# Publication of Complaint Decision

**Title of Incident**

Medication Error: Dispensing five times the labeled concentration of medication.

**Name and Registration Number**

Ford's Pharmacy (Manager, Peter Ford, #1558)

**Incident Description**

A complaint was lodged by a member of the public as a result of a prescription dispensed from Ford's Pharmacy for baclofen suspension. It contained five times (10 mg/mL) the labeled (2 mg/mL) concentration. It was administered for 7 days at which time the long-term care home nurse realized the suspension appeared different than previous preparations. The Coroner implicated baclofen overdose as a contributing factor in the death of the patient.

**Summary of Findings**

Investigation of the incident found the following:

**Compounding Policy and Procedure**

- The error originated with an incorrectly selected compounding sheet in the compounding suite. This document was for baclofen 10 mg/mL
- There was no staff training or policy regarding initial and independent second check of the selection of compounding sheets to match the prescription requirement from the dispensary
- Compounding was adherent to USP compounding standards but those standards would not apply to functions relating to dispensing that occurred within the compounding area

**Error Reporting**

- Near-miss incidents were not being recorded
- The lack of near-miss reporting made it impossible to ascertain whether this type of error had occurred previously
- The investigator for the College, at the first visit, provided a documentation tool for tracking errors and near misses and suggested its implementation
- The use of a near-miss tool was implemented but use declined over the span of a year

Dr. Ford and his staff expressed remorse and took responsibility for the event. Dr. Ford and his staff were forthcoming and cooperative throughout the investigation process.

**Analysis**

The Complaints Committee found Dr. Ford to have failed to:

1. Ensure the pharmacy complied with the Regulations of the New Brunswick College of Pharmacists, in particular *20.2.*
2. Practice to the standards of the Model Standards of Practice for Canadian Pharmacists (2009, NAPRA), in particular sections:

- ***Expertise in Medication and Medication Use*** *Item 45*
- ***Collaboration*** *Item 5*
- ***Safety and Quality*** *Items 3, 7, 8, 12 and 14*

The Complaints Committee found the management of pharmacy practice at Ford's Pharmacy to constitute professional misconduct secondary to:

1. Lack of adequate process and procedure at baseline (prior to incident) with respect to safely delegating practice to non-pharmacist/non-professional staff within the compounding environment.

2. Subsequent deficiencies in fulfilling the expectations outlined in the College Inspector's and Pharmacy Practice Advisor's reports.

**Orders of the Panel**

A. **Reprimand:** The Complaints Committee considered Dr. Ford's initial laxity in managing quality assurance measures and subsequent inaction to address them to be an abrogation of responsibility to patient wellbeing and therefore reprimands him. As the manager of the pharmacy, Dr. Ford has important responsibilities to ensure the safe and effective practice within that environment.

B. **Counsel:** Recommendations for the pharmacy were provided to Dr. Ford that constitute a considerable degree of quality improvement. Given the history of delayed improvements, the Complaints Committee was not assured these measures had been fully implemented. Therefore, over the next 12-16 months, the College will intensively monitor the issues and recommendations identified and any others that arise during inspections.

Dr. Ford was ordered to review and reflect upon Part XX-Responsibilities and Delegation of the Regulations of the NBCP as it pertains to the expectations of a pharmacy manager.

C. **Publication:** An account of this complaint and decision where Peter Ford is named as the manager will be published once in a New Brunswick College of Pharmacists' newsletter and for a period of two years in the public domain. The account of this event will remain on Dr. Ford's file for two years.

D. Pay a fine in the amount of $ 5,000

E. Pay a portion of the costs of the investigation and complaint process in the fixed amount $ 8,000

**Messages for Pharmacy Professionals**

- This error was the result of a lack of safety systems rather than attributable to a single member of the pharmacy team
- Compounding presents an added layer of patient risk which must be mitigated through quality assurance measures
- Professionals should document all errors whether they reach the patient or not
- Liquid compounds should be expressed consistently as “X mg/mL” to reduce risk of incorrect identification
- A single strength of liquid compound should be used in the practice thereby eliminating 2 (or more) concentrations being available. In the rare case this is not possible, justify and document reasons for using a different strength. Measures should be taken to ensure any justifiable non-standard strength is not readily selected by staff
- The Institute for Safe Medicine Practices (ISMP) identifies strategies for mitigating risks of medication errors associated with liquid preparations in pediatric and adult populations. Review these communications and consider recommendations with the aim of implementation
- Managers’ quality management program (QMP) should:
  - Include written policy / procedures
  - Involve all staff in developing new and improving existing policy / procedures through assigning responsibility for research, educational communications and outcome measurement pertaining to policy / procedure
  - Specify regular performance evaluations of professional and non-professional staff
  - Ensure advance communication regarding changes to presentation of electronic or printed prescription documents aimed at staff or patients so that the reader is prepared for changes in appearance
  - Include regular staff meetings where actual errors in the practice are deconstructed and addressed and trends in errors (reported provincially or nationally) are discussed and prevention strategies identified
- The complainant expressed satisfaction with the decision of the Complaints Committee and hopes that the complaint outcome results in pharmacy-wide improvements to prevent future errors.

**Date Posted** February 1 2018

**Date for Removal** January 31 2020