Introduction

An overburdened healthcare system, the pharmacy profession’s expanded scope of practice, and increased pressures to manage the costs associated with drug distribution have created a demand for pharmacies to enhance their efficiency.

The use of centralized prescription processing (central fill) systems can support enhanced efficiency by freeing the pharmacy from labour-intensive distributive functions. However, the inappropriate use of these systems can create unanticipated negative consequences and compromise patient safety and care. Therefore, pharmacy owners, pharmacists, and particularly pharmacy managers have a professional responsibility to assure compliance with these Standards and to ensure that they have appropriate policies, procedures and quality assurance programs in place to address safety, accuracy, security and patient confidentiality.

Purpose

These Standards are created under the authority of the Registration, Licensing and Professional Accountability Regulations, s. 41 (1) to support pharmacies in collaborating with one another in the dispensing process.

Standards of Practice

Central fill refers to one or more technical activities undertaken by a central fill pharmacy at the request of an originating pharmacy in the processing or preparing of a drug order.

The central fill pharmacy is defined as a pharmacy licensed by the Nova Scotia College of Pharmacists (NSCP) that provides central fill services for an originating pharmacy.

The originating pharmacy is defined as the patient contact pharmacy licensed by the NSCP that uses a central fill pharmacy to process or prepare drug orders.

Centralized prescription processing can only occur in and between pharmacies physically located in Nova Scotia and accredited by the NSCP.

1. Responsibilities of Both Pharmacies

   1.1. Centralized prescription processing can only occur in and between pharmacies physically located in Nova Scotia and accredited by the NSCP.

   1.2. Pharmacists involved in central processing, the pharmacy managers and owners of both pharmacies are responsible for:

       1.2.1. Maintaining the Standards of Practice and meeting requirements of the legislation, NSCP policies and the Code of Ethics;
1.2.2. The provision of adequate security (such as the use of a secure courier service) for the safekeeping of the drugs, and to protect the confidentiality and integrity of patient information and product;

1.2.3. Accurate record keeping and labelling that is in compliance with legislative requirements;

1.2.4. Ensuring that the prescription drug order has been properly prepared; and

1.2.5. Maintenance of a mechanism for tracking the prescription drug order through the stages of the patient care and drug product preparation process, including information on pharmacy personnel involved.

1.3. The originating pharmacy must have a written agreement with the central fill pharmacy, explicitly outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract in compliance with federal and provincial laws and regulations, including these Standards.

1.3.1. The agreement will be signed by the owner and manager of the originating pharmacy and the central fill pharmacy.

1.3.2. When there is a change in ownership or management, in order for the central fill arrangement to continue, the new owner or manager must sign the agreement indicating their endorsement.

1.3.3. The agreement will be available to the NSCP upon request.

1.4. The originating pharmacy is responsible to inform the NSCP 30 days in advance of the intent to operate or utilize the services of a central fill pharmacy by submitting the appropriate and completed form provided by the Nova Scotia College of Pharmacist.

1.5. Centralized prescription processing of any drugs listed in the Controlled Substances Act (CDSA) (e.g. narcotics, controlled drugs, benzodiazepine and other targeted substances, etc.) and its regulations can only be undertaken:

1.5.1. In compliance with the CDSA and its Regulations; and

1.5.2. With express and specific authorization from Health Canada’s Office of Controlled Substances.

1.6. A policy and procedures manual of the central fill process will be maintained by both the central fill and the originating pharmacies. The manual will outline:

1.6.1. How patient confidentiality and the privacy of patient health information will be maintained in accordance with any provincial or federal legislation;

1.6.2. How the parties will comply with provincial and federal legislation, standards, Code of Ethics and regulatory policy;

1.6.3. The processes involved in the processing of each prescription, from the originating pharmacy to the central fill pharmacy and the return to the originating pharmacy for dispensing, including a
trail of signatures for every step of the process, as well as the procedure for auditing these processes:

1.6.4. The procedures for ensuring that all prescription labels meet the requirements set forth by the NSCP and the mechanism used to disclose to the patient all pharmacies involved in dispensing the prescription order, including identifying the pharmacies on the prescription label or auxiliary label:

1.6.5. How the central fill pharmacy will process the records of requests from the originating pharmacy and maintain them for the purposes of filing and record keeping. All records will be maintained at the central fill pharmacy in accordance with the Registration, Licensing and Professional Accountability Regulations:

1.6.6. The process to establish effective two way communication between pharmacies on pertinent patient, therapeutic or prescription information so that the central processing arrangement enables the dispensing of the prescription in accordance with the legislation and Standards of Practice, including the requirements pertaining to counselling, monitoring and follow-up; and

1.6.7. The continuous quality assurance program established jointly by both pharmacies that includes participation by both pharmacies. The CQA program will provide for objective and systematic monitoring of the quality and integrity of the process on a continuous basis to improve, maintain and support patient care, ensure patient safety and confidentiality, and resolve identified problems.

2. Responsibilities of the Originating Pharmacy (In addition to 1.)

2.1. The originating pharmacy (patient contact pharmacy) is the pharmacy that bears the responsibility, under the Pharmacy Act, for receiving the order from the patient or their agent and ensuring the medication is provided to the patient or their agent.

2.2. The originating pharmacy must ensure that systems which guard patient safety throughout the entire process are in place.

2.3. The prescription authority (i.e. the prescription) and documentation relating to the prescription and patient, submitted to and/or created by the originating pharmacy, remain with the originating pharmacy.

2.4. The originating pharmacy remains responsible for meeting all legislative requirements and the Standards of Practice on all prescriptions. This includes reviewing all prescriptions, identifying and resolving drug related problems, assuring the therapeutic appropriateness of the prescription, and undertaking counselling, monitoring and follow-up with the patient. This also includes ensuring that the patient is provided with all medications ordered and that any changes to the patient’s drug therapy that has occurred between the time the order is prepared and the time the order is released to the patient are managed.
2.5. All interactions with the patient, their agent and health care professionals related to the patient’s therapy are the responsibility of the originating pharmacy.

2.6. The originating pharmacy must ensure that the patient or their agent knows, understands and has consented to the fact that prescriptions may be processed by a central fill pharmacy and that there may be transfer of personal health information.

2.7. As well as the name of the originating pharmacy, the label on the prescription must indicate that the medication was prepared by a central fill pharmacy and not by the originating pharmacy. Options include, but are not limited to, the prescription label, an auxiliary label, or a code on the prescription label.

2.8. The distribution of the completed prescription directly to the patient may be delegated by the originating pharmacy to the central fill pharmacy only in the event of an urgently needed prescription.

3. Responsibilities of the Central Fill Pharmacy (In addition to 1.)

3.1. The central fill pharmacy is responsible for meeting all legislative requirements, Standards of Practice and the terms of the agreement with the originating pharmacy related to the accuracy of labelling, packaging, processing and record keeping of the drug order.

3.2. The central fill pharmacy is responsible for the safety and integrity of the drug product, including the maintenance of cold chain until it is received by the originating pharmacy. There must be an established process in place that gives assurance to the originating pharmacy of this integrity.

3.3. When the central fill pharmacy is preparing non-customary products (e.g., non-traditional compounded prescriptions), it is responsible for meeting the terms of the agreement pertaining to 1.6.6, including providing sufficient information to the originating pharmacy so that the originating pharmacy can meet its responsibilities set out in 2.4.

References

Drug Establishment License forms and applications information, Health Canada