Administering a Substance by Inhalation

Purpose:

This guideline outlines legislative requirements and expectations for pharmacy professionals administering substances by inhalation as authorized by the *Pharmacy Act* and in accordance with O. Reg. 202/94. It is meant to be used alongside the Standards of Practice, Standards of Operation, and Code of Ethics.

Definitions:

Informed Consent: Consent to treatment is informed if, before giving it, the person received the information about the nature, expected benefit, potential risks or side effects, other options and consequences of not having the treatment (or any information that a reasonable person in the same circumstances would require to make a decision about the treatment) and the person received responses to any requests for additional information (*Health Care Consent Act*).

Pharmacist: For the purposes of this document where the term 'pharmacist' is used it is inclusive of pharmacy interns and students, and subject to any terms, conditions and limitations on their certificates of registration. Where this is not the case, it will be clearly identified.

Guideline:

A pharmacy professional is authorized under the *Pharmacy Act* to perform the controlled act of administering a substance by inhalation in accordance with the requirements established by O. Reg. 202/94 ("the regulations").

Pharmacists are authorized to administer by inhalation:

- A substance included in Schedule 2 of O. Reg. 202/94
  - for the purpose of patient education and demonstration
  - for the purpose of managing medication therapy (i.e., treatment)

Pharmacy technicians are not authorized to administer a substance by inhalation.

To administer a substance by inhalation in any other circumstances, a pharmacy professional would require delegation of authority, such as a medical directive or direct order, from another regulated health professional.

Before administering a substance by inhalation, pharmacists must:

1. Assess the patient

The pharmacist must assess the patient to determine the appropriateness of the therapy. The decision to administer a substance is based on the individual patient's need, history, current health status, consideration of potential risks and benefits, and the pharmacist's professional judgment.

2. Assess their competency

The pharmacist must only administer a substance by inhalation when they can do so competently and safely by:

- Possessing sufficient knowledge, skill and judgment respecting the substance to be administered and the device(s) used to administer the substance
- Having sufficient understanding of the condition of the patient
- Having the resources necessary to meet their professional obligations and standards of practice
- Being of sound physical, emotional and mental capacity
- Addressing gaps or learning opportunities, identified through self- and/or peer-assessment, with continuing education and/or additional training

3. Assess the environment

The Standards of Operation require the premises, facilities, and layout – along with its equipment, technology and staffing – to support practice, to mitigate risks associated with the delivery of services, and to safeguard the health, safety and wellbeing of patients.

- Administration of a substance must take place in an environment that is clean, safe, private, and comfortable for the patient, in a way that protects their confidentiality and dignity
- Safeguards and resources must be available to safely manage the outcome after administration

Community pharmacy owners and Designated Managers are expected to implement the Guiding Principles for Shared Accountability to support a suitable practice environment, which includes the physical working space as well as the practice culture, operating procedures, workflow, and resources available.

4. Obtain informed consent to treatment

Prior to administering a substance, the pharmacist must receive informed consent from the patient or their authorized agent.

- Consent is contingent on an individual's capacity to understand why and for what the consent is being sought
- There is no minimum age of consent in Ontario
- Consent may be express or implied
    - Express consent may be provided in writing or provided verbally and documented
    - A pharmacy professional may determine that implied consent is provided, based on the patient's action(s) or inaction in the circumstances at hand
- Confirmation that informed consent was received by the pharmacist must be documented on the patient record

5. Ensure Infection Prevention and Control (IPAC) Procedures are in place

Pharmacies must have evidence-based Infection Prevention and Control (IPAC) measures in place to prevent or reduce the risk of transmission of microorganisms to patients, the public, and personnel.

- A 'routine precaution' approach should always be undertaken, with all patients. This includes proper hand washing and, when appropriate, use of personal protective equipment.
    - Refer to Routine Practices and Additional Precautions for Preventing the Transmission of Infection in Healthcare Settings from the Public Health Agency of Canada (PHAC)
- In the hospital setting, the organization's IPAC Committee is responsible for establishing IPAC policies and procedures
- In the community setting, the Designated Manager is responsible for establishing IPAC policies and procedures

For additional information, refer to Appendix B, and the Ministry of Labour, Training and Skills Development for Occupational Health and Safety IPAC-related resources

6. Confirm proper storage

The pharmacist must determine that the substance is safe to administer by evaluating the stability and integrity of the drug.

- Procedures must be in place to ensure that temperature-sensitive drug products are received and stored according to manufacturer's recommendations.
- Please refer to the Guideline — Protecting the Cold Chain for further information

After administering a substance by inhalation, pharmacists must:

7. Monitor the patient

The pharmacist must ensure that the patient is monitored for adverse reactions in an appropriate location, for a sufficient amount of time.

- Refer to the Product Monograph for warnings, precautions and adverse reactions.
- Should a reaction occur, it should be immediately brought to the attention of the pharmacist for timely assessment of the patient and to determine the appropriate course of action.

8. Document and notify

Document

The relevant details of the administration of a substance must be documented on the patient record. This includes confirmation that informed consent was received by the pharmacist along with a brief overview of the information that was provided to the patient concerning the risks, benefits, and potential side effects.

Pharmacy professionals are expected to review and adhere to the College's Record Retention, Disclosure and Disposal Guideline and Documentation Guidelines.

Notify

Notification of the administration of a substance should be sent to both the prescriber of the substance (if any), as well as the patient's primary care provider (if any, and if known):

- Where a substance is administered for education or demonstration purposes, notification *may* occur if the pharmacist determines the administration was clinically significant or important for continuity of care.
- Where a substance is administered for treatment purposes, notification *must* occur within a reasonable time.

Documentation sent to the other health care professionals must be concise and include pertinent details respecting administration to ensure the patient record is complete.

Patients who do not have a prescriber (i.e., have been administered a non-prescription substance) or a primary care provider should be advised that they, or another health professional providing care to them in the future, are entitled to access this information at any time. Patients may also wish to have a copy of the documentation from their record.

Legislative References:

- *Pharmacy Act*

- PART VII.3, O. Reg 202/94

Additional References:

- Policy — Medical Directives and the Delegation of Controlled Acts
- Infection Prevention and Control Practice Tool
- Patient Assessment Practice Tool

APPENDIX A: Inhalation versus Intranasal Administration[i]

The inhalation route of administration delivers a substance whose intended site of deposition is the lower respiratory tract epithelium (bronchi/lungs), through the trachea and past the oropharyngeal region.

- Substances may be inhaled through the mouth (e.g., using metered dose inhalers, dry powder inhalers, etc.) or through the mouth and nose (e.g., using a nebulizer).

The intranasal route of administration delivers a substance whose intended site of deposition is the mucous membranes lining the nasal passages.

With either route, the purpose of administering the substance may be for a systemic effect as it enters the bloodstream, or for a local effect. Unlike administering a substance by inhalation, intranasal administration of a substance is not a controlled act governed by legislation and may be performed by anyone provided they have the knowledge and skill to do so safely.

- Pharmacy professionals administering a substance intranasally are still required to meet the Standards of Practice, Standards of Operation, and Code of Ethics, and the expectations of this guideline.

APPENDIX B: Additional IPAC Information

Ontario's Provincial Infectious Diseases Advisory Committee on Infection Prevention and Control (PIDAC-IPC) advises Public Health Ontario and produces best practice documents for healthcare organizations, such as:

- Best Practices for Environmental Cleaning for Prevention and Control of Infections in All Health Care Settings
- Best Practices for Hand Hygiene in All Health Care Settings, 4th Edition
- Infection Prevention and Control for Clinical Office Practice
    - IPAC Checklist for Clinical Office Practice

Ontario's Public Health Units have the authority to conduct inspections/assessments/investigations related to infection prevention and control (IPAC) practices.

- In the event of a communicable and/or infectious disease transmission risk related to the conduct of a pharmacy professional, the regional board of health will involve the College on the matter, per the Infection Prevention and Control Complaint Protocol

Implementation:

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Revision History:

VERSION #	DATE	ACTION
1	October 2012	Expanded Scope of Practice Orientation Manual.
2	February 2018	Guideline extracted from manual.
3	December 2020	Review, reformatting and inclusion of scope changes from O. Reg. 202/94.
4	November 2021	Inclusion of scope changes for technicians from O. Reg. 202/94.

5	July 2023	Guideline extracted from Administering a Substance by Injection or Inhalation Guideline. Inclusion of scope changes to O. Reg. 202/94.

[i] Guidance for Industry - Pharmaceutical Quality of Inhalation and Nasal Products. Health Canada; 2006 https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/chemical-entity-products-quality/guidance-industry-pharmaceutical-quality-inhalation-nasal-products.html