

Community Pharmacy Accreditation Assessment Criteria

The following chart outlines the community pharmacy operations criteria that are used by Community Operations Advisors (COAs) when conducting a community pharmacy accreditation assessment. The document is divided into categories and for each category specific standards, which have been taken from relevant legislation, policies, guidelines or standards of practice, is identified with a link to the appropriate reference. The guidance section illustrates specific insights or activities required to ensure adherence to the standard and is provided to assist practitioners in understanding expectations and preparing for an accreditation assessment.

For each standard, check the guidance that your pharmacy has in place and continue to work on achieving the remaining criteria prior to the accreditation assessment.

It is the Designated Managers responsibility to ensure all standards required for accreditation and operation of a pharmacy are implemented and maintained as outlined in section 166 of the DPRA. Failure to maintain the standards could result in referral to the Accreditation Committee and may constitute proprietary misconduct and/or professional misconduct.

Category: General	
STANDARD	GUIDANCE
The name of the Designated Manager or certificate of registration will be clear and displayed in the pharmacy. Reference: DPRA, s.146 (3); OCP Standards of Operation for Pharmacies	The name of the Designated Manager or certificate of registration must be clear and displayed in the pharmacy. The Designated Manager Certificate is available on the OCP website.
	The College must be notified of a change in Designated Managers. The Acknowledgement of <i>Change of Designated Manager</i> Form can be found on the OCP website.
All required signs will be displayed as per legislation. Reference: DPRA, O. Reg. 264/16, s.19; OCP Standards of Operation for Pharmacies	The Point of Care symbol in its unaltered trademarked form must be prominently and appropriately displayed so as to be easily visible to the public either before entering the pharmacy or immediately after entering.
	The <i>Notice to Patient</i> sign must be posted in an area where it can be easily seen by a person presenting a prescription.
	The <i>Usual and Customary Fee</i> sign must be posted in an area where it can be easily seen by a person presenting a prescription.
	The Point of Care symbol can be ordered by sending an email to FOS@ocpinfo.com .

	The <i>Notice to Patient</i> and <i>Usual and Customary Fee</i> signs can be ordered by sending an email to FOS@ocpinfo.com .
	The College must be notified of a change in Usual and Customary (Dispensing) Fee. Please send an email to pharmacyapplications@ocpinfo.com .
	The 'Narcotics Secured in a Time-Delayed Safe' sign must be displayed at each public entrance, and prominently in or adjacent to the dispensary area so that it is readable by a person presenting a prescription.
<p>The designated manager understands his/her role and responsibilities with respect to the accreditation and management of the pharmacy, including medication procurement and inventory management, supervision of pharmacy personnel, and required signage.</p> <p>Reference: DPRA, O. Reg 264/16, Part II; SOP for Schedule II and III Drugs; OCP Standards of Operation for Pharmacies</p>	The Designated Manager must understand their role and responsibilities with respect to the accreditation and management of the pharmacy, including medication procurement and inventory management, supervision of pharmacy personnel, and required signage.
	The Designated Manager should review the College's Designated Manager (DM) e-Learning module, which provides an overview of the key responsibilities of a Designated Manager, in order to have a better understanding of their responsibilities
Category: Drug Schedules	
STANDARD	GUIDANCE
<p>Drugs will be located in an area of the pharmacy consistent with the appropriate drug schedule classification and support approval/interaction with a pharmacy professional, as required.</p> <p>Reference: DPRA, O. Reg 264/16, Part II; SOP for Schedule II and III Drugs; OCP Standards of Operation for Pharmacies</p>	The pharmacist must be physically present in the pharmacy at the time of the sale of a Schedule I, II or III drug.
	All Schedule II drugs must be sold from the dispensary, where there is no public access and no opportunity for patient self-selection, after assessment by a pharmacist
	The pharmacy must develop a process to enable pharmacists to determine the appropriateness of Schedule II and III products for the patient in order to optimize therapeutic outcomes including a monitoring plan.
	Schedule III drugs must be available for sale in the pharmacy from the dispensary or from an area within 10 meters of the dispensary. A pharmacist or Intern must be available for consultation with the patient.
	The Designated Manager shall ensure that pharmacy personnel are knowledgeable regarding the necessity of pharmacists to consult with patients about Schedule II products. Pharmacy staff should review the content on the sales on non-approved marketed health products located on the OCP website.

	Low-dose ("OTC"; Schedule II) codeine products must not be visible to the public.
	Pharmacy staff should review the Supplemental Standards of Practice for Schedule II and Schedule III Drugs on the OCP website.
	Pharmacy staff should review the National Drug Schedules located on the National Association of Pharmacy Regulatory Authorities (NAPRA) website (www.napra.ca) regularly for product scheduling.
	Pharmacy staff should review the content on the sales on non-approved marketed health products located on the OCP website.

Category: Standards for Accreditation	
STANDARD	GUIDANCE
<p>The pharmacy and dispensary are designed, constructed and maintained to ensure the integrity and safe and appropriate storage of all drugs and medications and to permit optimal work flow management.</p> <p>Reference: DPRA, O. Reg 264/16, Part IV; Opening a Pharmacy Checklist; OCP Standards of Operation for Pharmacies</p>	The pharmacy floor area must not be less than 18.6m ² (200 ft ²).
	The pharmacy must have a separate and distinct patient consultation area offering "acoustical privacy".
	The pharmacy must be constructed and maintained in a manner that protects the privacy, dignity and confidentiality of patients and the public who receive pharmacy services.
	The dispensary must be designed, constructed and maintained so that it is not accessible to the public.
	The dispensary floor area must not be less than 9.3 m ² (100 ft ²).
	The dispensary must have a minimum work surface area of 1.12m ² (12ft ²) for preparation, dispensing and compounding of drugs adequate for the safe and appropriate operation of the Pharmacy.
	The dispensary must have a double sink with hot and cold running water.
	The pharmacy must have a process in place to ensure the regular cleaning of the pharmacy, including all premises, furniture, equipment and appliances, and automated pharmacy systems, if any.

	The pharmacy and dispensary must be maintained to ensure the integrity and the safe and appropriate storage of all drugs and medications; including, the proper conditions of sanitation, temperature, light, humidity, ventilation, segregation and security.
	The pharmacy must be designed to permit optimal workflow management, mitigate risk, support patient care and maintain safe and effective drug distribution while providing healthcare and services to patients.
<p>The pharmacy has the appropriate layout, equipment and technology to support practice.</p> <p>Reference: DPRA, O. Reg 264/16, s.19 & 22; Opening a Pharmacy Checklist; OCP Standards of Operation for Pharmacies, OCP Protecting the Cold Chain Guideline</p>	The pharmacy must have a computer system that includes technology necessary for the storage and retrieval of all documents associated with the practice of pharmacy.
	The pharmacy must have accessible and appropriate resources available that enables practicing registrants to utilize the necessary resources to make therapeutic decisions
	The pharmacy must have access to the current required references as listed in the Required Reference Guide for Ontario Pharmacies located on the OCP website.
	The pharmacy must have accessible and appropriate references available that enables practicing registrants to utilize the necessary resources to support the delivery of patient care.
	The dispensary must have equipment (i.e. balance, consumable materials such as bottles, child resistant & light resistant vials, mortars & pestles, metric graduates, spatulas, ointment pad, etc.) necessary for the safe and appropriate operation of the dispensary.
	The dispensary must have facilities and equipment available for the appropriate cleaning of equipment as well as a separate hand washing facility.
	All cold storage equipment that store medication must be maintained at the required storage temperature range.
	Cold storage equipment must be fit for purpose and well maintained
	Temperatures must be monitored regularly. For manual recording, the minimum and maximum temperature should be recorded twice per day.
	The Designated Manager is responsible for ensuring all medications found in the refrigerator during a temperature excursion are appropriate to dispense. The integrity of medications must be assessed and verified such that patients do not receive a potentially sub-potent product.
	Emergency preparedness processes should be in place to address any temperature excursions or breaks in cold chain (e.g. due to equipment failure, power outages, etc.).

	Standard operating policies and procedures must be in place within the pharmacy to ensure that the cold chain is maintained throughout the time a product is received, stored, dispensed and delivered and/or administered to the patient.
	All pharmacy and support staff involved in handling cold chain products must be trained on cold chain maintenance policies and procedures.
	Pharmacy staff should be familiar with the Protecting the Cold Chain Guideline and the associated references located on the OCP website.
	Pharmacy staff should review the standards specified in the Ontario Ministry of Health Vaccine Storage and Handling Guideline.
	The pharmacy must be constructed and maintained in a manner that protects the privacy, dignity and confidentiality of patients and the public who receive pharmacy services.
	The pharmacy must have procedures in place to ensure proper calibration and maintenance schedules are maintained for equipment used within the dispensary.
	The Designated Manager should review the Pharmacy Practice Management Systems (PPMS) Requirements and Supplemental Requirements.

Category: Standards of Operation

STANDARD	GUIDANCE
<p>The pharmacy will have systems and procedures in place to ensure the security of controlled substances according to national guidelines and provincial requirements.</p> <p>Reference: NCR, s. 42 & 43; OCP Standards of Operation for Pharmacies</p>	<p>The pharmacist must be responsible for ensuring that narcotics in the pharmacy are secure. Safeguards include performing a narcotic reconciliation on a regular basis (at least every 6 months), with a change in Designated Manager and after a theft or robbery.</p>
	<p>The pharmacist must be responsible for ensuring that controlled drugs in the pharmacy are secure. Safeguards include performing a controlled drugs reconciliation on a regular basis (at least every 6 months), with a change in Designated Manager and after a theft or robbery</p>
	<p>The pharmacist must be responsible for ensuring that targeted substances in the pharmacy are secure. Safeguards include performing a targeted substances reconciliation on a regular basis (at least every 6 months), with a change in Designated Manager and after a theft or robbery.</p>
	<p>Loss and theft of narcotics/controlled drugs/targeted substances must be reported to Health Canada-Office of Controlled Substances in Ottawa within 10 days. Please refer to the Controlled Substances: Reporting Loss or Theft Fact Sheets on the OCP website.</p>

	The pharmacy staff must follow the obligations outlined in the Safeguarding our Communities Act (Patch for Patch Return Policy). The pharmacy staff should review the Fact Sheet - <i>Patch-For-Patch Fentanyl Return Program</i> on the OCP website.
	All narcotics must be securely locked in a time-delayed safe, which is located inside the dispensary and which meets the requirements of the Medication Procurement and Inventory Management Policy.
	The pharmacist must take steps to thoroughly investigate every discrepancy identified during a reconciliation and to ensure that full documentation is available in a readily retrievable manner.
	Discrepancies were identified during the narcotic reconciliation.
	Discrepancies were identified during a random review of narcotic and controlled prescriptions.
	Pharmacy staff should review the Opioid Policy located on the OCP website.
	Pharmacy staff should review the OCP webpage on Naloxone – Dispensing, Selling or Providing
	Pharmacy staff should review the Controlled Substances: Security and Reconciliation Fact Sheet on the OCP website
	The pharmacist must take steps to identify forgeries. Please refer to the Forgery: Management and Reporting of Fraudulent Prescriptions and Forgery: Tips for Identifying Fraudulent Prescriptions Fact Sheets on the OCP website.
	Pharmacy staff should review the Controlled Substances: Destruction of Unserviceable Stock and Post-Consumer Returns Fact Sheet on the OCP website.
	Pharmacy staff should review the Controlled Substances: Orders, Purchases and Sales (Federal) Fact Sheet on the OCP website
	Pharmacy staff should review the Controlled Substances: Purchase & Sales Record Requirements (Federal) Fact Sheet on the OCP website
	Pharmacy staff should review the Pharmacy Safety Initiative resources on the OCP website
	Pharmacy staff should review the Opioid Policy on the OCP website.

	The pharmacy should have access to the National Pain Centre's 2017 Canadian Guideline for Opioids for Chronic Pain
	Pharmacy staff should review the Health Canada guidance document: Handling and destruction of post-consumer returns containing controlled substances (CS-GD-021).
	Pharmacy staff should review the Health Canada Guidance Document for Pharmacists, Practitioners and Persons in Charge of Hospitals: Handling and Destruction of Unserviceable Stock Containing Narcotics, Controlled Drugs or Targeted Substances.
	The Designated Manager must review the Narcotic Sales Report.
	The Designated Manager must review the Designated Manager – Medication Procurement and Inventory Management Policy on the OCP website
	The Designated Manager should review the Reconciliation of Controlled Substances e-learning module.
<p>The pharmacy has operational processes in place to ensure when prescriptions are delivered (or mailed), that they are both auditable and/or traceable with a receipt for the prescription signed by the patient or patient's agent.</p> <p>Reference: DPRA, s. 152; OCP Standards of Operation for Pharmacies</p>	The pharmacy must have a process in place to ensure all prescriptions delivered (or mailed) are traceable and auditable. Signature by the patient or agent upon receipt is required unless there is a valid reason for not signing. Documentation supporting the auditability and traceability of deliveries is mandatory, including circumstances leading to delivery without a signature
	The pharmacy must have a process in place to ensure confidentiality of all delivered prescriptions.
	Pharmacy staff should review the Fact Sheet - <i>Delivery of Prescriptions</i> located on the OCP website.
<p>The pharmacy will implement the AIMS, Assurance and Improvement in Medication Safety program in a manner that supports pharmacy professionals in meeting the requirements under the supplemental Standard of Practice.</p> <p>Reference: OCP AIMS program supplemental Standard of Practice; OCP Standards of Operation for Pharmacies</p>	Record: The pharmacy must have a process in place to enable the recording of all incidents and near misses by pharmacy staff for internal record keeping.
	The pharmacy must have a process in place to analyze individual pharmacy incidents and near misses in a timely manner for causal factors to reduce the likelihood of recurrence
	Share Learnings: The pharmacy must have a process in place to enable the prompt communication of appropriate details and actions taken of a medication incident or near miss to all pharmacy staff.
	Analyze: The pharmacy must have a process in place to utilize information (e.g. event reports) to guide the development of quality improvement initiatives.

	The pharmacy must have a process in place to implement appropriate steps to minimize the likelihood of incident recurrence.
	Document: The pharmacy must have a process in place to document Continuous Quality Improvement (CQI) plans and outcomes.
	The pharmacy must have a process in place to communicate Continuous Quality Improvement (CQI) plans and outcomes with staff.
	Monitor: The pharmacy must have a process in place to monitor outcomes of Continuous Quality Improvement (CQI) plans and improvements implemented.
	The pharmacy must have a process in place to complete the Safety-Self Assessment (SSA) at least once every 2-3 years.
	Pharmacy staff should review the content of the AIMS program located on the OCP website.
	Pharmacy staff should review the quarterly AIMS Response Team bulletin located on the OCP website

Category: Standards of Practice	
STANDARD	GUIDANCE
<p>The pharmacy will organize staffing and workflow to enable pharmacists to fulfill standards of practice and to optimize patient care.</p> <p>Reference: Model Standards of Practice for Canadian Pharmacists 48; OCP Standards of Operation for Pharmacies</p>	The pharmacy must have an environment and workflow process in place, including the provision of equipment and systems, which are necessary for the registrants to practice to their full scope and meet the standards of practice of the profession.
	The pharmacy must have an environment and workflow process in place, including the provision of appropriate staffing, that are necessary for the registrants to practice to their full scope and meet the standards of the practice of the profession.
	The pharmacy must have an environment and workflow process in place, including access to resources and training, that are necessary for the registrants to practice to their full scope and meet the standards of the practice of the profession.

	The pharmacy must have workflow processes in place to ensure accuracy in dispensing for patient safety.
	The pharmacy must have workflow processes in place to ensure prescription records are authorized at the time of dispensing and prior to release to the patient.
	The pharmacy must have workflow processes in place to ensure dispensing records are stored in such a manner that they are readily retrievable.
	The pharmacy must have workflow processes in place for pharmacy staff to 'flag' issues or opportunities to discuss with the patient such as: drug interactions, adherence, dosage changes, duplication of therapy, any other drug therapy problem or counselling to improve outcomes
	The pharmacy must develop a process for staff to gather relevant information to ensure patient files are complete and comprehensive including information such as indication, allergies, medical conditions, prescription history, use of over the counter/natural health products and changes to health status.
	The pharmacy must develop a process for staff to gather relevant information for new prescriptions to ensure patient files are complete and comprehensive including information such as indication, allergies, medical conditions, prescription history, use of over the counter/natural health products and changes to health status.
	The pharmacy must develop a process for staff to gather relevant information on refill prescriptions to ensure patient files are complete and comprehensive including information such as changes to allergies, medical conditions, prescription history, use of over the counter/natural health products, changes to health status and indication.
	The pharmacy must have a workflow process in place to ensure that opportunities for pharmacists to perform patient assessment, decision-making and communication are not bypassed. There must be a process in place, and adhered to, that ensures that the Pharmacist is alerted to these opportunities.
	The pharmacy must have a process in place to ensure all pharmacy staff registrants and trainees are provided with the appropriate level of supervision and/or delegation on a regular & ongoing basis.
	The pharmacy must have processes and procedures in place to support the safe and appropriate assessment and delivery of vaccines.

	The pharmacy must have operational policies and procedures in place that ensures that pharmacy professionals comply with their professional and legal obligations and are empowered to exercise professional judgement to optimize patient care.
	The pharmacy must develop a process to ensure a therapeutic check is conducted for patients receiving refill prescriptions, both on a regular basis and each time there is a change to the patient's medication regimen or health status to ensure ongoing appropriateness of therapy.
	The pharmacy must have processes and procedures in place to support transitions of care between hospital and community settings including proper medication reconciliation.
	The pharmacy must develop a process to ensure a therapeutic check is conducted for patients using multi- medication compliance aids, both on a regular basis and each time there is a change to the patient's medication regimen or health status to ensure ongoing appropriateness of therapy. This includes PRN medications.
	Pharmacy staff should review the Model Standards of Practice for Pharmacists located on the OCP website.
	Pharmacy staff should review the Code of Ethics located on the OCP website.
	The Designated Manager should review the Supervision of Pharmacy Personnel Policy located on the OCP website.
	The Designated Manager should review the Policy - Centralized Prescription Processing (Central Fill) located on the OCP website.
<p>Prescriptions that are dispensed will be accurately prepared, packaged and labelled according to legal and professional requirements.</p> <p>Reference: Model Standards of Practice for Canadian Pharmacists 1.37 - 1.42; OCP Standards of Operation for Pharmacies</p>	The pharmacy must ensure that all prescriptions are labelled as outlined in the Drug and Pharmacies Regulation Act (DPRA) including the trading name, ownership name, address and telephone number of the Pharmacy.
	The pharmacy must ensure that multi-compliance aids are labelled as per OCP Guideline including the information that would appear if each drug had been dispensed in individual vials, in addition to the description of the shape and colour of the tablet or capsule in a manner that meets the needs of the patient.
	Pharmacy staff should review the Guideline - <i>Multi Medication Compliance Aids</i> located on the OCP website.
	The Designated Manager should review the Policy - <i>Labelling Single Entity Drugs</i> located on the OCP website.

<p>Effective documentation and recordkeeping procedures will be in place that protect patient confidentiality.</p> <p>Reference: DPRA, O. Reg. 264/16, s. 19, 20 & 21; OCP Standards of Operation for Pharmacies</p>	<p>The pharmacy must ensure that personal health information of patients is protected as pharmacy services are received by patients</p>
	<p>The pharmacy must ensure that when disposing of confidential information that it be performed in a manner that ensures confidentiality.</p>
	<p>The pharmacy must either maintain records in a paper OR an electronic format OR it is moving towards a complete electronic record. All patient records, regardless of form must be readily retrievable and maintained appropriately for a time period not less than 10 years from the last professional pharmacy service. More information can be found on the OCP website.</p>
	<p>The pharmacy must develop a process to retrieve pertinent information regarding red flag scenarios/ drug therapy problems such as drug interactions, precautions and contraindications that have been managed (through discussion with the patient and/or prescriber) for future patient assessment.</p>
	<p>The pharmacy must have a process in place to document pertinent information in the patient record (i.e., gathered information, issues identified, decisions made, rationale and further follow up/ monitoring plan) in a way that is timely, readily retrievable, saved in a standardized fashion (like in a “patient chart”) and done consistently to ensure continuity of care and that patient outcomes are optimized.</p>
	<p>The pharmacy must develop a process to ensure that relevant information obtained during a medication review (i.e., use of other medications, over the counter products, natural health products, changes to health status and allergies) is entered into the patient record for future patient assessments.</p>
	<p>The Pharmacy must develop a process to ensure that relevant information obtained while delivering a service, which include important clinical documentation to support continuity of care, is entered into the patient record for future patient assessments.</p>
	<p>Pharmacy staff should review the Guideline - <i>Record Retention, Disclosure and Disposal</i> on the OCP website.</p>
	<p>Pharmacy staff should review the Fact Sheet - <i>Record Keeping and Scanning Requirements</i> on the OCP website.</p>
	<p>Pharmacy staff should review the Fact Sheet - <i>Releasing Personal Health Information</i> on the OCP website.</p>

Pharmacy staff should review the Information and Privacy Commissioner of Ontario's resource - *Circle of Care: Sharing Personal Health Information for Health-Care Purposes* on the OCP website

Category: Lock and Leave

STANDARD

The pharmacy has operational standards in place to ensure the Lock and Leave area completely restricts public access to all scheduled drugs.

Reference: [DPRA O. Reg 264/16, s.23](#)

GUIDANCE

The pharmacy must ensure that all Schedule III products are located inside the Lock and Leave area or in a locked section that is not accessible to the public in the absence of the Pharmacist.