



OPENING A NEW PHARMACY

A Checklist

When all completed paperwork is received by the Pharmacy Applications & Renewals department, the Practice Advisor is informed and an appointment for the opening assessment is made. It is important that the pharmacy owner and/or designated manager inform the Practice Advisor as soon as possible if there is to be a change in the date of assessment. If the Practice Advisor does not accredit the pharmacy and another visit is required, the pharmacy will be subject to a second assessment fee and the opening may be delayed.

It is the responsibility of the owner and/or Designated Manager to ensure the premises are ready for the assessment. The checklist below is designed to assist the Designated Manager, owner, and all pharmacy staff in preparing for the new opening assessment. Please note that the pharmacy should be in a state that it would be 'ready to open' on the day of the assessment. If it is not, this could result in the denial of accreditation and a second assessment/fee as noted above.

General

- Who is the Designated Manager?
- Who are the staff pharmacist(s)?
- Who are the regulated technicians (if applicable)?
- What are the hours of operation?
- What is the email address of the designated manager?
- Is the Designated Manager's certificate of registration or is there a sign identifying who the designated manager is posted in an area visible to the public?
 - To access a fillable certificate use the following link:
<http://www.ocpinfo.com/library/forms/download/Designated%20Manager%20Certificate.pdf>
- How will the pharmacist be identified? (i.e., name badge, lab coat embroidered with the pharmacist's name and title, etc.)
- Which pharmacist(s) will have narcotic signing authority?
 - Use the following web link to access the Narcotic Signing Request form:
<http://www.ocpinfo.com/library/forms/download/Narcotic%20Signing%20Request%20Form.pdf>

Signage

**DPRA, O. Reg 264/16, Part IV, s. 19
DIDFA, Reg. 936**

- Are the hours of operation posted?
- The Point of Care sign and the Usual and Customary Fee and Notice to Patients signs will be provided by the Practice Advisor upon completion of a satisfactory assessment. These signs are to be posted BEFORE opening.
 - Post Point of Care sign in an area visible to public
 - Display Usual and Customary Fee and Notice to Patients signs in an area easily seen by a person presenting a prescription to be filled.

Standards of Accreditation and Operation

DPRA, O. Reg 264/16, Part IV

1. Computer:

- Is the computer system set up and operational?
- Does the computer system allow access to internet sites and other electronic resources?
- Is there equipment available which allows the pharmacy to receive, send and make accurate copies of electronic and non-electronic documents? (e.g. fax machine)
- Does the pharmacy have equipment to scan documents (including written prescriptions) and to store them electronically?
- Is the computer system secure enough to ensure that only authorized persons have access to the system?
- Is each person uniquely identified?
- Does the system control which functions can be accessed by specific employees?
- Can the system create an accurate audit trail of those employees accessing the system?
- Is there a backup and recovery system for the computer?

Note: Backup should be done daily and stored off site (readily retrievable) or in a fire proof and theft resistant safe

<https://www.ocpinfo.com/library/forms/download/Designated%20Manager%20Certificate.pdf>

2. Accredited Area and Dispensary:

- What is the total size of the accredited area? (Minimum of 18.6 m² or 200 ft²)
- What is the dispensary floor area? (Minimum 9.3 m² or 100 ft²)
- Is the dispensary constructed in way that is not accessible to the public?
- Does the pharmacy have a separate and distinct patient consultation area offering 'acoustical privacy'?
- Is the accredited area part of a larger area (e.g. part a medical centre)?
- If so, how is the accredited area kept secure/physically separated from the non-accredited area?
- Are there two sinks (or one double sink) within the dispensary?
- Does the dispensary have a sink with hot and cold running water?
- Is there an adequate supply of soap?
- Is there a minimum of 1.12m² (12 ft²) of work surface for the preparation for dispensing and for the compounding of drugs?
- Is there a refrigerator to store drugs and medications only?
 - Is there a device to accurately display the internal optimal temperature of 2-8 °C?
- Is there sufficient equipment (e.g. Graduates, mortar and pestles, spatulas, etc.) for the operation of the dispensary?
- Is there a torsion or electronic balance? If electronic, sensitivity needs to be appropriate to meet the needs of the specific compounding practice.
- Is there a sufficient supply of the following consumable material?
 - Bottles and caps, ointment jars and caps
 - Distilled or de-ionized water (or similar approved type)
 - Child resistant vials including light resistant vials

3. Standards of Operation

- Is the pharmacy area clean, free from clutter and ready for opening to the public?
- Can all surface areas be easily cleaned and disinfected?
- Is there a waste disposal service for drugs and other medication?
- Is there a shredder or service for disposal of confidential information?
- Does the location of the fax machine protect patient confidentiality?

4. Library

- Are all required references available in the pharmacy?
 - To access the Required Reference Guide use the following link:
<https://www.ocpinfo.com/regulations-standards/additional-resources/>
- Are there resources appropriate to the specialty practice of the pharmacy (e.g. Geriatric dosage handbook for those servicing long-term care or retirement facilities; pediatric dosing guide)?
- Is there on-line access to the OCP legislation, Pharmacy Connection, and the ODB Formulary?

5. Drug Schedules/Inventory (DPRA, O. Reg 264/16, Part II)

- Are all Schedule II medications located in an area with no public access?
- Are non-prescription narcotics located away from public view?
- Are all Schedule III medications (Professional Products Area) located within 10m (30 ft.) of the dispensary?
- Where will narcotics and controlled drugs be kept to ensure they are ‘reasonably secure’?

6. Lock and Leave (DPRA, O. Reg. 264/16, Part V, s. 23)

- Is the pharmacy operating as a lock and leave? For further information on Operating a Lock & Leave, please refer to:
<http://www.ocpinf.com/practice-education/opening-operating-pharmacy/lock-leave/>
- If yes, does the area completely restrict public access to the Schedule I, II and III drugs when a pharmacist is not present?

Note: Lock and Leave must be operational and ready for approval at opening assessment.

7. Prescription Label (DPRA, s. 156)

- Does the prescription label include the trading name and ownership name (as filed with OCP), as well as the pharmacy’s address and telephone number (including area code)?

Specialty Services

Will the pharmacy focus on any of the following services?

- [Methadone](#)
Use the following web link to access a notice to members dispensing methadone:
<http://www.ocpinf.com/library/forms/download/Methadone%20Dispensing%20Form.pdf>
- [Long-term care](#)
- [Specialty Non-Sterile compounding](#)
- [Sterile compounding](#)
 - Does the pharmacy have a well lit and appropriately ventilated preparation area that is not accessible to the public?
 - Is this area specifically designed for sterile compounding?
 - Is the counter in this area made of a non-porous surface capable of being appropriately cleaned?

- Is there a sink with a supply of hot and cold running water located close to the sterile compounding area?
- Is there adequate and secure storage space to keep drugs, medications and equipment used in sterile compounding separate from the balance of drugs, medications and equipment used in the dispensary?
- Has any of the staff had formal training in sterile/specialty non-sterile compounding?
- Please have their credentials available during the assessment.

For questions about the Standards of Accreditation and Operation, please contact a Practice Consultant in the Pharmacy Practice department at pharmacypractice@ocpinfo.com.

Issues identified during the assessment will be reviewed with the pharmacist on duty and an action plan may be required. It is recommended that the Designated Manager be present or available the day of the assessment.

After a successful assessment, the Practice Advisor will contact OCP Pharmacy Applications & Renewals with the assessment result and then provide the pharmacist on site with the accreditation number. On the agreed opening date, OCP Pharmacy Applications will contact the pharmacy to confirm operations, followed by communication to the Ministry of Health and Long-Term Care (Ontario Drug Benefit) as final confirmation that the pharmacy is accredited and operating. The pharmacy Certificate of Accreditation and fee receipt will be forwarded to the pharmacy as soon as the paperwork is processed.

A follow-up assessment (aka 'call-back') will take place in approx. 3-6 months.