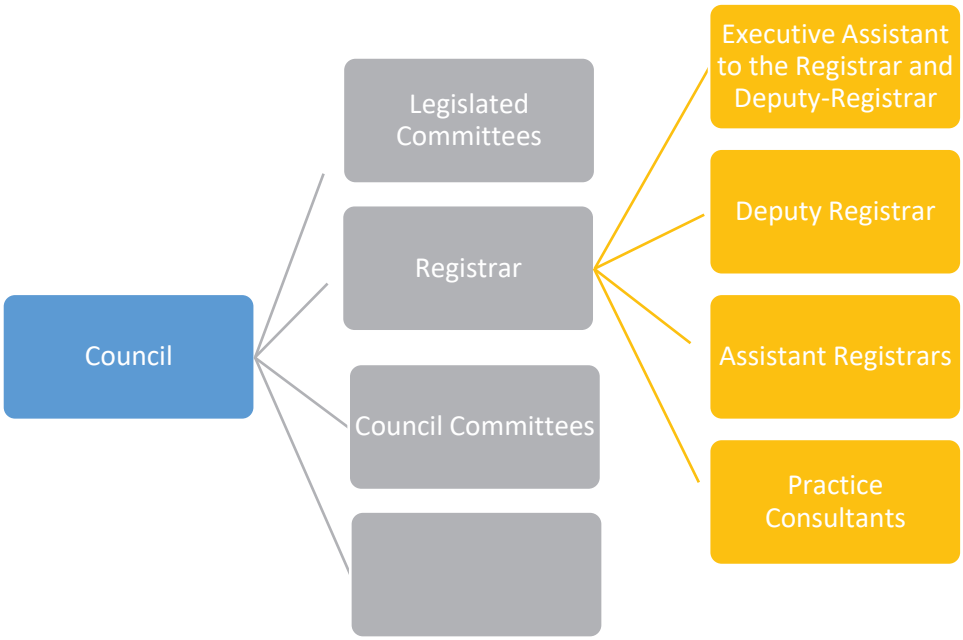
Values

These guiding principles reflect our commitment to public safety, ethical regulation, and accountability. They replace traditional values, ensuring that every action we take is grounded in our purpose:

- Accountability First: We uphold integrity in every decision and action, prioritizing transparency and responsibility to earn and maintain the public's trust.
- Unwavering Commitment to Equity: We are dedicated to creating a culturally sensitive, anti-racist regulatory environment, respecting and promoting fairness for all those who seek care in Manitoba.
- Person-Centered Excellence: We place the health and well-being of the people we serve at the center of our work, fostering compassionate, timely, and evidence-informed care.
- Collaboration and Inclusivity: By engaging with system-partners, interested, affected, or relevant parties, and communities, we advance the pharmacy profession through open dialogue and inclusive decision-making. Collaboration: We strive to include teamwork and partnership.

- Integrity-Driven Decision Making: With a focus on ethical practice and empathy, we consistently act to protect the public's interests and inspire trustworthiness in all regulatory practices.

The College's Council (hereafter referred to as Council) is divided into several committees, each designed to direct the work of the College to ensure the College meets its mandate of public protection. Each of them is described below.



Legislated Committees:

Executive Committee: makes recommendations to Council regarding matters arising in meetings.

Board of Examiners: considers and decides on applications for registration and conditional registration.

Complaints Committee: addresses formal complaints submitted by a patient or their agent, a co-worker, employer, or healthcare professional.

Discipline Committee: hears matters referred by the Complaints Committee pertaining to actions, practice or judgment not reflecting standards required by legislation and the Code of Ethics.

Dispensing Practitioners Committee: considers and decides on applications from practitioners who are not members to be designated as a dispensing practitioner in order to improve patient care and safety in remote communities that do not have reasonable access to pharmacy service.

Extended Practice Advisory Committee: provides oversight and makes recommendations to Council on matters that relate to extended practice pharmacists.

Council Committees:

Governance Committee: provides initial and ongoing review of, and makes recommendations to Council about the governance structure of the College.

Awards and Nominating Committee: recommends to Council the recipients of several awards that promote patient safety.

Finance and Risk Management Committee: oversees financial affairs of the College and is responsible for making recommendations to Council regarding organizational risk.

Audit Committee: reviews and drafts annual financial statements of the College after preparation by the auditor.

Quality Assurance Committee: This committee is subdivided into two subcommittees:

- Professional Development Division: responsible for assessing the competence and performance of pharmacists by establishing areas for continuing competence programs, and promoting and facilitating participation in professional development programs.
- Standards of Practice Division: recommends, reviews, and keeps current the standards of practice, practice directions, and practice guidelines for the purpose of improving pharmacy practice, patient health outcomes and patient safety.

As a registrant of the College (see section 3 of the manual), you will receive regular communication via quarterly newsletters, and a biweekly update called *The Friday Five,* which typically includes important updates relevant to daily practice, and notifications such as changes in the regulations and practice guidelines, as well as updates from government and health stakeholders. All registrants are encouraged to visit the College website regularly to stay informed on the most up to date information.

3 Registration categories for pharmacists and pharmacies

The following is an overview of the different registration categories for pharmacists and pharmacies. Note that under The Act and Regulation, a "member" refers to an individual whose name is on a register with the College, and who holds a pharmacist license of any category. The term "registrant", used throughout this document, refers to all pharmacy professionals (pharmacist, student, pharmacy technician, etc.).

REG Part 3

3.1 *A survey of registration categories*

3.1.1 Pharmacists

Under the *Pharmaceutical Act*, the College maintains six registers – pharmacists, interns, students, extended practice pharmacists, academic and a conditional register. All members within each register must meet the registration requirements set out in the Regulation and are restricted to activities permitted under that specific register.

Regulated Registrants
Pharmacists
Interns
Students
Extended Practice
Academic
Conditional
Non-Regulated Members
Non-Practising
Honorary
Honorary Life

Pharmacists

All applicants have to indicate their intended scope of pharmacy practice on their application. A registrant, as set out in Section 18 of the Regulations, has a responsibility to engage and perform only in those

aspects of the practice of pharmacy for which they have the requisite knowledge, skill and judgment.

Under the Regulation, applicants for registration as a pharmacist must provide a criminal record check (including a Vulnerable Sector Search), a child abuse registry check and an adult abuse registry check.

REG Part 5

Available to the public on its website, the College has a profile of each pharmacist listed on the register or conditional register, enabling the public to access information about their pharmacist. The profile contains the member's name, date of initial registration in Manitoba, category of pharmacist licence and any current certification of the member as an extended practice pharmacist. Information pertaining to any disciplinary action taken against a member within the last 10 years and any practice restrictions are also included in the member's profile. The Pharmacist Profile Directory is accessible on the College's website from the home page.

REG 123

Under the legislation, members must be covered by professional liability insurance that provides a minimum of $2,000,000 per claim or per occurrence and a minimum $4,000,000 annual aggregate. This insurance can be through an employer or through a personal insurance plan. It is important to know the limitations of an employer insurance plan.

Extended Practice Pharmacist

A pharmacist certified as a specialist (in an approved area of practice) working in a collaborative practice with a physician or a registered nurse (extended practice/Nurse Practitioner) and who meets the education, training and practice hour requirements specified in the Regulation may apply for registration as an extended practice pharmacist. Once approved, an extended practice pharmacist may prescribe a drug listed in Schedule I of the Manual (a prescription medication, also known as a NAPRA Schedule I drug) and order lab tests within the scope of their specialty in accordance with the applicable practice directions. More information on Extended Practice Pharmacist Professional Registration can be found on the College here.

Interns

Interns are registrants who are either in the fourth year of their pharmacy degree program or have completed a degree in pharmacy but have not yet met all the requirements for licensure in Manitoba. Internationally trained pharmacists, unlicensed out-of-province interns, and pharmacists pursuing reinstatement will be registered in this category while completing their registration requirements. An intern is

required to complete 600 hours of supervised practical training. However, 4th year pharmacy student in the College of Pharmacy, University of Manitoba can attain some of these hours prior to graduation as an undergraduate intern through the Advanced Practice Pharmacy Experience (APPE) rotations. The intern must secure a pharmacy and a preceptor pharmacist approved by Council to complete their internship.

A pharmacy intern under a member's supervision may engage in any aspect of the practice of pharmacy while completing internship hours **excluding** practices requiring additional training and being certified by the College. This includes activities such as administering injections and prescribing drugs from Schedule 3 (self-limiting conditions) of the Regulations, **unless** the intern has received the training in the undergraduate program at the College of Pharmacy, University of Manitoba, and the supervising pharmacist also has the authorization from the College. However, an undergraduate intern who works part time or over the summer at a pharmacy **cannot** administer injections or preform any activities that require additional training outside of their university APPE rotation.

Part of the intern training may include performing the final check of a prescription, if permitted by the preceptor. The preceptor or another licensed pharmacist does not have to perform the final check if that has been done by the intern (as allowed by the regulations section 70 (1j) and 70 (1k)). However, the preceptor would make this decision and bear the responsibility.

A graduating pharmacist who has completed the injection training in university must also apply to the College to receive authorization to administer injections once they become licensed. Newly licensed pharmacists can only administer injections once they have received authorization from the College.

Students

Registrants in their first, second, or third year of a pharmacy educational program approved by Council are under the "Student" registry. All activities undertaken by a student must be under the **direct** supervision of a member. The permitted activities of a student are described in the supervision section of this guide as well as the practice direction for Supervision.

Again, students who work part time or over the summer at a pharmacy **cannot** administer injections or preform any activities that require additional training outside of their university rotations.

Academic Registrants

The academic registry allows a person who is entitled to practise pharmacy in other jurisdictions to receive additional education and training in Manitoba. A person on the academic register may be referred to as a "pharmacy resident". An example of this would be a licensed pharmacist from another province who attends a Manitoba hospital for additional knowledge and training for a short period of time.

Non-practicing, honorary and honorary life members

The College By-laws have provisions for the membership categories of non-practicing, honorary member and honorary life member.

A *non-practicing pharmacist* is a member who has voluntarily retired or resigned from practice as a pharmacist or a member registered with the College but residing outside the province of Manitoba. These members, upon payment of a fee, are entitled to receive the Newsletter and Friday Five. They will also receive notice and may attend meetings of the College but are not entitled to vote at any meetings or nominate any candidate for election.

Council may confer on a non-pharmacist an *honorary membership* for valuable and notable service rendered to the profession of pharmacy. However, this individual is not considered a member (licensed pharmacist) of the College.

An *honorary life membership* in the College is conferred on a member of the profession, in recognition of meritorious service rendered on behalf of the profession of pharmacy.

3.1.2 Pharmacy technicians and pharmacy assistants (other persons)

REG 60 & 64

Prior to 2014, many of the support staff in the pharmacy dispensary were referred to as pharmacy technicians. This title is now restricted to those individuals who have qualified to become a pharmacy technician. The term, pharmacy assistant, can be used by those persons who are not qualified as technicians but are working in the dispensary.

A pharmacy technician is a person who has completed a pharmacy technician training program approved by Council. A pharmacy technician must also pass any examinations approved by Council and submit an application to the registrar.

National initiatives, including the development of a national pharmacy technician qualifying exam and an accreditation of pharmacy technician training programs, have been developed. The College must maintain a list of pharmacy technicians who have met the education and training requirements however, the list is not an indication of continued qualification. Pharmacy technicians are not members of the College.

A pharmacy technician can assist pharmacists and carry out some activities under indirect supervision. Details of these activities are included in the Supervision section later in this manual. The role and responsibilities of pharmacy technicians and pharmacy assistants are clearly described in the Regulation and are summarized in the table below.

Scope of Practice	Pharmacy Assistant/ Other Employee	Pharmacy Technician
Prepare and pre-package drugs for dispensing	✓	✓
Select an appropriate container	✓	✓
Replenish drug storage containers and dispensing machines	✓	✓
Attach the prescription label to a container	✓	✓
Record and retrieve data about a patient or prescription	✓	✓
Compound, if a pharmacist has approved the formulation and process	✓	✓
Enter prescription information into a database	✓	✓
Collect information from a patient for a patient profile	✓	✓
Manage drug inventory	✓	✓
Identify drug-related problems that require a referral to a pharmacist		✓
Review the information in a prescription for compliance with federal and provincial law		✓
Preform a final check when a medication was prepared for dispensing by another technician, student, intern or pharmacy assistant, but only if the pharmacy manager has received approval from College Council for the drug packaging and preparation process		✓
Dispense a drug if the supervising pharmacist has approved filling the prescription and the supervising pharmacist counsels the patient		✓

Scope of Practice	Pharmacy Assistant/ Other Employee	Pharmacy Technician
Instruct a patient on how to operate a medical device, but not provide an explanation involving the interpretation of the results of the device		✓
Ask for, and receive, a refill authorization from a practitioner on an existing prescription without any changes to the prescription as originally prescribed		✓
Preform necessary tasks at an external dispensing site		✓

A pharmacy technician can perform the final check on a medication to be dispensed to a patient only once the pharmacy manager has received approval from the College. The Pharmacy Technician Final Check application was developed by the College for use in both community and hospital pharmacy practice. It requires pharmacy managers to assess their current workflow and dispensing process in order to determine the changes deemed necessary for the procedure to be in place. Once the pharmacy has been approved, the pharmacy technician(s) can then perform the final check on medications. The pharmacist remains responsible for reviewing all prescriptions, new and refilled, to determine whether the prescription is therapeutically appropriate and safe for the patient, and conduct medication counselling. The following documents have been developed by the College to provide assistance in completing the application:

Pharmacy Technician Final Check Information Page
Pharmacy Technician Scope of Practice Chart

Please refer to the College website for information on how to become a pharmacy technician.

3.2 *Pharmacies*

REG Part 6

The Pharmaceutical Regulation permits the registrar to issue licences for the following categories of pharmacies:

- a community pharmacy,
- a hospital pharmacy, or
- a clinical practice pharmacy.

A licence is issued to the pharmacist listed as the pharmacy manager responsible for the pharmacy operation (only a pharmacist may act as a pharmacy manager). The pharmacy manager and pharmacy owner are jointly responsible to ensure the pharmacy operates in accordance with the Regulations, including the standards of practice and practice directions.

REG 124

Under the legislation, every owner must be covered by commercial general liability insurance with a minimum limit of $5,000,000.

Community pharmacy

A community pharmacy licence authorizes the operation of a pharmacy that offers retail sale of drugs to the public and will serve patients who will attend the pharmacy in person to receive their drugs. The pharmacy must be accessible to the public and the hours of operation must meet the needs of the community served by the pharmacy. A community pharmacy may deliver drugs to a patient in Manitoba or in another province if the patient normally attends the pharmacy without the pharmacy requiring a distant care component.

Hospital pharmacy

A hospital pharmacy licence will be issued to a pharmacy that is located within a hospital and will serve in-patients and out-patients of the hospital**.**

Clinical practice pharmacy

A clinical practice pharmacy licence will be issued if the pharmacy or pharmacist will not dispense, prepare for dispensing or sell drugs or products listed in the NAPRA Manual or for which a drug identification or natural health product number has been issued. The pharmacist will either provide care to patients and advise health care professionals about enhancing patient care or use the pharmacy for the sole purpose of training and educating pharmacy personnel. The facility must comply with the Clinical Practice Pharmacies Practice Direction.

Components of Community or Hospital Pharmacy

A community or hospital pharmacy must indicate on their application if one or more of the following additional components is also being applied for:

a) **central-fill component**- the pharmacy will store and prepare, package and label drugs pursuant to a prescription for dispensing for other pharmacies. The Central Fill Practice Direction outlines the requirements for the pharmacy providing centralized prescription processing services as well as the pharmacy obtaining the prescription processing services.

b) **secondary hospital component** – the hospital or community pharmacy will provide pharmacy services for patients in another hospital, which is usually a smaller acute care hospital without a licenced pharmacy in a rural setting. The level of pharmacy

practice must meet the needs of the hospital and typically involves drug distribution, limited hours and patient care services. The Secondary Hospital Services Component Practice Direction outlines the requirements for this component.

c) **personal care home component** – the pharmacy will serve residents of a personal care home as defined in *The Health Services Insurance Act*. This component ensures that residents living at a personal care home have access to their medications in a coordinated manner.

d) **distance care component** – the pharmacy will also serve patients who do not reside in Manitoba and who will not attend the pharmacy in person. This component is for International Prescription Service (IPS) pharmacies and out of province mail order pharmacies.

e) **external dispensing component** – the main pharmacy may operate an external dispensing site located in a Manitoba community that does not have reasonable access to pharmacy services. An external dispensing site is a place where medications are stored, prepared, packaged and then dispensed directly to patients. It is either staffed by a pharmacy technician or may be a mechanical automated dispensing system. These locations can only be open when the main pharmacy is also open. The main pharmacy must be linked to the external site by computer and by live two-way video and audio communication so patients can communicate with a pharmacist at the main pharmacy and supervision can be provided to any technician at the external site.

f) **satellite pharmacy component** – the main pharmacy establishes a satellite facility located in a Manitoba community that does not have reasonable access to pharmacy services. The satellite pharmacy must have a pharmacist on site during all hours of operation and the pharmacist **must** work with a physician or a registered nurse (extended practice). No drugs may be left on site when the satellite pharmacy is not open.

g) **lock and leave component** - a community pharmacy may also apply for a lock and leave component whereby the pharmacy is located within a larger operation and the pharmacy manager must close off the dispensary and public access to Schedule III drugs while the larger operation remains open. The Lock and

Leave Component Practice Direction states specific requirements and conditions for this type of pharmacy component.

All components of community and hospital pharmacy must comply with all regulations and applicable practice directions.

REG Part 17

Advertising

Advertising in Manitoba pharmacies must maintain the honor and integrity of the image of a pharmacist and the pharmacy profession and must always support safe and appropriate use of medications. The use of descriptive or qualifying terms such "licensed" or "prompt", or any vague terms referencing prices such as "cheap" or "lowest", detract from the public esteem of the profession, and may influence the public into situations of medication overuse or purchasing of large quantities. The Advertising in Manitoba Pharmacies Practice Direction applies to printed material, radio or television advertisements, and any other promotional material made available to the public, including by electronic means. Pharmacists are encouraged to promote their services and businesses in a manner that promotes and advances the values and visions of the profession.

4 Maintaining professionalism

Professionalism is defined as "a set of attitudes, skills and behaviors, attributes and values which are expected from those to whom society has extended the privilege of being considered a professional".

Code of Ethics

The Code of Ethics governs the conduct of members, students, interns and owners. It contains ten general statements describing the key principles to follow in the practice of pharmacy. Descriptors are available for each statement to provide pharmacists with examples of how the statements might apply in pharmacy practice.

The Explanatory Document: Applying the Code of Ethics in Pharmacy Practice can be viewed on the College's Resource Library, or by linking: https://cphm.ca/resource/Code-of-Ethics-Explanatory-document/

Statement I	Pharmacists shall maintain a high standard of professional competence throughout their practice.
Statement II	Pharmacists shall cooperate with colleagues and other health care professionals to ensure optimal patient-centered care.
Statement III	Pharmacists shall contribute to societal health needs and promote justice in the distribution of health resources.
Statement IV	Pharmacists shall respect and protect the patient's right of confidentiality.
Statement V	Pharmacists shall respect the autonomy, values and dignity of each patient.
Statement VI	Pharmacists shall respect and maintain a professional relationship with each patient.
Statement VII	Pharmacists shall hold the health and safety of each patient to be of primary consideration.
Statement VIII	Pharmacists shall act with honesty and integrity.
Statement IX	Pharmacists shall respect the rights of patients to receive healthcare.
Statement X	Pharmacists shall respect and honour the profession of pharmacy.

The Code of Ethics requires a pharmacist to act professionally. A member must not practise under conditions that compromises their professionalism or requires another pharmacist to practise under such conditions.

The statements of the Code of Ethics are anchored in the basic principles of biomedical ethics. These core ethical principles dictate a healthcare professionals' ethical duty to patients, society and profession and they are as follows:

1. Beneficence – the need to do what benefits the patient
2. Non-maleficence – the need to avoid harm
3. Autonomy – the respect for the person and their personal liberty to determine their own actions
4. Justice – the need to treat people fairly

Both the Code of Ethics and standards of practice discuss the importance of working collaboratively with other health care professionals and other persons who provide care to the patient to ensure optimal patient-centered care. Pharmacists must recognize the skills, knowledge, competencies, and roles of the other providers and communicate effectively and appropriately with them.

5 Examining pharmacist-patient relationships

5.1 *Establishing a professional relationship*

The Code of Ethics states that pharmacists must maintain a professional relationship with each patient and their primary consideration is the health and safety of each patient.

The pharmacist must identify the patient's health needs and expectations, collect the information required to provide pharmacist services to the patient and make decisions in the best interest of the patient. The patient's autonomy to make their own informed health care decisions must be respected.

It is the responsibility of a registrant to set, maintain, and communicate the boundaries of a therapeutic relationship. The pharmacist is the healthcare professional, having a duty to protect the well-being of the patient. Forming a relationship with a patient outside a professional setting potentially exposes the registrant to serious regulatory consequences. The College's Practice Guideline for Professional Boundaries in Therapeutic Relationships provides more insight to registrants and the public of the expectations on a registrant to maintain those boundaries.

Strong and effective communication skills result in meaningful patient-pharmacy partnerships and effective pharmacy processes that ensure patient safety and positive patient outcomes. The College has developed a Communication and Conflict Resolution Toolkit as a resource for all registrants.

The Transfer of Patient Care Practice Direction and the Termination of a Patient Relationship Practice Direction outline the requirements if either the patient or pharmacist terminates the professional relationship.

5.2 *Establishing and maintaining confidentiality*

In addition to the requirements in the Code of Ethics, standards of practice and practice directions, pharmacists are reminded that they must meet the requirements of other applicable privacy legislation such as the *Personal Health Information Act* (PHIA).

Confidentiality is critical in a professional relationship with the patient.

All communication about a patient's health, including drug therapy, must be conducted in a manner that maintains confidentiality.

To ensure that confidentiality is maintained, a pharmacist must move to a private counselling area before having a conversation with a patient which involves personal health information. The area for confidential communication must have sound barriers that prevent conversations from being overheard and visual barriers that prevent others from seeing what drug, health product or medical device is being provided or discussed. Pharmacy staff must also prevent others from seeing patient health information.

The responsibility to ensure confidentiality includes everything from conversations with the patient to conversations with other health professionals and documentation and disposal of records.

5.3 *Ensuring patient safety*

The Code of Ethics - Statement VII states that pharmacists shall hold the health and safety of each patient to be of primary consideration. In the Regulation, Section 83 – Ensuring Patient Safety states that a pharmacist must review each prescription and the patient's record and take appropriate action when an actual or potential drug related problem is identified.

The Ensuring Patient Safety Practice Direction outlines the pharmacist's responsibilities. A pharmacist should find out what condition or symptom is being treated, any previous history of complaint and length of patient's present symptoms. A medication history including diseases, allergies, current medication therapy as well as medications previously tried should also be conducted. A pharmacist must determine if there is an actual or potential drug related problem, specific to the patient and the drug therapy such as the patient receiving the wrong product or an inadequate or excessive dose or if patient is non-adherent. In collaboration with the patient and the prescriber, the pharmacist must take the appropriate action to address the actual or potential drug related issue.

Pharmacists must evaluate the health needs of the patient and the appropriateness of the therapy prescribed. Through effective and ongoing patient counselling, a pharmacist can provide the patient with sufficient information to enable the patient to manage their drug therapy safely and effectively. Pharmacists can also determine the possible effectiveness of the drug therapy and assess if the patient is experiencing any adverse reactions or possible drug interactions.

6 Dispensing

6.1 *Responsibility for Dispensing*

The Pharmaceutical Act includes in the practice of pharmacy, the compounding and dispensing of drugs.

The Act states:

***"dispense"** means to provide a drug pursuant to a prescription, but does not include the administration of a drug.*

The Regulation states:

***"preparing a drug for dispensing"** means to count, measure or pour the amount of a drug designated in a prescription into a container and label the container for the purposes of dispensing, and includes pre-packaging a drug before a prescription is received.*

It is important to keep in mind the following requirements and limitations regarding dispensing:

1. The **assessment and approval** of prescriptions for filling or refilling must only be done by a pharmacist, an academic registrant, or an intern.

2. Once the prescription is assessed and approved, or in anticipation of the approval, the drug preparation, packaging, and labelling (preparing a drug for dispensing) can be done by a pharmacist, intern, pharmacy student, technician or another person (pharmacy assistant).

3. The final check of the process in # 2 above must only be done by a pharmacist, an intern, or by a pharmacy technician at a pharmacy that has applied and received approval by the College.

4. Patient counselling must only be done by a pharmacist, an academic registrant or an intern. Patient counselling, as described in the standards of practice, includes the provision of sufficient information to enable the patient to safely and effectively use the drug through direct conversation with the patient or their agent. Failing direct communication, this standard could be satisfied by providing written information. However, the provision of written information does not take the place of direct verbal

communication with the patient but can be used when direct verbal communication is not possible.

5. After approval and patient counselling, the drug may be given or delivered to the patient or their agent by a pharmacist, intern, pharmacy student, technician, another person (pharmacy assistant) or delivery person.

6.2 Quality assurance

The Medication Incident and Near-Miss Event Practice Direction states the pharmacist's responsibility to expeditiously address, document and report incidents, discrepancies and adverse events in dispensing medications and in providing patient care.

Definitions:
*A **medication incident** is described as 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, systems, and include prescribing, order communication, product labeling/packaging/nomenclature, compounding, dispensing, distribution, administration, education, monitoring and use.*

*A **Near-Miss Event** is 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.*

The Apology Act:
This provincial act allows members of the health care team, including pharmacists, to apologize to patients who have been subjected to medical errors that may or may not have resulted in harm. *The Apology Act* gives pharmacists the ability to express empathy and display compassion to their patients in times of distress. Any apology made by or on behalf of the pharmacist is not admissible in court and is not an admission of fault. This Act therefore reconciles the tension between being open and sincere with patients, even if circumstances resulting in the incident are still uncertain, and safety for health care providers from legal liability. An information sheet on *The Apology Act* was created by the Manitoba Institute for Patient Safety and can be found here.

Safety IQ Program

In June 2021, the College launched a Safety Improvement in Quality (Safety IQ) program, a standardized continuous quality improvement (CQI) program aimed to enhance patient safety in community pharmacies. Its elements include reporting, analyzing, documenting, and shared learning from medication incidents and near-miss events. CQI in community pharmacy focuses on preventing medication errors and is continually looking for ways to improve medication dispensing, therapy management, and counselling. More information can be found on the College website at: https://cphm.ca/practice-education/quality-assurance/safety-iq/

The College is committed to fulfilling its mandate to protect the health and well-being of the public by supporting community pharmacies in building a culture of safety surrounding medication errors, rather than a culture of blame. Safety culture encourages all employees to engage with safety initiatives to safeguard patients, report errors without fear of punishment, and expect fair treatment for everyone. It optimizes workflows and management practices to learn from medication incidents and near misses.

The pharmacy owner, pharmacists, as well as pharmacy technicians and assistants all have a responsibility to do what they can to prevent medication incidents. The current practice direction requires that all drug incidents be recorded and the pharmacy manager review and implement measures required to prevent re-occurrence. Near misses that are recurrent or could potentially cause harm if not corrected must also be reported to identify trends and preventive recommendations. Recording, reporting, and analyzing all medication discrepancies is a crucial part of prevention. Near-misses should be used as opportunities to examine the pharmacy's workflow and recognize areas on which pharmacy teams need to improve in order to enhance patient safety.

The Institute for Safe Medication Practices (ISMP) Canada is a national non-profit organization committed to the advancement of medication safety in all health care settings. The College has been working collaboratively with ISMP Canada in advocating for medication safety through analysis and prevention of medication incidents, in order to improve overall patient safety in our health care system. ISMP regularly publishes Safety Bulletins that suggest medication system improvement strategies for enhancing patient safety by confidentially sharing the information received about medication incidents which have occurred. The bulletins also share alerts and warnings specific to the Canadian marketplace. Pharmacists are encouraged check ISMP Canada's website

regularly at www.ismp-canada.org for practice tips and monthly newsletters, and to get involved in the movement to advocate for patient safety.

7 Patient education and counselling

When dispensing a medication to a patient, pharmacists are expected to provide the patient with the necessary information to allow him or her to receive the optimal benefit from the drug therapy. Patient counselling must only be done by a licenced pharmacist, an academic registrant, or an intern. Pharmacy students, under the direct supervision of a licenced pharmacist, can counsel patients.

Each time a drug is dispensed pursuant to a prescription, a pharmacist must provide the patient with sufficient information to enable the patient to manage their drug therapy safely and effectively. The Patient Counselling Practice Direction outlines the specific requirements for patient counselling as well as documentation.

7.1 *Dialogue with a patient*

When a drug is dispensed or sold to a patient for the first time, the pharmacist must discuss the following:

1. Confirm the patient's identity,
2. Identify the name and strength of the drug being dispensed,
3. Identify the purpose of the drug,
4. Provide directions for use including frequency, duration and route of therapy,
5. Identify the importance of compliance and the procedure if a dose is missed,
6. Discuss common adverse effects, drug and food interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur,
7. Discuss activities to avoid,
8. Discuss storage requirements,
9. Provide prescription refill information,
10. Provide information on how to monitor response to therapy,
11. Provide information regarding expected therapeutic outcomes,
12. Provide information regarding when to seek medical attention, and
13. Provide other information unique to the specific drug or patient.

If the patient or their representative has language or communication difficulties, the pharmacist must use reasonable means to provide the required information to the patient.

If a drug therapy problem is identified during counselling, then appropriate action must be taken to resolve the problem.

For repeat and refill prescriptions, the pharmacist may exercise professional judgment as to the content of dialogue. **For clarity, patient counselling is not an option on refill prescriptions, only the content may differ from the first time dispensing.** Pharmacists are encouraged to ask specific questions regarding changes to dosage regimens, compliance, efficacy, and the presence of adverse effects.

If the patient refuses to participate in patient counselling, the pharmacist shall document the refusal in a permanent record. Documentation of patient counselling is discussed in Section 7.4.

7.2 *Written material*

The pharmacist is encouraged to provide appropriate written supplemental information with each new prescription. However, it cannot replace the need and requirement for individual patient counselling on all prescriptions. Pharmacists must be familiar with the content of the information provided and review the material in context of that particular patient. When reviewing the drug information leaflet with the patient, the pharmacist should discuss the information pertinent to the patient or any information that may be missing and details, such as side effects which may cause patient concern.

7.3 *Deliveries and Patient's Agents*

When a patient has requested delivery of their medication, the pharmacist shall make all reasonable attempts to contact the patient directly to provide counselling. Failing this, the pharmacist must provide written drug information and a pharmacy contact number for any patient enquiries. Follow-up telephone contact is even more important when attempts to counsel the patient prior to the delivery have failed.

If a patient sends someone to pick up their prescription, they are not necessarily giving consent to have their personal health information disclosed to that individual. It is essential that pharmacists use their professional judgment in these situations to ensure that patients are appropriately counselled on their medications while not compromising the security of their personal health information. In some cases, it may be reasonable to provide counselling through the agent while in other instances it may be more appropriate for the pharmacist to contact the patient by phone to provide counselling on their medication. Providing relevant written drug information may be helpful in these cases, but it does not take the place of patient counselling. Documenting the manner in which patient counselling was provided to the patient is recommended.

7.4 *Documentation*

Section 73 of the Regulation states upon dispensing a medication and counselling the patient, a counselling record must be made. Section 3.0 of the Patient Counselling Practice Direction further outlines documentation requirements for patient counselling. A simple example of a counselling record or log should allow for identifying a particular prescription dispensed, whether counselling was provided or if it was refused by the patient and identify the pharmacist that interacted with the patient. The counselling record should allow for space in which to document any additional discussions that took place with the patient outside of regular counselling (e.g., change in dose, change in appearance, etc.). All patient interactions and counselling documented on the counselling record must be retained for 5 years. Pharmacy managers need to review the Records and Information Practice Direction, and ensure a system is in place to provide patient counselling and retain the required records.

7.5 *Responsibilities with Schedule II and III drugs*

Manitoba has adopted the National Association of Pharmacy Regulatory Authorities (NAPRA) Supplemental Standards of Practice for Schedule II and III Drugs. This document outlines the minimum standards for pharmacists when consulting on the use of medications in each drug schedule. It is important to review the Sale of Schedule II Drugs Practice Direction and the Sale of Schedule III Drugs Practice Direction.

Schedule II drugs may be sold without a prescription and are available only from a licensed pharmacist in an area of the dispensary with no public access and no opportunity for patient selection. A licensed pharmacist **must** enter into dialogue with the patient or designate seeking to purchase or treat a condition using a Schedule II drug.

Exempted Codeine Preparations (containing 8mg of codeine) are Schedule II drugs that can only be issued by a pharmacist pursuant to a prescription. Prescriptions can be written by a physician, dentist, nurse practitioner (with CDSA prescribing authority), or a pharmacist. All such preparations dispensed **must** be entered into the patient's DPIN profile, and the pharmacist is responsible for ensuring that the patient has not received or is currently using additional similar prescription/non-prescription medications that would put the patient at risk of additive toxicity. If the pharmacist is issuing the prescription, they must comply with the standards specified in the Exempted Codeine Preparations Practice Direction, Prescribing Practice Direction, and Prescribing and Dispensing Practice Direction, along with their descriptor documents. For

more information on prescribing and its fundamentals, please see section 9 of this manual.

Schedule III drugs may be sold in a self-selection area of the pharmacy immediately adjacent to the dispensary and under the direct supervision of a licensed pharmacist who is available to assist the patient or designate in medication selection. A licensed pharmacist must be available and accessible to a person who needs to self-select a Schedule III drug.

A pharmacist must be available and take reasonable steps to provide information and assistance to patients who are purchasing Schedule II and III drugs. When the patient requests a Schedule II or III product, the pharmacist shall collect information to assess the patient's knowledge and needs before providing advice. When the patient asks for a product by name the pharmacist shall use this opportunity to assess the patient's knowledge about the product and provide additional information if required.

8 Compounding

In accordance with the Pharmacy Facilities Practice Direction, pharmacies must have space and equipment necessary to provide compounding as part of the practice of pharmacy.

Compounding personnel must maintain their competencies to provide compounded drug products and services suitable to their level of competency, facilities, equipment, and training. A pharmacy must make appropriate accommodations to obtain a compounded product or refer the patient to another pharmacy with appropriate facilities or competencies when the treatment required by the patient is beyond the scope of the member's professional practice or competence.

The College Council has approved the adoption of the following National Association of Provincial Regulatory Authorities (NAPRA) Compounding Standards in Manitoba:

- NAPRA Model Standards for Pharmacy Compounding of Non-Sterile Preparations, along with the associated Guidance Document for Pharmacy Compounding of Non-sterile Preparations
- NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations, and
- NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations.

It is the expectation that any community or hospital pharmacy in Manitoba has the ability to dispense a simple compounded product, when appropriate, to a patient. A simple compounded product is defined as a Level A compound within the NAPRA Model Standards for Pharmacy Compounding of Non-Sterile Preparations. Review the Guidelines for Pharmacists Regarding the Provision of Non-Sterile Compounding Services for more information.

Compounding may be performed by a pharmacy assistant, pharmacy technician, pharmacy student or intern under a pharmacist's supervision if a pharmacist has approved the formulation and process.

Please see the College's page on Pharmacy Compounding Standards for more information, resources, and FAQs.

9 Prescribing

9.1 *An introduction to pharmacist prescribing*

REG Part 15

The Pharmaceutical Regulation authorizes the following distinct types of prescribing:

- adapting a prescription - Section 69(4),
- renewing continued care prescriptions - Section 122,
- prescribing in a public health emergency - Section 118(4),
- pharmacist prescribing of the following:
  - a drug listed on Schedule II or III or an unscheduled drug with a drug identification number or natural health product number,
  - a medical device approved by Health Canada – Section 118(1),
- prescribing for a condition listed in Schedule 3 of the Regulation (see Appendix E), often referred to as a self-limiting condition prescribing. Schedule 3 to the Regulation lists the conditions and the category of drugs limited to self-limiting condition prescribing**–** Section 118(2).
- prescribing for uncomplicated, recurrent cystitis in non-pregnant women, using a drug indicated for such in a product monograph authorized by Health Canada – Section 118 (5)
- Extended practice pharmacist prescribing – prescribing of a drug listed in Schedule I of the Manual (NAPRA) **by an extended practice pharmacist within the scope of their specialty –** Section 118(3).

Adapting a prescription, prescribing a continued care medication, prescribing in a public health emergency and prescribing of a Schedule II or Schedule III drug or a medical device, may be performed by any licensed pharmacist on the College register in accordance with practice directions approved by council.

A pharmacist may prescribe a drug listed in Schedule 3 of the regulations for a self-limiting condition (not including smoking cessation) once they receive a Certificate of Authorization to Prescribe a Drug for Self-Limiting Conditions (not including smoking cessation) from the College. In order to prescribe a drug for smoking cessation, a pharmacist must receive a Certificate of Authorization to Prescribe a Drug for Smoking Cessation from the College. Likewise, to prescribe for uncomplicated cystitis, a pharmacist must complete the required training, and apply for and receive approval from the College.

For more information on how to receive authorization from the College, please see section 9.7 Prescribing of Drugs for Self-Limiting Conditions and prescribing for uncomplicated cystitis.

Only a member who is an extended practice pharmacist may prescribe a drug listed in Schedule I of the Manual (NAPRA) within the scope of their specialty.

Types of prescribing

A Licensed Pharmacist

Adapting a prescription	**Continued Care Prescriptions**	**Prescribing in a public health emergency**	**Prescribing of a Schedule II or III drug or a medical device**
Altering dosage strength, interval or formulation	Renewing a prescription for continuity of care	Only when the minister has given notice to council of a public health emergency	Upon assessing the patient and determining the drug needed and prescribing to enhance compliance and/or allow coverage by a third-party payer.

Pharmacist with Additional Training

Prescribing of a drug for a self-limiting condition (Schedule 3 to the Regulation)
A licensed pharmacist who has received a Certificate of Authorization to Prescribe a Drug for Self-Limiting Conditions (not including smoking cessation) and/or a Certificate of Authorization from the College to Prescribe a Drug for Smoking Cessation.
Prescribing of a drug for uncomplicated cystitis (section 118(5) of the Regulation)
A licensed pharmacist who has received a Certificate of Authorization to Prescribe a Drug for uncomplicated cystitis.

Extended Practice Pharmacist

Prescribing of a drug listed in Schedule I of NAPRA manual
Pharmacist certified as a specialist and registered as an extended practice pharmacist can prescribe medications within the scope of their specialty practice

Although a pharmacist may be authorized to prescribe in emergencies and adapt a prescription, the pharmacist is **never** obligated to prescribe. As with all activities, a pharmacist is expected to practise within their area of competence, to evaluate each situation and to make a conscious

decision whether or not to prescribe. Evaluation of the situation will require many of the same considerations made when dispensing drugs pursuant to prescriptions, but there are some additional requirements that will be described below.

Determining if you are or are not prescribing

When a drug-related problem is identified while filling a prescription a pharmacist may choose to do what has always been done: contact the prescriber to discuss their concerns about the prescription. If, as a result of that conversation, the original prescriber directs the pharmacist to make a change to the prescription, the prescription may be changed under the authorization of the prescriber and the pharmacist signs or initials it as before. In this case the pharmacist is not the prescriber. However, the pharmacist may adapt the prescription if consultation with the prescriber is not possible or not necessary. The pharmacist will in fact become the prescriber and will be expected to follow the standards for adapting a prescription. Under the limitations of the Regulation, a pharmacist can only adapt the dosage strength, the dosage interval or regimen and/or the formulation of the drug.

ACT S.79

Generic substitution following the Manitoba Drug Benefits and Interchangeability Formulary is not considered prescribing. Subsection 79(1), of *The Pharmaceutical Act,* indicates that when a pharmacist is presented with a prescription for a drug listed on the Formulary, they will dispense either the brand name product or an interchangeable product listed and charge the patient the cost of the lowest priced interchangeable product. Under The Act, the prescriber can instruct the pharmacist either **in writing** on the prescription **or verbally** to provide "No Substitution" or the patient may advise the pharmacist of their preference for "No Substitution". In either case, the pharmacist will dispense the specific drug prescribed and charge the listed cost of that specific product. A pharmacist should ensure the instructions for "No Substitution" are documented on the prescription and patient's record and whether the instructions were received from the prescriber or the patient.

The Pharmaceutical Act, under Section 79(2), discusses the protocol if a lowest cost generic is not available from the manufacturer. If the lowest priced interchangeable product is not available despite reasonable efforts to obtain it, the amount charged for another interchangeable product must be the cost of the **next lowest priced** interchangeable product that is available.

In environments where there are automatic substitution policies or treatment protocols, there may be situations where a pharmacist will make changes to prescriptions that are not considered prescribing. If a pharmacist is following the direction of a policy, a protocol, or a prescription or drug order and is not required to assess the situation and use their judgment, they are not prescribing. In a hospital or personal care home facility where a committee of health professionals has determined, for example, that all orders for drug B will be replaced with drug A, or a drug order states "if INR is between X and Y, give warfarin Z mg daily", the pharmacist is not prescribing. If a pharmacist is required to assess the situation to determine whether a policy or a protocol applies to this patient in this situation, they may be making a prescribing decision. If in doubt, the pharmacist should adhere to appropriate prescribing standards.

9.2 *Fundamentals of prescribing*

There are several concepts common to all types of prescribing with which all pharmacists must be familiar. These concepts include:

- individual requisite knowledge, skill and judgment,
- adequate information,
- informed decision,
- approved indications, and
- documentation and notification of other health professionals.

The Prescribing Practice Direction incorporates all of these concepts into the written guidelines.

9.2.1 Competence

A pharmacist should prescribe a drug or medical device for which they have the knowledge, skill and judgment with regard to the drug or device and also the condition for which it is prescribed. A pharmacist should not prescribe for any patient unless they know what condition is being treated and have knowledge and understanding of the condition.

9.2.2 Adequate information

A pharmacist must have enough information about the specific patient's health status to ensure that the prescribing decision will maintain or enhance the effectiveness of the drug therapy and will not put the patient at increased risk. A pharmacist must conduct a patient assessment prior to prescribing and must only prescribe for a patient they have seen and assessed in person (note that exemptions for this requirement may be in place due to the COVID-19 pandemic). The Prescribing Practice Direction outlines the information that should be

acquired in a patient assessment. A patient assessment includes but would not be limited to the following:

a) Demographic information
b) Signs and symptoms
c) Laboratory and other test results
d) Medical history
e) Allergies
f) Current medications
g) Extent and result of current treatment
h) Pregnancy and lactation status if applicable
i) Patient preferences

9.2.3 Informed Decision

A pharmacist prior to issuing a prescription must provide the patient with sufficient information to enable the patient to make an informed decision about the treatment.

This information is further described in the Prescribing and Dispensing Practice Direction, which includes:

1. the nature of the treatment,
2. its anticipated effect,
3. the significant risks involved, and
4. the therapeutic alternatives to the treatment.

The pharmacist must answer any specific questions asked by the patient. The patient's consent is valid if the patient is informed and believed to have the capacity to understand the information presented.

9.2.4 Approved indications

All drugs prescribed must be for indications approved by Health Canada for that drug **or** be considered best practice or accepted clinical practice in peer-reviewed clinical literature. Examples of peer-reviewed literature include published journals, current clinical practice guidelines or consensus guidelines. If the indication for use is not Health Canada approved, it may be part of an approved research protocol.

9.2.5 Documentation and notification of other health professionals

A prescription must be written in a clear, concise, easy-to-read format including all required information and the pharmacist must sign the prescription. **The pharmacist must include on the prescription the treatment goal, diagnosis, or clinical indication at the time the prescription was written.**

The practice direction states when a prescription is issued, a prescribing record must be made and retained documenting all details included on the prescription as well as the rationale for the prescribing decision, the follow-up plan and notification of other health professionals. The rationale for prescribing should include pertinent details of the pharmacist's assessment and the patient history.

9.3 *Adapting a prescription*

The Adaptation of a Prescription Practice Direction outlines the guidelines for this type of prescribing.

Adaptation of a prescription must be based on an existing prescription written by a licensed practitioner and is limited to:

- Dosage strength,
- Dosage interval and/or
- Formulation.

A prescription can be adapted if the pharmacist has knowledge of the patient, the condition being treated and the drug therapy and **IF** one or more of the following applies:

1. The drug prescribed is not commercially available or may be temporarily unavailable from the supplier,
2. Information is missing from the prescription and sufficient information about the drug therapy can be obtained from the patient, the patient's record or other sources to determine that the adaptation will support compliance of the prescribed dosage,
3. Adaptation will facilitate patient adherence,
4. Adaptation will enable the patient to benefit from approved or existing third-party coverage.

A prescription for a drug covered under *The Controlled Drugs and Substances Act* **can** be adapted only when the total amount of milligrams prescribed is not exceeded.

The pharmacist must document and keep a record of all information related to adaptation of the prescription including:

1. Create a new prescription record signed by the adapting licensed pharmacist.
2. Clearly reference on the new prescription, the location of the original prescription.
3. Document the patient's agreement to the adaptation.
4. Document the following:

a) Patient name and, when available, the personal health information number (PHIN),
b) Licensed pharmacist's name and signature or initials,
c) Original prescription information,
d) Rationale for the decision to adapt,
e) Description of adaptation and
f) Follow-up plan when appropriate to do so.

The prescriber of the original prescription must be promptly notified and provided with the pharmacy name and address as well as the documented information above.

For further information, please see the Practice Aid: Adaptation.

Checklist for Adaptation of a Prescription

When adapting a prescription, a pharmacist must:

- ☑ have an original prescription from an authorized prescriber,
- ☑ have knowledge of the patient, the condition being treated and the drug therapy,
- ☑ obtain the patient's agreement with the adaptation,
- ☑ create a new prescription with pharmacist signature,
- ☑ document the rationale for the decision to adapt the prescription and notify the original prescriber promptly.

9.4 *Continued Care prescriptions*

REG 122

A licensed pharmacist under *The Pharmaceutical Act* is authorized to refill a prescription beyond those authorized on the original prescription if:

a) the patient has a continuing need or a chronic condition which is considered stable;
b) the prescribing practitioner has died or retired within the previous six months or the prescribing practitioner has not responded to a refill authorization request and it would be onerous or impossible for the patient to contact or attend the original practitioner issuing the prescription in a timely manner.
c) the patient's history with the prescribed drug has not changed;
d) the patient has not experienced any adverse reactions to the medication; and
e) the prescription was originally filled by the same pharmacy.

A pharmacist who authorizes a refill for a continued care prescription must promptly notify the original practitioner who issued the prescription, unless the practitioner has died or retired.

A pharmacist cannot authorize a refill quantity which is larger than the refill quantity prescribed on the original prescription. A pharmacist can only renew a continued care prescription once and cannot place refills on the prescription. A benzodiazepine cannot be renewed through continued care unless the drug is used to manage a convulsive disorder or if there is a risk of a seizure due to sudden withdrawal of the medication. Drugs covered under *The Controlled Drugs and Substances Act* also **cannot** be renewed as a continued care prescription.

A pharmacist must use their professional judgment to evaluate each situation and the information available. If the patient appears to be using continued care refills to avoid visiting their prescriber, then the refill must not be authorized. **Remember that the authority to prescribe must never be interpreted to be an expectation to prescribe.** This statement is true even when considering whether to renew a prescription.

9.5 *Prescribing in an emergency*

Emergency prescribing is expected to be a rare occurrence. If a public health emergency was to occur in all or part of the province, the Minister of Health may give notice to the College that the situation necessitates pharmacists be able to prescribe drugs outside their current authorization. Council may then approve members to prescribe under conditions set out by council until the state of emergency ends. The currently approved policy by Council for emergency situations can be found in the Emergency Preparedness Resource Kit for Pharmacists.

9.6 *Prescribing for Schedule II and III Drugs and Medical Devices*

Under the Pharmaceutical Regulation, any member can prescribe:

a) a drug listed on Schedule II of the NAPRA manual (non-prescription, pharmacy access only),
b) a drug listed on Schedule III of the NAPRA manual (non-prescription, patient self-selection area)
c) a drug with a drug identification or natural health product number which is not listed in the NAPRA manual,
d) a Health Canada approved medical device.

Some possible conditions for pharmacists prescribing these medications or medical devices may be for a patient's insurance coverage or to incorporate a Schedule II or III drug or a vitamin preparation into a patient's compliance packaging.

9.7 *Prescribing of Drugs for Self-limiting Conditions and for Uncomplicated Cystitis*

Pharmacists can receive authorization from the College to prescribe for the self-limiting conditions listed in Schedule 3 of the Manitoba Pharmaceutical Regulations (with or without smoking cessation), and for uncomplicated cystitis.

Successful completion of the Self-Limiting Conditions Independent Study Program, a completed Application for Authorization to Prescribe a Drug Included in Schedule 3 to the Pharmaceutical Regulation for Self-Limiting Conditions (not including smoking cessation) and a Certificate of Authorization to Prescribe a Drug for Self-Limiting Conditions from the College of Pharmacists of Manitoba is required before pharmacists can prescribe for the conditions and the drugs (not including smoking cessation) listed in Schedule 3 to the Manitoba Pharmaceutical Regulations. More information can be found on the College website here.

In order to prescribe a drug for smoking cessation, Manitoba pharmacists must view the Fundamentals of Self-Limiting Conditions Prescribing for Manitoba Pharmacists presentation (or through the Self-Limiting Conditions Independent Study Program), have successfully completed a smoking cessation program approved by Council, have read the product monographs of the drugs that the pharmacist is prescribing, reviewed other resources when necessary or appropriate, completed an Application to Prescribe a Drug Included in Schedule 3 to the Pharmaceutical Regulations for Smoking Cessation and received a Certificate of Authorization to Prescribe a Drug for Smoking Cessation from the College of Pharmacists of Manitoba before they can prescribe a drug listed in Schedule 3 to the Pharmaceutical Regulations for smoking cessation. More information can be found on the College website here.

In order to prescribe a drug for uncomplicated cystitis, Manitoba pharmacists must have successfully completed the “Uncomplicated Cystitis Independent Study Program for Manitoba Pharmacists”, including the Fundamentals of Self-Limiting Conditions Prescribing for Manitoba Pharmacists presentation, have read the product monographs of the drugs that the pharmacist is prescribing and reviewed other resources when necessary or appropriate, completed an Application For Authorization to Prescribe for Uncomplicated Cystitis, and received a Certificate of Authorization to Prescribe a Drug for uncomplicated cystitis from the College of Pharmacists of Manitoba. More information can be found on the College website here.

SCHEDULE 3 – DRUGS THAT A MEMBER MAY PRESCRIBE (IF APPROPRIATE TRAINING PROGRAMS COMPLETED)

SCHEDULE 3
(Subsection 118(2))

DRUGS THAT A MEMBER MAY PRESCRIBE (IF TRAINING PROGRAM COMPLETED)

Condition	**Prescription Drug Category (ATC — (anatomic therapeutic chemical classification)**
Atopic dermatitis Allergic contact dermatitis Irritant contact dermatitis Urticaria	D07AA: Corticosteroids, weak (group I) D07AB: Corticosteroids, moderately potent (group II)
Acne vulgaris	D10AE01: Benzoyl Peroxide D10AF01: Clindamycin D10AF51: Clindamycin, combinations
Tinea pedis	D01AE: Other antifungals for topical use
Candidal stomatitis	A07AA02: Nystatin
Unspecified haemorrhoids without complication	C05AA: Corticosteroids
Vasomotor and allergic rhinitis	R01AD: Corticosteroids R01AX03: Ipratropium Bromide
Seborrhoeic dermatitis (excluding pediatric)	D01AE: Other antifungals for topical use
Recurrent oral aphthae	A01AC: Corticosteroids for local oral treatment
Vomiting of pregnancy, unspecified	R06AA59: Doxylamine, combinations
Smoking Cessation	N07BA: Drugs used in nicotine dependence

M.R. 136/2016

9.8 *Extended Practice Prescribing*

REG 94-97

A pharmacist may apply for registration as an extended practice pharmacist if they:

a) Meet one or more of the qualifications under section 96 of the regulation,
b) is qualified as a specialist under a program approved by Council (Section 96(g)) or
c) has a postgraduate clinical degree of Pharmacy (Pharm D, Masters or PH.D.) or
d) has successfully completed certification program approved by Council, such as Diabetes Educator or Respiratory Educator.

The pharmacist must also meet the specialty practice hours requirements listed in Section 96 of the Regulation.

An extended practice pharmacist must practise in a collaborative practice with a physician or a registered nurse (extended practice). There is a possibility to practice with a registered nurse if approved by the Council and the Minister. Once registered with the College as an extended

practice pharmacist, they will have additional prescribing authorization for Schedule I drugs of the Manual but only within the scope of their specialty.

9.9 *Prescribing and Dispensing*

When a patient receives a prescription from a prescriber, they have the right to choose the pharmacy where they would like to fill the prescription. If a pharmacist issues a prescription to a patient, the patient still has the right to determine where he/she will have the prescription filled. The Regulation requires that the patient also be provided with the prescription. The Prescribing and Dispensing Practice Direction sets out the guidelines whereby a prescribing pharmacist can dispense a prescription they issued. The prescribing pharmacist must advise the patient or their agent that they may choose to have another pharmacy dispense the prescription. The patient should be presented with information about the medication and therapeutic alternatives so they can make an informed decision about filling the prescription. The patient must have the mental capacity to make an informed decision and provide the pharmacist with informed consent to dispense the drug that they prescribed. This consent must be documented on the prescription record.

A pharmacist shall not refuse to prescribe a drug because a patient or their agent refuses to fill the prescription at the prescribing pharmacist's practice site.

10 Administration of drugs

REG Part 14

Any licensed pharmacist may administer a prescription or non-prescription drug to a patient by the following means:

a) Orally including sublingual and buccal;
b) Topically, including ophthalmic, otic and intranasal;
c) Via inhalation.

Only a pharmacist who holds current authorization may administer a drug using an "advanced method" which includes the following methods:

a) Intradermal, subcutaneous or intramuscular injection;
b) Intravenously through an established central or peripheral venous access device;
c) Rectal administration.

There are several Canadian approved programs that currently offer an administration by injection training program. At the end of the program, the pharmacist is trained to give injections via intradermal, subcutaneous, and intramuscular routes. None of the programs qualify the pharmacist to administer drugs intravenously or rectally, and no programs have been approved by CPhM Council to date.

A member who is authorized may administer any of the following drugs:

1. An influenza (regular or high dose) or COVID-19 vaccine that is part of Manitoba's Seasonal Influenza Immunization Program to a person who is 5 years of age or older.
2. The following vaccines listed under Schedule 2 of the Regulations, which are publicly funded vaccines provided under a provincial immunization program free of charge to a patient who is 7 years of age or older and meets the provincial eligibility criteria:
    - Human papillomavirus (HPV) vaccine
    - Tetanus-diphtheria-acellular pertussis (Tdap) vaccine
    - Pneumococcal polysaccharide (Pneu-P-23) vaccine
    - Tetanus-diphtheria (Td) vaccine
3. Any other vaccine prescribed by an authorized practitioner to a person who is 7 years of age or older.
4. A drug other than a vaccine prescribed by an authorized practitioner to a person 5 years of age or older.

Pharmacies must register with Manitoba Health, Healthy Living and Seniors (MHHLS) as a vaccine provider to order the publicly funded vaccines from the Provincial Vaccine Warehouse. Please refer to the MHHLS website for more information.
http://www.gov.mb.ca/health/publichealth/cdc/div/manual/index.html

Manitoba's eligibility criteria for all publicly funded vaccines can be found at the following link:
http://www.gov.mb.ca/health/publichealth/cdc/vaccineeligibility.html

If a drug or a vaccine is not listed in Schedule 2 to the Regulation, then the vaccine would require a prescription from an authorized practitioner in order for a pharmacist to administer it through an advance method (regardless of its scheduling status on the NAPRA National Drug Schedules). Pharmacists are not considered authorized practitioners according to the provincial and federal legislation (only medical practitioners, dentists and nurse practitioners are included).

However, if a patient meets the eligibility criteria to receive a publicly funded vaccine, but the vaccine is not listed in Schedule 2 of the Regulations, then the pharmacist **must** refer the patient to a public health office or back to the prescriber to receive the immunization. Under no circumstances can a pharmacist charge a patient for a publicly funded vaccine **unless** the patient is ineligible to receive it.

The College advises all pharmacists to consult Manitoba Health's website often for eligibility criteria of publicly funded vaccines.

For clarification, NAPRA Schedule II, and Schedule 2 to the Pharmaceutical Regulation, are not the same. NAPRA Schedule II are non-prescription drug products sold from the dispensary by pharmacists. Schedule 2 to the Pharmaceutical Regulation are publicly funded vaccines that do not require a prescription to be administered by a pharmacist through an advanced method.

10.1 *Authorization to administer injections*

A pharmacist who wishes to become authorized to administer injections must:

1. successfully complete a CCCEP competency-mapped (stage 2) accredited injection program which includes a written education component and a live practical skill workshop;
2. complete the Manitoba Module: Administration of Injections;
3. possess and maintain valid certification in CPR Level C (or HCP) and Emergency or Standard First Aid from an accredited training program; and
4. apply to the College and receive authorization.

Additional training must be completed for intravenous administration of drugs through an established central or venous access line. In addition to completed training, a certified member must be practicing in a

collaborative practice with a physician or registered nurse (extended practice) and the practice must meet requirements approved by council.

Please refer to the College's website for more information on any of the above-mentioned steps.

10.2 *Practice Direction – Administration of Drugs by Injection*

The Administration of Drugs including Vaccines Practice Direction outlines standards and guidelines that pharmacists and pharmacies must follow for this restricted activity. For this expanded scope of practice, the pharmacist must be competent and/or authorized for administration of drugs and must possess and maintain certification in CPR Level C (or HCP) and emergency or standard first aid.

The pharmacy must maintain a policy and procedure manual that includes administration of drugs and emergency response protocols. The pharmacy must be able to provide a clean, safe, appropriately private and comfortable environment for the administration. A readily accessible supply of epinephrine syringes for emergency use, diphenhydramine, cold compresses and non-latex syringes must be available. The pharmacy must provide for proper disposal of waste materials. It is the responsibility of the pharmacist administering the drug to ensure the pharmacy has met these requirements prior to any administration.

Prior to administration, the pharmacist must perform a basic assessment of the patient proportional to the complexity of administration as well as assess the appropriateness of the drug for the specific patient. Permission and informed consent must be obtained from the patient after providing the patient the name of the medication, its indication, benefits and risks, expected reactions, side effects and other relevant information as per the practice direction. The clearly labeled drug must be stable, been prepared aseptically and have been properly stored. The pharmacist must ensure the route of administration and the site has been appropriately prepared. To ensure the safety of the pharmacist and the patient, the pharmacist must take appropriate precautions by washing hands before and after caring for the patient and wearing gloves to prevent contact with body fluids or contaminated surfaces or objects.

The pharmacist must monitor the patient post injection and be prepared to respond to any complications. Documentation of the administration must be done in compliance with the regulations and practice directions. Relevant information should be forwarded to other health professionals and provincial health agencies as appropriate.

10.3 *Documentation for all types of Administration*

When a pharmacist administers a drug to a patient, a record must be made and retained in the pharmacy with the following information:

a) the patient's name and address;
b) the name of the drug and total dose administered;
c) for an advanced method or vaccination, the manufacturer, lot number and expiry date of the drug;
d) for an advanced method, the route of administration and location on the body where the drug was administered;
e) the name of the pharmacist administering the drug;
f) the date and time of administration;
g) any adverse events; and
h) the price, if there is a charge for administration.

11 Ordering Tests

REG Part 13

The *Pharmaceutical Regulation* provides pharmacists with the authority to order and receive the results of laboratory tests following the guidelines and restrictions set out in the Regulation and the practice direction. Pharmacists are therefore able to play a more active role in monitoring of patient's medication therapy.

A stepwise approach to lab-test ordering by Manitoba pharmacists began on February 19, 2019, with nine participating pharmacies. Feedback from these pharmacies will be used to optimize the final phase of implementation that will allow all pharmacists/pharmacies that have met College requirements to order lab tests. Discussions with Manitoba Health, Seniors and Active Living on full implementation of lab-test ordering for pharmacists are ongoing, but the COVID-19 emergency has caused delay. The College will notify pharmacy professionals when updates are available. More information on Lab Test Ordering can be found here.

11.1 *Ordering tests – all members*

All pharmacists who would like to order lab tests for outpatients or in a community or clinical practice setting once full implementation is introduced must complete the Manitoba Module: Ordering Laboratory Tests (including the post-test) and receive a Statement of Participation. Successful completion of the Manitoba Module does not automatically grant pharmacists the authority to order lab tests for outpatients in Manitoba. Following successful completion of the Manitoba Module, a pharmacist must sign into their profile on the College website and declare they have completed the required training. This process will be implemented once pharmacists in Manitoba are able to order lab tests for outpatients. Further information will be posted on the College website once available, but some information can be found here in the meantime.

Any pharmacist may order and receive the results of a screening or diagnostic test specified in Schedule 1 of the Regulation (Appendix C). The test order must be in relation to a drug prescribed to a patient and with the objective to monitor the patient's drug therapy regime to ensure that it is safe and optimal. Pharmacists working in a hospital may order laboratory tests for in-patients as determined by hospital policy rather than the schedule in the Regulation.

SCHEDULE 1 – TESTS THAT A MEMBER MAY ORDER

Serum drug levels	Thyroid function
Serum creatinine	Complete Blood Count
Blood Urea Nitrogen	Liver Function
International Normalized Ratio (INR)	Electrolytes
Partial Thromboplastin Time	Iron Indices
Lipid panel	Vitamin levels
HbA1C (glycolated hemoglobin)	Total & Direct Bilirubin
Blood glucose	Albumin
	Total Protein

*Further descriptors within the categories can be found on the Manitoba Pharmacist Laboratory Requisition Form here.

11.2 *Ordering tests – extended practice pharmacists*

In addition to laboratory tests listed in Schedule 1, an extended practice pharmacist is permitted to order and receive results of screening and diagnostic tests that are within the scope of their practice. An extended practice pharmacist may also order a test in relation to any drug that they may have prescribed for the patient.

11.3 *Ordering tests – hospital pharmacy*

A hospital pharmacist may, in accordance with hospital pharmacy policy, order and receive results of screening and diagnostic tests for a person who is an in-patient of the hospital. In this case, the hospital pharmacist is bound by hospital policy which may restrict or limit activities and/or follow-up actions permitted. Hospital policy will determine the laboratory tests a pharmacist may order for in-patients.

11.4 *Practice Direction – Test Orders*

The Test Orders Practice Direction stipulates the conditions when ordering a test, the actions a pharmacist must undertake and the documentation that must be completed. The Test Orders: Process Map for Community Pharmacists maps out the information and workflow of ordering a test.

A laboratory test may be ordered to ensure optimal medication therapy and must be within the scope of the pharmacist's practice. The pharmacist must counsel the patient regarding the test – the clinical significance of the test, potential implications of the results, the proper procedure for the test and how the results will be communicated to the patient. The prescriber of the medication must be provided with relevant information about the patient's condition and the rationale for the test. The results of the test and any recommendations must also be communicated to the prescriber promptly and without delay.

When ordering laboratory tests, the pharmacist **must** be available and readily accessible to respond to and act on any critical tests results or must have alternate arrangements or a designate in place. The pharmacist must document and maintain a record of all patient laboratory test results and should be able to easily access this information either electronically or in written form.

12 Test Interpretation

In the Standards of Practice, Standard 7 states a member must interpret a patient-administered automated test in a competent and accurate manner. A pharmacist shall interpret test results which are within their knowledge, skill, and experience and for automated tests that are approved by Health Canada.

The Test Interpretation Practice Direction outlines the responsibilities of the pharmacist undertaking this activity and the requirements for documentation. A pharmacist should confirm the test was performed correctly by the patient taking into consideration various factors which may affect the results and discuss the results in a confidential manner. The patient should be given an interpretation of the test results and explained what action they should take and what action if any the pharmacist will take and if the patient should see their practitioner.

For all tests interpreted, a pharmacist must document the following information:

1. Name and address of patient
2. Pharmacist interpreting the test
3. Nature of the test
4. The result of the test
5. Any recommendations made or actions taken as a consequence of the test results
6. Date of the test
7. Date the test was interpreted

The documentation should be recorded in an easily retrievable manner either electronically or in written form.

13 Supervision

There are two levels of supervision: direct and indirect. In the Regulation, when the term, "supervision" is used without reference to direct supervision it can be interpreted as "indirect" supervision. If a pharmacist or pharmacy technician provides either direct or indirect supervision, they must:

- be competent and authorized to perform the activity being supervised,
- be competent to supervise the performance of the activity being supervised,
- be satisfied that the supervised individual has the knowledge, skills and experience to perform the activity,
- ensure that the individual being supervised complies with the legislation governing the practice and specific activity, and
- ensure that the individual does not engage in any activity that requires a pharmacist or pharmacy technician to perform the final check of that activity.

In addition, when providing **direct** supervision, a licensed pharmacist or pharmacy technician must:

- be physically present and immediately available when the supervised individual is performing the restricted activity, and
- be able to observe and promptly intervene and stop or change the actions of the individual who is under supervision.

When providing **indirect** supervision, a licensed pharmacist or pharmacy technician must:

- have procedures in place that:
  - comply with the standards, and
  - ensure the safety and integrity of the dispensing or compounding of drugs by the individual you are supervising,
- ensure that the individual they are indirectly supervising complies with the procedures, and
- be readily available for consultation by the individual who is under supervision and, if necessary, for providing hands-on assistance to the individual.

The Supervision Practice Direction states that a licensed pharmacist may supervise an intern, a pharmacy technician, a pharmacy student or other individuals in the practice of pharmacy. A pharmacist on the conditional register for temporary practice or who has conditions placed on their

licence which precludes them from providing supervision may not supervise other individuals.

A member must be satisfied that interns, students, pharmacy technicians and other persons being supervised are authorized to perform the activity, and that they have the knowledge, skills and ability to perform the activity safely and effectively. These individuals may require a period of orientation to the workplace procedures.

Only licensed pharmacists or listed pharmacy technicians with the College may supervise technicians-in-training during their Structured Practical Training (SPT) program. Pharmacists are permitted to serve as a preceptor for an intern and as a supervisor for a technician-in-training at the same time, as long as other additional supports are present in the pharmacy to allow for proper supervision. Additionally, a supervisor for a technician-in-training may serve as a supervisor for more than one pharmacy technician-in-training at the same time, as long as additional supports are present in the pharmacy to allow for proper supervision.

A pharmacy technician serving as a supervisor for a pharmacy technician-in-training must be:

a) listed for a minimum of 2 years if he/she graduated through a CCAPP accredited pharmacy technician program; OR
b) listed for a minimum of 1 year if he/she qualified through the 'transition stream'; OR
c) he/she was referred and approved by the Registrar.

Pharmacist to Staff Ratio

The Regulation does not provide for a specific pharmacist to staff ratio, however, Standard of Practice #14 states:

> "*A member and an owner must ensure that a pharmacy is operated with a ratio of members to pharmacy technicians, interns, students and other staff or workers that ensures safe and effective pharmacy practice.*"

Supervision of Students, Pharmacy Technicians and Other Persons

Interns are authorized by the *Pharmaceutical Regulation* to perform the same restricted activities as a licensed pharmacist under either direct or indirect supervision. The supervising pharmacist must use the rules previously described and their professional judgment to determine which level of supervision is appropriate. Registration with the College is required to be classified as an intern or a pharmacy student.

A pharmacy student under direct supervision, in addition to performing the tasks of a pharmacy technician or other persons (pharmacy assistant), may also:

- compound where the formulation and process has been approved by a pharmacist;
- educate a patient about their drug or drug therapy; and
- receive and record prescriptions.

REG 64

Section 64 of the Regulation outlines the activities that an individual employed in a pharmacy who is not a member, intern, pharmacy technician or student can perform.

Following the rules of supervision outlined previously, individuals who are employed in a pharmacy (pharmacy assistant) can assist by:

- preparing and pre-packaging a drug for dispensing,
- selecting an appropriate container,
- replenishing drug storage containers and dispensing machines,
- attaching the prescription label to a container,
- compounding if a member has approved the formulation and process,
- entering prescription information into a database, and
- managing drug inventory.

In addition to these activities, a pharmacy technician may under a member's supervision:

- identify drug-related problems that require a referral to a pharmacist;
- review the information in a prescription for compliance with federal and provincial law;
- preform a final check when a medication was prepared for dispensing by another technician, student, intern, or pharmacy assistant, but only if the pharmacy manager has received approval from the College Council for the drug packaging and preparation process;
- dispense a drug if the supervising pharmacist has approved filling the prescription and the supervising pharmacist counsels the patient;
- instruct a patient on how to operate a medical device, but not provide an explanation involving the interpretation of the results of the device;
- ask for, and receive, a refill authorization from a practitioner on an existing prescription without any changes to the prescription as originally prescribed; and

- perform necessary tasks at an external dispensing site.

REG 61

A pharmacy technician-in-training may perform the tasks of a pharmacy technician under the direct supervision of a pharmacist or a pharmacy technician.

A pharmacy technician continues to be qualified if they have worked as a pharmacy technician for at least 600 hours in the preceding three-year period. At least once every two years, a pharmacy manager must conduct a performance review for each pharmacy technician or ensure that a review is conducted.

The review must:

- document the hours worked as a pharmacy technician since the last review,
- assess performance in terms of quality of patient care, administrative skills and ability to work with the rules governing the pharmacy and pharmacy practice, and
- document the professional development activities the pharmacy technician has participated in that are consistent with the professional development program approved by council.

The College must maintain a list of pharmacy technicians who have met the basic education/training requirements, however not the ongoing requirements for practice hours or continuing competency. **The pharmacy manager is responsible for ensuring the pharmacy technician continues to meet the practice hours and continuing competency requirements.**

14 Patient records and documentation

Documentation and patient records should serve as a record of the critical thinking, problem-solving skills and judgment the pharmacist used and to describe events or discussions they had with patients and their caregivers. They will also help the pharmacist and other members of the pharmacy team provide better patient care. [1]

14.1 *Documentation*

Documentation establishes accountability and responsibility for professional activities. It is a key component in demonstrating how a pharmacist exercises their professional judgment.[2]

Documentation should contribute to continuity and/or coordination of care and should be organized in such a way that the patient's needs, the pharmacist's actions, and patient outcomes are accurately described.[3]

Note that a pharmacist is creating a permanent health care record every time they document. The following points should be considered to ensure that the record accurately reflects the care provided to the patient.[4]

- Documentation should occur immediately after the activity.
- Significant information must not be purposefully omitted. Include all information deemed necessary to support the identification of drug-related problems, recommendations and decisions.
- Writing should be clear, logical and precise.
- All documentation should be legible and non-erasable.
- Notes should not be deleted, removed or rewritten from any part of the record. If an error is made in a manual record, cross out the error with a single line, initial it and date it. If an error is made in an electronic record, leave it and cross-reference it to the corrected statements provided.

Many standardized styles are used to document clinical activities, including:

- SOAP (Subjective, Objective, Assessment and Plan);

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[1] Documentation guidelines for pharmacists 2004, Ontario College of Pharmacists, Pharmacy Connection Jan-Feb 2004
[2] Documentation guidelines for pharmacists 2004, Ontario College of Pharmacists, Pharmacy Connection Jan-Feb 2004
[3] Documentation guidelines for pharmacists 2004, Ontario College of Pharmacists, Pharmacy Connection Jan-Feb 2004
[4] IMPACT Clinical Documentation Guidelines, http://www.impactteam.info/documents/ClinicalDocumentationGuidelines.pdf

- DRP (Drug-related problem, Rationale, Plan);
- DAP (Data, Assessment, Plan);
- DDAP (Drug-related problem, Data, Assessment, Plan); and
- FARM (Findings, Assessment, Recommendations, Monitoring).

A standardized style is not required and may not always be appropriate. However, using a standardized style encourages complete data and consistent processes, and improves the organization of your thoughts. [5]

14.2 *Patient records*

The Standard of Practice #12 (Records and Information Practice Direction) states that a member and an owner must create, maintain and retain records as required by the legislation in a form and manner that allows them to be accessed promptly as needed to provide patient care and to comply with legislative requirements. Pharmacists should remember that all records about a patient are accessible by the patient under *The Personal Health Information Act*.

14.2.1 What is a patient record?

In the past, a pharmacy record would include the demographic information of the patient and a profile of the medications dispensed. The Regulation authorizes members an expanded scope of pharmacy practice whereby pharmacists can prescribe, order laboratory tests and administer medications. Documentation of these patient care services is mandatory under the legislation and practice directions and must be also included in the patient record.

A patient record must contain:

- patient profile,
- a drug profile, and
- a record of care.

A **record of care** includes:

- drug-related problems and the actions taken or monitoring plans created to deal with them,
- prescriptions adapted,
- drugs prescribed,
- drugs administered by injection,
- lab tests ordered, and

[5] IMPACT Clinical Documentation Guidelines, http://www.impactteam.info/documents/ClinicalDocumentationGuidelines.pdf

- other information such as prescriptions that were not filled and summaries of consultations with other health care providers.

The requirements for the patient record are included in Appendix F.

In addition to being complete and accurate, records must be clear, concise and in a format that facilitates sharing to ensure continuity of care can be provided to the patient. All records must be current and be easily retrieved.

14.2.2 Record retention

REG 79

The original prescription becomes a part of the prescription record which must be retained for 5 years from the last date of the last refill.

According to the Regulation, the retention period is also 5 years from last activity on the patient record for the following records:

a) Prescription record;
b) Drug label;
c) Patient profile;
d) Counselling record;
e) Drug acquisition and sales;
f) Prescriptions or copies of them, if they were refused to be filled;
g) Drug administration record;
h) Test interpretation record;
i) Test ordering and results record; and
j) Prescribing record.

These records can be recorded and retained either electronically or in written form. However, if a signature or initial is required on the record then it must be an original or electronic signature or initial.

The Records and Information Practice Direction outlines the requirements for electronic records and the need for a computer system to identify each user who is granted access, to control access to users and also to create an audit trail of access. The computer system must have sufficient security to ensure only authorized users have access. Backup of electronic records should occur daily and be tested regularly. The electronic records should be retrievable in the event that the system malfunctions or is destroyed.

Pharmacy records including back-ups stored on or off-site must have adequate security to protect the records from unauthorized access, theft, use or loss.

15 Continuing Education

The profession of pharmacy is an ever-changing field, as new medications, evidence, and technology come to light every day, bringing with it new and exciting opportunities to make a difference in the lives of patients. Pharmacists are on the front lines of patient education and are a wealth of clinical knowledge for other health care providers. All pharmacists have a lifetime commitment to learning, and the College encourages all members to constantly strive in updating their knowledge and keeping it current by participating in continuing education and professional development activities.

To be eligible for license renewal, all pharmacists in Manitoba are required to participate in a minimum of 25 hours of professional development between November 1st and October 31st of each year. Of the 25 hours, a minimum of 15 hours must be from accredited learning activities.

Pharmacy technicians are required to participate in a minimum of 15 hours of professional development learning activities from June 1st[st] to May 31st of each year. Of the 15 hours, a minimum of 5 hours must be from accredited learning activities.

The College website provides information on upcoming professional development opportunities and previously recorded programs. All registrants are encouraged to check the College website regularly for new opportunities and more resources under “Practice and Education” here.

Conclusion

A Guide to Pharmacy Practice in Manitoba provides an overview of the pharmacy regulations and legislation. It is imperative that all registrants review and become familiar with all the referenced materials in addition to reading this manual. Registrants must consider what actions must be taken to comply with the legislation and other learning required to apply the expanded scope to individual pharmacy practice.

The scope of pharmacist practice is constantly being updated and broadened. The legislative framework offers opportunities for pharmacists to fully use their skills and training and to lead the way in pharmacy practice and to optimize patient care.

The legislation and standards will inform and guide specific areas of an individual's pharmacy practice. They will not, however, dictate its scope. Each pharmacist controls their scope of practice. Each pharmacist must decide how they will incorporate these opportunities into their day-to-day work.

Appendix A - Code of Ethics

Statement I	Pharmacists shall maintain a high standard of professional competence throughout their practice.
Statement II	Pharmacists shall cooperate with colleagues and other health care professionals to ensure optimal patient-centered care.
Statement III	Pharmacists shall contribute to societal health needs and promote justice in the distribution of health resources.
Statement IV	Pharmacists shall respect and protect the patient's right of confidentiality.
Statement V	Pharmacists shall respect the autonomy, values and dignity of each patient.
Statement VI	Pharmacists shall respect and maintain a professional relationship with each patient.
Statement VII	Pharmacists shall hold the health and safety of each patient to be of primary consideration.
Statement VIII	Pharmacists shall act with honesty and integrity.
Statement IX	Pharmacists shall respect the rights of patients to receive healthcare.
Statement X	Pharmacists shall respect and honour the profession of pharmacy.

Appendix B - Standards of Practice

Standards of practice

56(1) The following standards of practice are established:

1. Patient counselling

Each time a drug is dispensed pursuant to a prescription, a member must provide the patient with sufficient information to enable the patient to safely and effectively manage his or her drug therapy.

2. Referring a patient

A member must refer the patient to another appropriately qualified regulated health professional when (a) the care or treatment required by the patient is beyond the scope of the member's professional practice or competence; (b) the patient's condition cannot be effectively treated within the practice of pharmacy; or (c) the patient's condition has not adequately or appropriately responded to drug therapy or other therapy provided by the member.

3. Collaborative care

A member must work collaboratively with other health care professionals and others who provide care to the patient, as circumstances require, in order to provide integrated care and avoid duplication of services. When a member and one or more other persons are providing care to a patient, the member must (a) treat the other provider with respect; (b) recognize the skills, knowledge, competencies, and roles of the other provider, and communicate effectively and appropriately with them; and (c) explain to the patient the member's role and responsibility.

4. Prescribing and dispensing drugs

A member who prescribes a drug must provide a written prescription to the patient and advise the patient that he or she may choose to have the prescription dispensed at another pharmacy or by the prescribing member.

5. Administration of drugs

A member who administers a drug to a patient must (a) do so only with the patient's authorization; (b) have policies and procedures in place respecting the administration of drugs and be prepared to immediately respond in emergencies, like anaphylaxis; and (c) only administer a drug if the pharmacy has facilities that are appropriate for the administration.

6. Drug distribution

A member must comply with the conditions of sale for all prescription and non-prescription drugs, in accordance with applicable legislation, to ensure the safety and quality of drugs being distributed.

7. Test interpretation

A member must interpret a patient-administered automated test in a competent and accurate manner.

8. Extemporaneous compounding

A member must ensure that extemporaneous compounding is done in a manner that ensures the preparation is safe and of an appropriate consistency and quality.

9. Incidents and discrepancies

A member must expeditiously address, document and report incidents, discrepancies, and adverse events in dispensing drugs and in providing patient care.

10. Transfer of patient care

If a patient or his or her authorized representative requests that the patient`s care be transferred to another member or to another health care professional, the member must ensure that a copy of the information specified by the patient is provided to the pharmacy or health professional specified by the patient as promptly as the circumstances require.

11. Termination of relationship with patient

A member who terminates a relationship with a patient must have reasonable grounds for doing so and document those reasons on the patient record. The member must give the patient notice of the intention to terminate care and provide such notice as is commensurate with the continuing care needs of the patient. However, advance notice is not required if (a) the patient poses a risk to the member or to others at the practice site or if the patient has failed to respect professional boundaries; and (b) the member provides for continuity of care by offering to provide information to another member.

12. Records and information
An owner must not request or require a member to use, disclose or otherwise deal with a record containing the personal health information of a patient in a way that is not consistent with the obligations that a member has under The Act, this regulation, *The Personal Health Information Act* or under any other law. A member and an owner must create, maintain and retain records as required under *The Act* and this regulation and in a form and manner that allows them to be accessed as promptly as needed in order to provide patient care and to otherwise comply with the requirements of *The Act*, this regulation, *The Personal Health Information Act* and any other law. A pharmacy manager and an owner must ensure that the policies and procedures of the pharmacy are consistent with the obligations that members have under *The Personal Health Information Act* and any other law.

13. Policies and procedures re safe practice
A pharmacy manager must establish, implement and maintain written policies and procedures to
(a) identify, mitigate and avoid situations that expose patients and staff to inappropriate risk;
(b) ensure safe and effective pharmacy practice; and (c) set out the role of staff in the pharmacy with respect to the matters set out in clauses (a) and (b).

14. Pharmacist to staff ratio
A member and an owner must ensure that a pharmacy is operated with a ratio of members to pharmacy technicians, interns, students and other staff or workers that ensures safe and effective pharmacy practice.

15. Pharmacy facilities
A pharmacy manager and an owner must ensure that the facilities in the pharmacy are safe, sanitary, appropriate and accessible for the professional practice conducted in the pharmacy.

16. Technology
A pharmacy manager and an owner must establish, implement and maintain written policies for the assessment and use of technology that ensures safe and effective pharmacy practice.

17. Drug product acquisition and handling
A member is responsible for ensuring the safety, accuracy and quality of the products and services that the member acquires or supplies.

Appendix C - Schedule 1 - Tests a member may order

SCHEDULE 1
(Section 100)

TESTS THAT A MEMBER MAY ORDER

Serum drug levels

Serum creatinine

Blood Urea Nitrogen

International Normalized Ratio

Partial Thromboplastin Time

Lipid panel

HbA1C (glycolated hemoglobin)

Blood glucose

Thyroid function

Complete Blood Count

Liver function

Electrolytes

Iron Indices

Vitamin levels

Total & Direct Bilirubin

Albumin

Total Protein

Appendix D - Schedule 2 – Vaccines a member may administer as a part of provincial program

SCHEDULE 2
(Section 110)

VACCINES THAT A MEMBER MAY ADMINISTER AS PART OF A PROVINCIAL PROGRAM

human papillomavirus (HPV) vaccine
influenza vaccine
pneumococcal polysaccharide (Pneu-P-23) vaccine
tetanus-diphtheria-acellular pertussis (Tdap) vaccine
tetanus-diphtheria (Td) vaccine

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Appendix E
Schedule 3 – Drugs a member may prescribe (if a training program has been completed)

SCHEDULE 3
(Subsection 118(2))

DRUGS THAT A MEMBER MAY PRESCRIBE
(IF TRAINING PROGRAM COMPLETED)

Condition	**Prescription Drug Category (ATC — (anatomic therapeutic chemical classification)**
Atopic dermatitis Allergic contact dermatitis Irritant contact dermatitis Urticaria	D07AA: Corticosteroids, weak (group I) D07AB: Corticosteroids, moderately potent (group II)
Acne vulgaris	D10AE01: Benzoyl Peroxide D10AF01: Clindamycin D10AF51: Clindamycin, combinations
Tinea pedis	D01AE: Other antifungals for topical use
Candidal stomatitis	A07AA02: Nystatin
Unspecified haemorrhoids without complication	C05AA: Corticosteroids
Vasomotor and allergic rhinitis	R01AD: Corticosteroids R01AX03: Ipratropium Bromide
Seborrhoeic dermatitis (excluding pediatric)	D01AE: Other antifungals for topical use
Recurrent oral aphthae	A01AC: Corticosteroids for local oral treatment
Vomiting of pregnancy, unspecified	R06AA59: Doxylamine, combinations
Smoking Cessation	N07BA: Drugs used in nicotine dependence

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Appendix F
Documentation Requirements

Type of Record	Required information
Patient Profile	a) The patient's name, address and telephone number b) The patient's date of birth c) The patient's personal health identification number d) The patient's sex/gender e) Any known drug allergies, sensitivities and other contraindications or precautions f) Disease states and chronic conditions
Prescription Record (Regulation - Section 70(1))	a) The name and address of patient b) The name and address of the prescriber c) The name of drug d) The number of refills e) The manufacturer f) The strength and quantity g) The directions for use h) The date the drug and each refill is dispensed i) The total price charged j) The signature or initials of the person preparing the drug for the final check and the member doing the final check k) The signature or initials of the member approving the prescription for filling or refilling when the final check is performed by someone who is not a member or postgraduate intern
Adapted Prescription Record (Practice Direction – Adaptation of a Prescription)	a) Patient name and PHIN when available b) Licensed pharmacist's name and signature or initial c) Original prescription information d) Rationale for the decision to adapt the prescription e) Description of adaptation f) Follow-up plan, when appropriate g) Patient's agreement to adaptation

Type of Record	Required information
Prescribing Record (Practice Direction – Prescribing)	a) The name and address of the patient b) The date of birth c) The name of drug/device prescribed d) The strength(if applicable) and quantity e) The directions for use f) The number of refills g) The name of the licensed pharmacist issuing prescription h) The date of the prescription i) The treatment goal, diagnosis or clinical indication j) The rationale for the prescribing decision k) The follow-up plan l) Other health professionals notified
Drug Administration Record (Regulations - Section 113)	a) The name and address of the patient b) The name of the drug and total dose administered c) For advanced method or vaccination by any method, identification of the manufacturer: i. Identification of manufacturer ii. Lot number and expiry date of the drug iii. The route of administration iv. The location on body where drug was administered d) the name of the member administering the drug e) the date and the time of administration f) Any adverse events g) The price, if there is a charge for administration
Test Ordering and Results Record (Practice Direction – Test Orders)	a) The name and address of the patient b) The name of the pharmacist requesting the test c) The nature of the test ordered or recommended d) The rationale for ordering or recommending e) The health professional to whom results or recommendations will be forwarded f) Any recommendations made or actions taken as a consequence of the result received and the date they occurred

	g) The date the test was ordered or recommended h) The date the results were received i) The date the results were communicated by the pharmacist to the practitioner responsible for the patient's care
Type of Record	**Required information**
Test Interpretation Record (Practice Direction – Test Interpretation)	a) The name of the patient b) The address of the patient c) The name of the pharmacist interpreting the test d) The nature of the test e) The result of the test f) Any recommendations made or actions taken as a consequence of the result received g) The date of the test h) The date the test was interpreted