Newfoundland and Labrador Pharmacy Board

Standards of Practice

Supplemental Standards of Practice for Schedule II and III Drugs

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Supplemental Standards of Practice for Schedule II and III Drugs

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National Association of Pharmacy Regulatory Authorities
Association nationale des organismes de réglementation de la pharmacie

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Introduction

On May 12, 1995 the National Association of Pharmacy Regulatory Authorities (NAPRA) adopted Harmonized Drug Schedules in Canada: the Final Report of the Canadian Drug Advisory Committee (CDAC). The report included background information on the drug schedule harmonization process in Canada, a discussion of the cascading principles for drug scheduling, an outline of the scheduling factors, and recommendations for three schedules of drugs. One of the recommendations of the committee was the need to establish standards of practice for the pharmacist when consulting on the use of medications in each drug schedule. The original Standards of Practice[1] were adopted by the NAPRA council in 1995.

The drug schedules are based on cascading principles. First, a drug is assessed against factors for Schedule I. If sufficient factors pertain, it remains in Schedule I. If not, the drug is assessed against factors for Schedule II and so on. Schedule II drugs require professional intervention from the pharmacist at point of sale and possibly referral to another practitioner. The drugs must be retained in an area that does not allow for self selection. Schedule III medications may present certain risks to specific populations. They are sold in a self selection area of the pharmacy under the direct supervision of a pharmacist, subject to any local professional discretionary requirements which may increase the degree of control. This area is known as the "professional services area". The pharmacist is accessible and approachable to assist the patient in medication selection. A description of the factors for Schedule II and III, currently used by the National Drug Scheduling Advisory Committee (NDSAC), is included in Appendix A.

Since 1995, the pharmacy environment has changed regarding many practice issues: prescribing by pharmacists, increased access to consumer information about self-medication, and new drugs with potential for abuse. These changes, coupled with the development of a new document entitled *Model Standards of Practice for Canadian Pharmacists (April 2003)*, necessitated the development of these Supplemental Standards of Practice for Schedule II and III Products. They were prepared with the input of the National Advisory Committee on Pharmacy Practice and the National Advisory Committee on Pharmacy Operations (see Appendix B) between August 2004 and March 2005. These Standards then were reviewed by the NAPRA Executive Committee and the Council of Pharmacy Registrars of Canada before being sent to 19 academic, regulatory, and professional organizations for external review. The NAPRA Board of Directors adopted the Supplemental Standards of Practice for Schedule II and III Drugs in June 2005.

[1] Allen, B.E., Suveges L.G., Standards of Practice – Nonprescription Drugs: A Report to NAPRA [Endorsed October 1995]

Standard #1

The pharmacy manager shall ensure that nonprescription products are located in the area of the pharmacy which is consistent with the appropriate drug schedule classification stated in the legislation.

- Schedule II drugs will be located in the prescription service department or in an area adjacent to the prescription service department ensuring there is no opportunity for self selection by the patient.

- Schedule III drugs shall be located in an area adjacent to the prescription service department. This area shall provide self selection to the patient but also the opportunity for patient-pharmacist consultation.

Compliance Requirements

- The pharmacy manager shall ensure that pharmacy personnel are knowledgeable regarding:
  - the availability and location of Schedule II, Schedule III, and unscheduled products;
  - the reasons for the location of products; and
  - the necessity of pharmacists to consult with patients about Schedule II products.

- The pharmacy manager shall ensure that when written information is available, it is made available to the patient and is easily accessible.

- The pharmacy manager shall encourage patients to access the pharmacist. This may be done through signage or by assigning a pharmacist to be physically located in the nonprescription drug area.

- The pharmacist shall be easily distinguished from other pharmacy personnel.

- Pharmacy personnel shall refer all health related questions to the pharmacist.

Standard #2

The pharmacist shall respect the patient's right to privacy and confidentiality.

Compliance Requirements

- The pharmacist shall consult in an area where the patient feels comfortable. This could be a private consultation area, a semi-private area, or a quiet, secluded portion of the pharmacy.

Standard #3

When the patient requests a consultation regarding a Schedule II or III product, the pharmacist shall collect information to assess the patient's knowledge and needs before providing advice.

Compliance Requirements

- The pharmacist shall introduce themselves to patients seeking advice or patients exhibiting behavior suggesting confusion over product selection.

- The pharmacist shall question the patient regarding:
  - the symptoms or condition being treated;
  - the history of the complaint including, but not limited to, length of time symptoms have been present, other therapies tried, and seriousness of illness;
  - the patient's pertinent medical history including, but not limited to, past/present medications, current disease states, sensitivities, allergies and adverse reactions, dietary restrictions; and
  - confirmation of pregnancy, possible pregnancy, or breast feeding.

- The pharmacist shall consider all the information before recommending a therapy for the patient, including but not limited to:
  - potential or actual drug interactions with current medications; and
  - potential or actual age/food/disease related interactions.

- The pharmacist shall use other methods to determine health status, as per provincial law, such as:
  - available lab values;
  - other health indicators, such as blood pressure; and
  - referring to the patient's medication profile or electronic health record, if appropriate.

- The pharmacist shall refer the patient to another health care professional when the pharmacist has deemed the condition to be one of a serious nature, is unsure of the diagnosis, or cannot be treated appropriately with non-prescription medications.

- Once the pharmacist recommends a treatment, they shall advise the patient to contact the pharmacist, or another health care professional if there is no improvement, or worsening of symptoms.

- When the patient asks for a product by name the pharmacist shall use this opportunity to assess the patient's knowledge about the product and provide additional information if required.

Standard #4

The pharmacist shall take the necessary steps to fulfill their professional obligations when recommending Schedule II, Schedule III, or unscheduled products.

Compliance Requirements

- The pharmacist shall provide the following information to the patient:
  - name of the drug(s) and dosage;
  - expected length of therapy;
  - expected benefit(s) and when improvement shall be noticed;
  - adverse effects, allergic reactions;
  - expected outcomes of the disease process and suggested therapy;
  - nonpharmacological measures, if any; and
  - an alternate plan if the therapy is not palliative or the symptoms change or worsen.

Standard #5

The pharmacist shall document the patient interaction on the patient profile if deemed appropriate.

Compliance Requirements

- Documentation shall occur as part of ongoing therapy on the patient profile.

- The pharmacist is responsible for documenting the interaction or may delegate the documentation to other personnel.

- The documentation shall include, but not be limited to:
    - name of individual;
    - contact information;
    - allergies, sensitivities;
    - medical conditions;
    - recommended therapy;
    - counseling provided;
    - outcomes expected;
    - follow up date if required;
    - communication with other health care professionals as appropriate for continuity of care or if abuse is suspected; and
    - other information pertinent to the situation that is necessary for continuity of care.

Appendix A

Factors Considered by NDSAC for National Drug Schedule Recommendations

Factors for Schedule II

1. The initial need for a drug is normally identified by the practitioner, in addition chronic, recurrent, or subsequent therapy must be monitored by the pharmacist.

2. The drug must be readily available under exceptional circumstances when a prescription is not practical.

3. The drug is intended for administration in a health care setting or under direction of a health care professional, or is in an injectable dosage form and is not otherwise included in Schedule I.

4. Evidence of abuse of the drug has been reported, due to its inherent pharmacological action which has the potential for abuse.

5. The selection of the drug requires intervention by the pharmacist to confirm that an appropriate self-assessment has been made by the patient.

6. Use of the drug may delay recognition or mask the symptoms of serious disease.

7. The drug may cause important adverse reactions, including allergies, or interacts with other drugs, foods, or disease states that cannot be adequately addressed through product labeling.

8. Use of the drug requires reinforcement or an expansion of the direction for use through pharmacist-patient dialogue.

9. The drug is a new ingredient for self medication and monitoring by the pharmacist is necessary to facilitate observation and reporting of any unexpected event.

10. The maximum labeled dosage directions exceed the generally accepted or usual limits for Schedule III status.

Factors for Schedule III

1. The initial need for the drug is normally identified by the patient, physician, or pharmacist, but chronic, recurrent, or subsequent therapy can be monitored by the pharmacist.

2. The maximum recommended duration of use of the drug is limited and specified on the product label.

3. The maximum recommended duration of use of the drug is not specified on the label, but continued use may delay the recognition or mask the symptoms of serious disease.

4. The drug is used to treat a persistent, chronic, or recurring condition and the availability of the pharmacist to provide advice can promote appropriate use.

5. The drug is used for self-treatment of self-limiting ailments; however, where product selection has been identified as likely to cause patient confusion and the availability of the pharmacist to provide advice can promote appropriate use.

6. The drug demonstrates adverse effects, including allergies, or interacts with other drugs, foods, or disease states that can be identified in product labeling, but appropriate product selection and explanation of risk may require the advice of the pharmacist.

7. The drug is a new ingredient for self-selected self-medication and the availability of the pharmacist to provide advice can promote appropriate use.

8. The drug has inherent pharmacologic action which has the potential for non-medical use which may result in adverse patient outcomes.

9. The maximum labeled dosage directions exceed the generally accepted or usual limits for unscheduled status.

Appendix B

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