

Health Canada “Manufacturing and Compounding Drug Products in Canada: A Policy Framework” Guidelines for P.E.I. Community and Hospital Pharmacists

October 2001

In response to pharmacists’ questions about “manufacturing” and “compounding”, Health Canada released *Manufacturing and Compounding Drug Products in Canada: A Policy Framework* in June 2000. The Policy Framework defines these terms and clarifies the kinds and quantities of medications or products that a pharmacist may compound. The Policy Framework outlines a number of important guiding principles, including:

- The professional practice of compounding must not be used to bypass the drug review and approval system.
- Patients must continue to have access to individualized drug therapy, which in some cases requires custom compound medications.
- Drugs which are available in Canada must be safe, effective and of high quality.

Following are some common questions and answers from the hospital perspective regarding “Manufacturing” and “Compounding”:

Q: What is the difference between “manufacturing” and “compounding”?

“Manufacturing” is a commercial activity that is regulated under the *Food and Drugs Act* and its Regulations, *Good Manufacturing Practices* (GMP) and other federal legislation. Manufacturers must have comprehensive risk management strategies in place and are subject to routine inspection by Health Canada. Manufacturers pay annual fees for Establishment Licenses, entitling them to fabricate, package, label, import, distribute or sell drug products to drug wholesalers, pharmacists and prescribers.

Compounding” is a professional activity performed by pharmacists pursuant to or in anticipation of a prescription for individual patients. Pharmacists are regulated by provincial regulatory authorities, and compounding is done in accordance with current standards of good pharmacy practice.

Q: Can we compound for patients in our hospital? What about other patients?

You may compound sterile or non-sterile products for patients with whom the hospital has an established pharmacist-patient-prescriber relationship. This includes:

- **Patients of your own hospital**, and patients of other hospitals or facilities under the same hospital management board.
- **Patients of another hospital**, if there is a formal agreement between two Boards, CEOs or pharmacies that respects the current standards of practice and defines the specific patient population to be served.

- **Patients of a community pharmacy**, if there is a formal agreement* between your hospital and a community pharmacy that respects the current standards of practice and defines the specific patient population to be served.

*Refer to Appendix A for sample formal agreement with a community pharmacy

Q: A hospital in a different health region has asked us to supply unit-dose packaged medications and IV admixtures for its inpatient use. Is this permissible? We have separate hospital Boards.

Yes, you may supply the compounded medications, provided your hospitals are in the same province and there is a formal agreement between the two pharmacies that respects the current standards of practice and defines the patient population to be served.

Q: Can we promote specialty compounding to the public, community pharmacies as a revenue-generator for our hospital or pharmacy?

No, the Policy Framework specifically prohibits promoting or advertising compounding services. You can receive compensation for compounding a product for another pharmacy but if your pharmacy or the hospital promotes or advertises that it compounds or repackages drugs, the full provisions of the Food and Drugs Act for selling and distributing drugs will apply.

Q: What can we compound? What quantities can we compound?

If you meet current “guidelines and standards that ensure quality and safety of the pharmaceuticals they compound”, you may:

- a) Compound sterile & non-sterile dosage forms that are not commercially available, e.g.:
 - compounded creams and ointments
 - suspensions, syrups, capsules or other unavailable dosage strengths or forms
 - sterile products in a strength or form not commercially available.
- b) Combine commercially available products, e.g.:
 - mix two or more topical products as directed by a prescription
 - aseptically mix together sterile pharmaceuticals into a final dosage form that may or may not be commercially available, e.g., reconstitute a vial of drug and inject the contents into a minibag within a centralized IV admixture (CIVA) program.
- c) Repackage medications in ready-to-administer or ready-to-dispense units.

The Policy Framework states that pharmacists may prepare “*limited quantities ... in anticipation of receiving a prescription*”. Compounding “inordinate” amounts (quantities in excess of prescriptions received or anticipated) is not permitted.

Q: Can we compound products in advance?

Yes, *bulk compounding* in anticipation of receiving prescriptions is permitted as long as the products are not commercially available and your pharmacy has a history of receiving valid prescriptions for the products.

Q: What can't we compound?

Pharmacists *may not* compound products that are commercially available in a ready-to-use form. You can not make generic copies of commercially available:

- topical products, e.g. hand lotions, antiseptic solutions.
- oral products such as pediatric suspensions or syrups
- parenteral products made from raw/non-sterile ingredients (e.g. making morphine 10mg/ml injection from morphine powder), although, as noted above, reconstituting a vial and adding the contents to an IV bag within a CIVA program is acceptable.

In addition, pharmacists may not compound:

- Investigational New Drugs (INDs), except as provided for within the terms and conditions of an IND submission filed with Health Canada.
- Products whose active ingredients are not commercially available in Canada, and are not emergency or investigational status.

Q: Can we create a formula so that our compounded product isn't exactly the same as the commercially available product (e.g. use a different flavor or strength)?

If the modification were merely to circumvent the Policy Framework, then no, this practice would not be permitted. This contravenes Policy Framework principle that *the professional practice of compounding must not be used to bypass the drug review and approval system.*

However, if the modification is for a legitimate clinical reason (e.g. your patient cannot tolerate the commercial flavoring or needs a pediatric strength that is not commercially available), this practice would be permitted. This satisfies the Policy Framework principle that *patients must continue to have access to individualized drug therapy, which in some cases requires custom compounded medications.*

Q: If premixed parenteral drugs are commercially available (e.g. antibiotics, KCl), may we mix these drugs ourselves in our CIVA program or are we obligated to buy the commercial product?

You are not obligated to buy a commercially available product if the end product can be assembled by mixing existing commercially available sterile products. However, you must compound them within the context of a program that meets “guidelines and standards that ensure quality and safety of the pharmaceuticals compounded”. For a hospital pharmacy, this requirement would be met through a formal IV admixture program with appropriately documented policies, procedures and quality assurance processes. As well, remember you are not permitted to compound inordinate amounts and you must have a history of receiving prescriptions for these items.

Q: We don't buy ready-to-use commercially manufactured parenteral products (e.g. KCl, heparin, lidocaine, dopamine bags). Because we don't have an IV admixture program in our hospital, nurses routinely mix these commercially available products. Should we continue this practice?

No, nurses cannot compound products that are commercially available in ready-to-use format. Nurses are not exempt from the guiding principles of the Policy Framework.

Commercially available IV products are manufactured in sterile facilities with stringent quality control, testing measures and standards. Pharmacists are permitted to aseptically mix

commercially available products within controlled circumstances and in accordance with current standards of practice. Neither of these conditions can be duplicated on a nursing unit.

Q: Are products sold by a commercial CIVA batching service considered to be “commercially available”?

No, these products are not “commercially available” from a manufacturer as defined in the Policy Framework. The batching service provider reconstitutes and mixes commercially available parenteral medications within the context of an IV admixture program for a pharmacy. The CIVA batching service must have a formal arrangement with the pharmacy, respecting the standards of practice and defining the specific patient population to be served. An arrangement between the hospital and a CIVA batching service is voluntary.

Q: What is the policy on repackaging?

You can repackage medications so that they fit into your medication distribution system. This includes repackaging medications into unit-doses, blister packaging or commonly prescribed quantities. Repackaging and labeling must meet current guidelines and standards that ensure the quality and safety of the repackaged medications.

However, don’t lose sight of the Policy Framework guiding principle *that professional practices must not be used to bypass the drug review and approval system*. Although not spelled out as a requirement *per se*, you should consider the spirit of the Policy Framework and consider purchasing:

- unit-dose-packaged medications where the commercial packaging meets the hospital’s format and labeling requirements
- small sizes of commercially packaged and labeled bottles of ward stock medications, rather than repackaging from bulk bottles.

The guiding principle from the Policy Framework is that *drugs which are available in Canada must be safe, effective and high quality*. Commercially packaged products are subject to rigid quality control measures, demonstrated stability in the packaging used, government-approved labeling and routine inspection.

Q: How do I get more information?

The full text of the Policy Framework is available on the Health Canada website (www.hc.sc.gc.ca/hpb-dgps/therapeut). Use the search function to locate the document title: *Manufacturing and Compounding Drug Products in Canada: A Policy Framework (June 2000)*.

You may also link into this information through the Napra website (www.napra.org) under Federal Legislation.

Appendix A

Sample Formal Agreement

Community General Hospital
123 Main Street
Beautiful Town, PE

Date

Mr. Joe Smith, Manager
Local Retail Pharmacy
222 Pine Avenue
Beautiful Town, PE

Dear Mr. Smith;

This letter will confirm our arrangement wherein Community General Hospital (CGH) pharmacy agrees to compound selected pharmaceuticals for Local Retail Pharmacy.

The hospital agrees to prepare compounded intravenous pharmaceuticals (in minibags or large volume IV bags as appropriate) for clients of Local Retail Pharmacy who are:

- discharged from CGH, and
- registered with the regional home care program.

CGH assures that these pharmaceuticals will be prepared under aseptic conditions, following the Canadian Society of Hospital Pharmacists' *Standards for Preparation of Sterile Products in Pharmacies*.

In accordance with the agreed-upon procedures, Local Retail Pharmacy will fax copies of intravenous home-care prescriptions to CGH pharmacy by noon daily, to ensure drug preparation by 1700 h daily. Local Pharmacy agrees to pick up the compounded pharmaceuticals from CGH by 1730 h daily. Dispensing to patients, in accordance with the P.E.I. Pharmacy Board's Regulations, will be done by Local Pharmacy.

Our fee for the compounding service will be \$x.xx per IV bag, plus the cost of the drug and the IV solution. The hospital will itemize the cost per bag, and invoice you monthly.

This agreement remains in force until terminated by either party. The hospital assumes no responsibility for the dispensing of the products after distribution to Local Pharmacy.

Sincerely,

Fred Brown, Pharmacy Manager, CGH

Agreed by:

Joe Smith, Pharmacy Manager, Local Pharmacy

Date

