



OPENING A NEW PHARMACY

A Checklist

When all completed paperwork is received by the Client Services department, the inspector is informed and an appointment for the opening inspection is made. It is important that the pharmacy owner and/or manager inform the inspector ASAP if there is to be a change in the date of inspection. If the inspector does not accredit the pharmacy and another visit is required, the pharmacy will be subject to a second inspection 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 inspection. The checklist below is designed to assist the manager, owner, and all pharmacy staff in preparing for the new opening inspection. Please note that the pharmacy should be in a state that it would be 'ready to open' on the day of the inspection. If it is not, this could result in the denial of accreditation and a second inspection/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 licence of the designated manager displayed or is there a sign identifying who the designated manager is?
 - To access a fillable certificate use the following link:
 - [http://www.ocpinfo.com/Client/ocp/OCPHome.nsf/object/DM+Certificate/\\$file/DM_Certificate.pdf](http://www.ocpinfo.com/Client/ocp/OCPHome.nsf/object/DM+Certificate/$file/DM_Certificate.pdf)
- How will the pharmacist be identified? (i.e., name badge, lab coat embroidered with the pharmacist's name and title, etc.)
- Which pharmacist(s) will have Narcotic signing authority?
 - Use the following web link to access the Narcotic signing request form:
 - [http://www.ocpinfo.com/Client/ocp/OCPHome.nsf/object/Narcotic+Signing+Request+Form/\\$file/Narcotic+Signing+Request+Form.pdf](http://www.ocpinfo.com/Client/ocp/OCPHome.nsf/object/Narcotic+Signing+Request+Form/$file/Narcotic+Signing+Request+Form.pdf)

Signage

DPRA Reg 58/11, Part IV, s. 26

- Is there a sign posted identifying the pharmacy that operates the remote dispensing location and the name of the designated manager?
- Is there a notice informing the public where the patient records for medications dispensed from the location will be located?
- 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 Inspector upon completion of a satisfactory inspection. 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 sign in an area easily seen by a person presenting a prescription to be filled.

Standards of Accreditation and Operation

DPRA Reg 58/11, Part IV

1. Computer – Section 21(4):

- 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? For example, a 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

2. Accredited Area and Dispensary – Section 21 & 22:

- 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 anti-microbial 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 & caps, ointment jars & caps
 - Distilled or de-ionized water (or similar approved type)
 - Child resistant vials including light resistant vials

3. Standards of Operation (DPRA Reg 58/11, Part IV s. 24)

- 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 (DPRA Reg 58/11, Part IV s. 25)

- Are all required references available in the pharmacy?
 - Are there texts 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?
 - Is there a subscription to an approved Drug Information Service?

Note: the Required Reference Guide is available on the OCP website www.ocpinfo.com

5. Drug Schedules/Inventory (DPRA Reg 58/11, 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 Reg 58/11, Part V, s.38)

- Is the pharmacy operating as a lock and 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 inspection.

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.ocpinfo.com/Client/ocp/OCPhome.nsf/web/Notice+to+Members+dispensing+Methadone>
- Long-term care
- Custom 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?
 - Have any of the staff had formal training in sterile/custom compounding?
 - Please have their credentials available during the inspection.

Issues identified during the inspection will be reviewed with the pharmacist on duty and an action plan may be required.

After a successful inspection, the inspector will contact OCP-Client Services with the inspection result and then provide the pharmacist on site with the accreditation number. On the agreed opening date, OCP Client Services 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 inspection (aka 'call-back') will take place in approx. 3-6 months.

For questions, please contact a Practice Advisor in the Professional Practice department or an inspector at profprac@ocpinfo.com