Ontario College of Pharmacists
Putting patients first since 1871

NOTICE OF PHARMACY RENOVATION

To remain compliant with the regulations under the Drug and Pharmacies Regulation Act (DPRA), the College must be notified and approve of any material change to the size or physical layout of an existing accredited pharmacy. This form should also be used if the pharmacy is moving to a new unit number at the same municipal address.

The Director Liaison must submit a completed Notice of Pharmacy Renovation form along with a floor plan labelled with the following details at least **45 days** prior to commencing any renovations to a pharmacy:

- Total square footage of area to be accredited – if the pharmacy is part of a larger area, clearly delineate the pharmacy portion and identify how the accredited area is kept secure/physically separate from the non-accredited area
- Total square footage of dispensary (area behind the counter)
- Location of required two sinks in the dispensary (if the pharmacy does Level B or C compounding you must also show the additional sink in the compounding room)
- Location of acoustically private consultation area in the accredited area
- Location of compounding area(s) and C-PEC (hood) if any

Pharmacy Information

A	Pharmacy Name			Accreditation Number
	Street Address	City	Province ON	Postal Code

Description of the Pharmacy Changes

B	Provide details of the proposed changes
	Proposed Completion Date

Non-Sterile Compounding Checklist

This list is only meant as a guide and is not exhaustive. Please refer to the NAPRA Model Standards for Pharmacy Compounding of Non-Sterile Preparations. The standards are accompanied by a Guidance Document for Pharmacy Compounding of Non-Sterile Preparations ("GD") for complete details.

The requirements can be found in the NAPRA Guidance Document for Pharmacy Compounding of Non-sterile Preparations ("Guidance Document" or GD)

Facilities for level A non-sterile compounding

- ❑ Separate space designated for compounding (GD 8.1)
- ❑ Sink with clean water supply, with hot and cold running water close to the compounding area (GD 5.4.1.4)

Facilities for Level B non-sterile compounding

- ❑ Physically separated room dedicated to compounding (GD 8.2)
- ❑ May require a ventilated containment device when small quantities of ingredients or preparations that require ventilation are compounded occasionally, including certain powders, aromatic products, or hazardous products (GD 8.2). Room must be well-ventilated (GD 8.2)
- ❑ The C-PEC is installed in the compounding room and should either be externally vented (the preferred option) or have redundant HEPA filters in a series. (GD 9.2.1)
- ❑ Larger workspace and greater protection from cross-contamination (GD 8.2)
- ❑ Sink with clean water supply, with hot and cold running water inside the compounding room, at least 1 meter away from any C-PEC (GD-5.4.1.4)
- ❑ Eyewash station and/or any other emergency or safety equipment as required (GD 9.1.1)
- ❑ Work surfaces and furniture, as well as floor and wall surfaces, must be designed to facilitate repeated cleaning (section GD-5.4.1.5). Work surfaces and furniture should be constructed of smooth, impervious, and non-porous materials, preferably stainless steel.
- ❑ If hazardous drugs or materials are being handled, the surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the non-sterile compounding area should be smooth, impermeable, free from cracks and crevices, and made of non-shedding material. (GD 9.1.1)

Facilities for Level C non-sterile compounding

- ❑ Physically separated room dedicated to compounding (GD 9.1.1)
- ❑ Sink with clean water supply, with hot and cold running water inside the compounding room, at least 1 meter away from any C-PEC (GD-5.4.1.4)
- ❑ The C-PEC is installed in the compounding room and should either be externally vented (the preferred option) or have redundant HEPA filters in a series. (GD 9.2.1)
- ❑ Well-ventilated room with external venting through HEPA filtration (GD 9.1.1)
- ❑ Well-ventilated room with appropriate air exchange (at least 12 ACPH) and negative pressure (at least -2.5Pa) relative to surrounding rooms (GD 9.1.1)
- ❑ Appropriate containment device (C-PEC) (GD 9.1.1)
- ❑ Eyewash station and any other emergency or safety equipment required (GD 9.1.1)
- ❑ Must be constructed with smooth impermeable surfaces (e.g., ceilings, walls, floors, fixtures, shelving, counters, and cabinets) to promote adequate cleaning and decontamination (GD 9.1.1)
- ❑ The heating, ventilation and air conditioning system must be constructed to prevent contamination of the areas surrounding the compounding room and to ensure the comfort of personnel wearing PPE (GD 9.1.2)
- ❑ The negative pressure of the controlled room (C-SEC) should be maintained and measured continuously, and an alarm system should be in place to immediately advise personnel of non-compliance. (GD 9.6.3)
- ❑ Windows and other openings must not lead directly outside or to a non-controlled area (other than the doors designated for accessing the room). (GD 9.1.3)
- ❑ Hazardous products must be stored in a room with appropriate ventilation (GD 9.1.5)

New Pharmacy Information (Complete only if the pharmacy is moving to a new unit)

C

New Location

Pharmacy Name			Proposed Move Date
Street Address with Unit Number	City	Province ON	Postal Code
Pharmacy Business Email Address	Phone Number		Fax Number

Designated Manager

must complete the Role of the Designated Manager form (Section D)

Designated Manager Name	OCP NUMBER

Pharmacy Hours

❑ Open **24** Hours	From	To	Closed
Monday			❑
Tuesday			❑
Wednesday			❑
Thursday			❑
Friday			❑
Saturday			❑
Sunday			❑

Usual and Customary Dispensing Fee

The usual and customary dispensing fee is the single specific amount set by the operator of a pharmacy as required by the Drug Interchangeability and Dispensing Fee Act. Any adjustment to this fee must meet the conditions established by *R.R.O. 1990, Reg. 935* and be communicated to the patient according to *R.R.O. 1990, Reg.936*. Usual and customary services directly linked to dispensing a prescription include gathering information, analysis and options based on information gathered, and offering follow up to the patient as appropriate. For more information, please review the guideline Dispensing Components Included in the Usual and Customary Fee.	Dispensing Fee **$**

Banner & Franchise

If the pharmacy is affiliated with a Banner, please indicate the Banner Name The pharmacy is affiliated with a central office where they use a recognized name and may participate in centralized buying, marketing, professional programs, etc.	Banner Name
If the pharmacy is affiliated with a Franchise, please indicate the Franchise name The pharmacy is owned by a franchisee who enters a business relationship with a company (franchisor) for the legal usage of the franchisor's name and products.	Franchise Name

The Role of the Designated Manger

(Complete only if the pharmacy is moving to a new unit)

D

A Designated Manager (DM) is a pharmacist in Part A of the register who is designated by the owner of the pharmacy as the pharmacist responsible for managing the pharmacy. While the College holds all its registrants accountable for their practice, Designated Managers carry additional responsibilities related to their role. The DM accepts the same accountability and responsibility as the owner and corporate directors for ensuring that the pharmacy conforms to the requirements set out in the Drug and Pharmacies Regulation Act and Regulations, which govern the accreditation, ownership, and operation of pharmacies.

The DM understands that their contact information will be shared with Pharmapod, a third-party vendor, for the purposes of the administration and set-up of the AIMS Program.

The College's **Designated Manager (DM) e-Learning module** provides an overview of the key responsibilities of a Designated Manager. It is recommended that new Designated Managers access it, in order to have a better understanding of their responsibilities.

As the Designated Manager of the Pharmacy, please indicate your acknowledgment of the following 4 statements by initialing in each box and signing below:

☐ Before starting the role of DM, I will:

- Activate AIMS Pharmapod account upon receipt of instructions from Pharmapod (sent within 2wks of effective date)
- Review the standards and expectations of the Assurance and Improvement in Medication Safety (AIMS) Program
- Review The Responsibilities of a Designated Manager for the AIMS Program e-learning module
- Review the regulations and operational requirements for the profession and the business as well as the policies and procedures that are in place at the pharmacy
- Conduct a full inventory and reconciliation of all narcotic, controlled and targeted substances. This count can be used for future reconciliations.
- Review past assessment history which should be discussed with the owner. If the assessment reports are not available to review, once the change in DM has occurred with the College, previous assessment results are available to the DM through their online account.

☐ The DM is accountable for the following pharmacy functions:

- Professional Supervision of the Pharmacy
- Facilities, Equipment, Supplies and Drug Information
- Record Keeping and Documentation
- Medication Procurement and Inventory Management
- Training and Orientation
- Safe Medication Practices
- Assurance and Improvement in Medication Safety (AIMS) Program

☐ The DM is responsible for meeting the Standards of Operation for Pharmacies and is required to be up to date with any changes to the College policies and guidelines.

☐ The DM is required to display their license or a Designated Manager Certificate for public view and it is the expectation of the College that the DM actively and effectively participates in the day-to-day management of the pharmacy.

I hereby acknowledge that I have read, and I understand the Model Standards of Practice for Pharmacists, as approved by the Board of Directors of the Ontario College of Pharmacists and the policies mentioned above and I accept the responsibilities as defined in the Drug and Pharmacies Regulation Act (DPRA) Section 166.

☐ I agree

Pharmacy Name	
Designated Manager Name	OCP Number
Designated Manager Signature	Date Signed

Pharmacy Services

E

Please indicate the services to be offered and/or utilized.

❑ Dispense Methadone for Methadone Maintenance Treatment (MMT)?

- The pharmacy dispenses Methadone for patients in a Methadone Maintenance Treatment (MMT) program for opioid use disorder. See Opioid Policy and the Key Requirements for Methadone Maintenance Treatment (MMT) - Fact Sheet

If yes, is the pharmacy accepting new patients for MMT? ❑Yes ❑No

❑ Transfer custody of Methadone for Methadone Maintenance Treatment (MMT) to a prescriber?

- The pharmacy prepares methadone doses for transferring to a prescriber. See Opioid Policy and CPSO's Advice to the Profession: Prescribing Drugs (companion resource to the Prescribing Drugs Policy)

❑ Utilize Central Fill Services?

- The pharmacy, under contract or policy, **sends prescription orders to a central fill pharmacy** for preparation and packaging. See Centralized Prescription Processing (Central Fill).

If yes, does the pharmacy utilize?

Multi-Medication Compliance Aids (Blister Packs)	**❑Yes ❑No**
Non-sterile compounded preparations	**❑Yes ❑No**
Sterile compounded preparations	**❑Yes ❑No**
Vial Dispensing	**❑Yes ❑No**

❑ Provide Central Fill Services?

- The pharmacy, under contract or policy, **prepares and packages** prescription orders on the originating pharmacy's direction. See Centralized Prescription Processing (Central Fill).

If yes, does the pharmacy provide central fill for:

Multi-Medication Compliance Aids (Blister Packs)	**❑Yes ❑No**
Non-sterile compounded preparations	**❑Yes ❑No**
Sterile compounded preparations	**❑Yes ❑No**
Vial Dispensing	**❑Yes ❑No**

❑ Compound **Level A NON-STERILE** preparations?

- Level A is required when compounding non-hazardous drugs, and includes having a separate, designated compounding area and general requirements for policies, procedures, training and equipment. Level A is the minimum requirement for pharmacies engaged in any compounding activities whatsoever, regardless of the type of preparation, quantity or frequency. (Refer to the algorithm and Section 8 of the Guidance Document for Pharmacy Compounding of Non-sterile Preparations)

❑ Compound **Level B NON-STERILE** preparations?

- Level B is required when compounding hazardous drugs that require ventilation, including a dedicated room that is separate from the rest of the pharmacy and specialized policies, procedures, training, equipment and/or instruments. (Refer to the algorithm and Section 8 of the Guidance Document for Pharmacy Compounding of Non-sterile Preparations)

❑ Compound **Level C NON-STERILE** preparations?

- Level C is required when compounding hazardous drugs (including those in NIOSH Group 1 or in WHMIS as very irritating to the respiratory tract, skin or mucous membranes). Level C requirements include a room under negative pressure, a ventilated containment device and appropriate personal protective equipment. Refer to Section 9 of the Guidance Document. (Refer to the algorithm and Section 8 of the Guidance Document for Pharmacy Compounding of Non-sterile Preparations)

Continued next page

Pharmacy Services

E

❑ Compound **STERILE, non-hazardous** preparations?

- The pharmacy is compounding sterile preparations that require specialized equipment and specialized training/knowledge to customize a medication for a patient. This includes the reconstitution, manipulation or repackaging of sterile or nonsterile products to produce a sterile final product. See Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations for examples of non-hazardous sterile preparations and more information.

❑ Compound **STERILE, hazardous** preparations?

- The pharmacy is compounding sterile preparations with hazardous products that require specialized equipment and specialized training/knowledge to customize a medication for a patient. This includes the reconstitution, manipulation or repackaging of sterile or nonsterile products to produce a sterile final product. See Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations for more information.

❑ Service Long Term Care/Nursing Homes?

- The pharmacy provides medication management services to residents of **licensed** long term care homes.

Director Liaison Acknowledgement

F

Director Liaison Name	OCP Number
Email Address	Phone Number
Signature	Date

A Community Operation Advisor will review the proposed changes to the pharmacy and contact the Director Liaison or Designated Manager of the pharmacy if they have any questions or concerns. Once the Operation Advisor is satisfied that the proposed changes comply with DPRA regulations, an email will be sent confirming the renovation has been approved by the College.

Submit completed form by email to pharmacyapplications@ocpinfo.com,
or by fax to 416-847-8399,
or by mail to the attention of Pharmacy Applications & Renewals at 483 Huron St, Toronto, ON M5R 2R4