New Brunswick College of Pharmacists Practice Directive

Centralized Drug Order Processing (Central Fill)

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PURPOSE

To enable efficient drug distribution systems within the practice of pharmacy in New Brunswick while assuring safety, accuracy, security and patient confidentiality for the protection of the public.

POLICY

Centralized Drug Order Processing (Central Fill) refers to the processing, by a *central fill pharmacy*, of a request from an *originating pharmacy* to prepare a drug order or to perform processing functions such as packaging medication to be dispensed by the *originating pharmacy* pursuant to a valid prescription.

The *central fill pharmacy* is defined as a pharmacy accredited by the New Brunswick College of Pharmacists (NBCP) acting as an agent of an *originating pharmacy* to fill or process a drug order.

The *originating pharmacy* is defined as a pharmacy accredited by the New Brunswick College of Pharmacists that uses a *central fill pharmacy* to fill or process drug orders. The originating *pharmacy* is responsible for the direct patient care.

1.0. RESPONSIBILITIES OF BOTH PHARMACIES

- 1.1. Central Drug Order Processing (Central Fill) can only occur in and between pharmacies physically located in New Brunswick and accredited by the New Brunswick College of Pharmacists (NBCP).
- 1.2. Pharmacists and pharmacy managers of both pharmacies are responsible for:
 - 1.2.1. Maintaining the Standards of Practice and meeting legislative requirements (including privacy legislation), NBCP policies/practice directives, and the Code of Ethics;
 - 1.2.2. The provision of adequate security measures to protect the confidentiality and integrity of product and patient information:
 - 1.2.3. Accurate record keeping and labeling in compliance with legislative requirements;
 - 1.2.4. Ensuring that the drug order has been properly prepared:
 - 1.2.5. Maintenance of a mechanism for tracking the drug order through the stages of the drug product preparation and patient care processes, including information on pharmacy personnel involved;
- 1.2.6 Implementation and maintenance of a continuous quality assurance program at each of their respective locations.

- 1.3. As well as the name of the *originating pharmacy*, the labeling must indicate clearly that the medication was packaged 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.
- 1.4. 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 agreement in compliance with applicable federal and provincial laws and regulations, including this policy.
 - 1.4.1. The agreement will be signed by the pharmacy manager of the *originating pharmacy* and of the *central fill pharmacy*.
 - 1.4.2. When there is a change in pharmacy manager (in either pharmacy), in order for the central fill arrangement to continue, both pharmacy managers must sign a new agreement indicating their endorsement.
 - 1.4.3. A copy of the agreement notification (a template is attached to this document) must be submitted to the New Brunswick College of Pharmacists as notification of the intent to operate a Centralized Drug Order Processing (Central Fill) operation.
- 1.5 Except as permitted in Section 35 of the *Narcotic Control Regulations*, Section G.03.005 of Part G of the *Food and Drug Regulations* and Section 55 of *the Benzodiazepines and Other Targeted Substances Regulations*, drugs listed in the Controlled Drugs and Substances Act (CDSA) and regulations (e.g. narcotics, controlled drugs, benzodiazepine and other targeted substances, etc.) cannot be processed by Centralized Drug Order Processing(Central Fill) until such time as the Office of Controlled Substances provides direction as to the manner in which centralized drug order processing can occur in compliance with the (CDSA) and its regulations.
- 1.6. Policy and Procedures Manual:

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. The steps involved in the processing of each drug order from the *originating pharmacy* to the *central fill pharmacy* and the return to the *originating pharmacy* for dispensing; documentation of the trail of signatures for every step of the process; as well as the auditing procedure for these processes;
- 1.6.2. The labeling system used to identify the pharmacies involved in preparing and dispensing the drug order;
- 1.6.3. 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. These records will be retained in either original form, or electronically at the *central fill pharmacy* for a period of not less than 15 years (as defined in Regulation);
- 1.6.4. The process to establish effective two-way communication between pharmacies on pertinent patient or prescription information;

- 1.6.5. The continuous quality assurance programs in place at both pharmacies involved in the central fill process which will objectively and systematically monitor the quality and integrity of the process and continuously review this data to:
 - maintain and improve drug order and prescription order safety and accuracy;
 - maintain, improve and support patient care;
 - ensure patient safety and confidentiality and;
 - · resolve identified problems.

2.0. RESPONSIBILITY OF THE ORIGINATING PHARMACY: (IN ADDITION TO 1.0)

- 2.1. The *originating pharmacy* is responsible to inform the NBCP 30 days in advance of the intent to operate or utilize the services of a *central fill pharmacy* by submitting directly to the NBCP, a copy of the agreement notification form that confirms it holds an agreement with a central fill pharmacy.
- 2.1.1 Notification of change of information originally provided on the central fill agreement will be submitted to the NBCP within seven (7) days of the change occurring.
- 2.2 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 his/her agent and providing the medication to the patient or his/her agent.
- 2.3. The *originating pharmacy* must ensure that systems which safeguard patient safety throughout the entire process are in place.
- 2.4. The prescription order and documentation relating to the prescription and the patient remain in the *originating pharmacy*.
- 2.5 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, and assuring the therapeutic appropriateness of the prescription.
- 2.6. All interactions with the patient, his/her agent and health care professionals are the responsibility of the *originating pharmacy.*
- 2.7 The *originating pharmacy* must ensure that the patient or his/her 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.

3.0. RESPONSIBILITY OF THE CENTRAL FILL PHARMACY: (IN ADDITION TO 1.0)

- 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 as defined in clause 1.4 related to the accuracy of labeling, packaging, processing and record keeping of the drug product preparation, including ensuring that the label accurately represents the contents of the package.
- 3.2. The *central fill pharmacy* is responsible for the safety and integrity of the drug product, including the maintenance of cold chain (if applicable), until 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 The *central fill pharmacy* must provide access to the *originating pharmacy* all records relevant to assessing the quality of service provided to the *originating pharmacy*. The *central fill pharmacy* must also allow authorized personnel from the *originating pharmacy* to conduct visits to the central fill production facilities to assess compliance with the terms of the agreement between the two pharmacies.

Bibliography

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(TEMPLATE) This template may be used in situations where two pharmacies wish to enter into an agreement whereby one pharmacy will provide the dispensing functions (central fill pharmacy) for another pharmacy (originating pharmacy).

CENTRAL FILL PHARMACY AGREEMENT NOTIFICATION FORM

Intent to Utilize Centralized Drug Order Processing

A copy of this agreement notification form must be filed with the NBCP.

A new notification form must be filed if any changes occur to the information provided below.

		-	_	
Date of Notification:				
Date of Notification.				
Bate of Helineation.				

THIS AGREEMENT IS BETWEEN:

Originating Pharmacy	Centralized Processing Pharmacy			
Pharmacy Name:	Pharmacy Name:			
Pharmacy Address:	Pharmacy Address:			
Pharmacy NBCP Accreditation Number:	Pharmacy NBCP Accreditation Number:			
Pharmacy Telephone Number:	Pharmacy Telephone Number:			
Pharmacy Email Address:	Pharmacy Email Address:			
Proposed Date for Start of Centralized Drug Order Processing:	Proposed Date for Start of Centralized Drug Order Processing:			
Pharmacy Manager Name:	Pharmacy Manager Name:			
Pharmacy Manager NBCP License Number:	Pharmacy Manager NBCP License Number:			

The agreement must include details of:

- the proposed service and the responsibilities and requirements of each pharmacy
- how the service will comply with federal and provincial legislation and how it adheres to the standards of practice and the New Brunswick College of Pharmacists Centralized Drug Order Processing (Central Fill) Practice Directive.

A copy of the agreement shall be kept on file at each of the pharmacies named above and shall be available to the NBCP upon request.

When there is a change in pharmacy manager the current agreement is no longer valid and the new pharmacy manager(s) must sign a new agreement indicating their endorsement and send a new agreement notification form to the NBCP within seven (7) days of the change.

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I must provide advance notice of the intent to operate or utilize the services of a central fill pharmacy and include the date it was provided to the New Brunswick College of Pharmacists in the agreement.

Originating Pharmacy – Signature of Pharmacy Manager	Central Fill Pharmacy – Signature of Pharmacy Manager			
Signed atDate	Signed atDate			

The originating pharmacy is responsible to provide the NBCP with 30 days advance notice of the intent to operate or utilize the services of a central fill pharmacy.

(Form adapted from Nova Scotia College of Pharmacists)