



SASKATCHEWAN
COLLEGE OF
PHARMACISTS

Emergency Post-Coital Contraception

Standards and Guidelines for Pharmacists Prescribing

**October 1, 2003
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Changes to the law in Saskatchewan (Appendix A) allow the pharmacist to prescribe emergency post-coital contraception (emergency contraception). These changes also specify the conditions under which this can occur. The following standards and guidelines expand upon these conditions, and describe the standards pharmacists are expected to follow.

Eligibility

Only properly trained licensed pharmacists may prescribe emergency contraception. This means successful completion of programs accredited for at least 3.0 CEUs that aim to ensure the competency of pharmacists to prescribe emergency contraception and meet the following learning objectives:

- Essential components of an assessment for a woman requesting EPC
- Ensure adequate education of patients requesting EPC
 - appropriate indication for use
 - mechanism of action
 - efficacy & safety
- Differentiate prevention of pregnancy from pregnancy termination
- Compare the available products with respect to safety and efficacy

Acceptable programs include those offered by the Continuing Professional Development for Pharmacists Unit (CPDP), College of Pharmacy and Nutrition, and the Canadian Pharmacists Association.

Pharmacists must follow the protocols described in the training.

Documentation

Bylaw 14.13.10.3 in Appendix A describes the documentation and record keeping requirements. Therefore, generating a prescription similar in format to a verbal prescription received from a physician, and recording the prescription in the patient's profile should normally meet these requirements.

Members should also document the service. As options, model forms are attached. Select the most suitable form(s):

- "EPC Assessment/Counselling" provided by CPDP;
- "Informed Consent for Emergency Contraception" and "How to Use Emergency Contraceptive Pills - Patient Information" reprinted with permission from the College of Pharmacists of British Columbia. They are also available by following the links at <http://www.bcpharmacists.org/>.

Planned Parenthood and other agencies highly recommend that these, or other forms with similar information, be used routinely to assure proper assessment and patient understanding of appropriate follow up.

Consent and Minors

Adult patients are able to provide consent for treatment if it is informed and voluntary. For minors, the mature minor rule applies. A pharmacist may provide minors with emergency contraception without parental or guardian consent if the pharmacist determines that the minor is of sufficient intelligence and understanding of the nature of the proposed health care to be capable of giving consent, is able to fully appreciate the nature and consequences of receiving the proposed treatment, and is able to communicate a health care decision respecting the proposed treatment.

Duty to Report

When a pharmacist prescribes emergency contraception, bylaw 14.13.10.4 requires the pharmacist, with the patient's consent, to advise the patient's physician as soon as possible. If the patient does not have a physician, the pharmacist may still prescribe without advising any physician.

If a patient, who is a minor, requesting emergency contraception discloses that unwanted sexual activity has occurred, the pharmacist is compelled by *The Emergency Protection for Victims of Child Sexual Abuse and Exploitation Act* and *The Child and Family Services Act* to report the incident to a proper authority such as a police officer. These Saskatchewan Statutes require reporting to a child protection officer or a police officer where any person, including a pharmacist, has reasonable grounds to believe that a child has been or is likely to be subjected to sexual abuse. Various factors govern reporting and each circumstance must be judged upon its own merits. For example:

- 1) Under *The Emergency Protection for Victims of Child Sexual Abuse and Exploitation Act*:
 - a justice of the peace or judge may issue emergency protective intervention orders to protect a child victim (a person actually or apparently under 18 years of age) from sexual offenders;
 - any person, who has reasonable grounds to believe that a child has been or is likely to be subjected to sexual abuse, is required to report as described above;
- 2) Under *The Child and Family Services Act*:
 - a child (an unmarried person actually or apparently under 16 years of age) is deemed to be in need of protection when a parent's act or omission, has caused, is causing or is likely to cause the child to, amongst other things, be exposed to harmful interaction for a sexual purpose, including prostitution or conduct specified within the meaning of the *Criminal Code*
- 3) Under the *Criminal Code*
 - the legal age of consent is 14 years of age. A female who is 12 or 13 may still consent to sexual activity where: (a) her partner is at least 12 but less than 16; (b) her partner is less than two years older than she is; (c) her partner is neither in a position of trust nor is the female in a relationship of dependency with her partner.

When a pharmacist has reasonable grounds for believing that sexual abuse has, or is likely to occur, or if a child or minor is, or is likely to be exposed to inappropriate sexual activity, the pharmacist must report to the proper authority. Reasonable grounds are considered to be a *bona fide* belief in a serious possibility based upon credible evidence and more than suspicion.

Confidentiality and Privacy

Where a legal duty to report exists, privacy legislation allows the pharmacist to disclose the pertinent information without patient consent to a proper authority. Disclosure must be limited to the relevant information collected during the normal course of providing service. Relevant means only the information that was collected and forms the grounds to believe that a legal duty to report exists. Pharmacists cannot take extraordinary measures to invade the privacy of the individual to determine if this duty exists. Pharmacists must be careful about seeking information beyond the usual questions. Also, no other information about the patient or from the records in the pharmacy can be disclosed unless lawful authority exists (i.e. under a warrant or subpoena).

Because of its sensitive nature, the pharmacist must provide emergency contraceptive services in a positive, non-judgmental manner that protects the privacy of the individual and confidentiality of the information provided. It is recommended that interactions with the patient occur in a private area of the pharmacy. For further information, consult "Patient Confidentiality and the Release of Confidential Records" in the Pharmacy Reference Manual or at <http://napra.ca/pages/skPharmacyReferenceManual/default.aspx>.

Advertising, Public Awareness and Referrals

Pharmacies may advertise the availability of emergency contraceptive services in any media according to SCP bylaw 14.12. This means that advertising must:

- not diminish the integrity of the profession;
- not be false, misleading, fraudulent, deceptive, ambiguous or confusing;
- be relevant to the public's ability to make an informed decision;
- be verifiable by facts;
- not advertise fees unless an approved sign is used and it completely discloses fees and services paid by the purchaser and others.

SCP will provide to interested parties, such as Regional Health Authorities and Planned Parenthood, lists from our records of pharmacies offering this service. For this reason, and if the pharmacy advertises the availability of services, reasonable steps must be taken to ensure that a licensed pharmacist eligible to provide the service is on duty at all times that the pharmacy is open to the public. If a qualified pharmacist is unable to be on duty, then pharmacists must be able to refer the patient to the nearest pharmacy of the patient's choice where the service can be provided at that time. Please refer to the SCP web site: <http://napra.ca/pages/skEmergencyContraceptionPrograms/default.aspx> for the list of pharmacies.

Compensation

Usual and customary drug costs and fees for service may be charged in accordance with the guidelines of the Representative Board of Saskatchewan Pharmacists as may be negotiated with third parties such as the Saskatchewan Prescription Drug Plan and the Non-Insured Health Benefits Program of Health Canada.

Objections

Pharmacists who object to providing these services must comply with the “Statement Regarding Pharmacists’ Refusal to Provide Products or Services for Moral or Religious Reasons” found in the Pharmacy Reference Manual or at:
<http://napra.ca/pages/skPharmacyReferenceManual/default.aspx>

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Appendix A

Excerpts of Amendments to *The Pharmacy Act, 1996*, *The Drug Schedules Regulations, 1997* and the *Bylaws of the Saskatchewan College of Pharmacists Allowing Pharmacist Prescribing of Emergency Post-Coital Contraception*

1) Bill 22 “An Act to amend *The Pharmacy Act, 1996*”

Section 14 (2) which states in part “Subject to this Act, regulatory bylaws may be made pursuant to section 13 for the following purposes” is amended by adding the following clause after clause (i):

“(i.1) governing the prescribing and dispensing of drugs by members”.

2) The Drug Schedules Regulations, 1997

Add the following after section 9:

“9.1 A licensed pharmacist may, subject to the terms, conditions and restrictions on his or her license, prescribe any drug in Schedule I that is an oral contraceptive if, in the circumstances, the provision of a sufficient quantity of the drug for emergency contraception is required to meet the patient’s needs.”

3) Bylaws of the Saskatchewan College of Pharmacists

1.0 Bylaw 14.13.1 is repealed and replaced by:

14.13.1 Except as provided otherwise in section 14.13.10 and in the Narcotic Control Regulations or the Food and Drug Regulations (Canada), no pharmacist shall sell a substance containing a Schedule I drug unless:

- the sale is made pursuant to a verbal or written prescription received by the pharmacist; and
- where the prescription has been transferred to the pharmacists under section 14.13.4, the requirements of section 14.13.5 have been complied with.

2.0 Bylaws 14.13.10 and 14.13.10.1 are repealed and replaced by:

14.13.10 Sale of Schedule I Drugs Without a Prescription

14.13.10.1 A pharmacist may sell a Schedule I drug, without having received a prescription therefore, to:

- a) a drug manufacturer;
- b) a practitioner as defined in the Act who is authorized to prescribe the drug or use the drug in the practice of his profession;
- c) a drug wholesaler;
- d) a licensed pharmacist; or
- e) a publicly operated pharmacy;
- f) upon receipt of a written order signed by a duly authorized representative and he shall retain the written order for the drug for a period of at least two years from the date of filling the order.

14.13.10.2 Upon having received training as approved by Council, a pharmacist may prescribe and sell a Schedule I drug to a member of the public, in the absence of a prescription from a medical practitioner, when under emergency or urgent circumstances the pharmacist deems it to be in the best interests of the patient to provide a reasonable quantity of an oral contraceptive sufficient to meet the patient's needs and a diagnosis or assessment by a practitioner for emergency contraception is not required, as the pharmacist is able to assess the patient's needs for emergency contraception.

14.13.10.3 When a pharmacist:

- a) sells a Schedule I drug pursuant to section 14.13.10.2, he shall make a written record containing the following information:
 - i) the date and file reference number for the sale;
 - ii) the name and address of the person for whose benefit the drug is given;
 - iii) the proper name, common name or brand name of the specified drug and the quantity thereof;
 - iv) his name;
 - v) the directions for use;
 - vi) the name of the medical practitioner if designated by the patient; and,
 - vii) the reasons and circumstances under which the sale is made.
- b) prescribes a Schedule I drug pursuant to section 14.13.10.2, he shall make a written record containing the following information:
 - i) the date;
 - ii) the name and address of the person for whose benefit the drug is given;
 - iii) the proper name, common name or brand name of the specified drug and the quantity thereof;
 - iv) the drug's strength where appropriate;
 - v) the dosage;
 - vi) the amount prescribed;
 - vii) explicit instructions for patient usage of the drug; and,
 - viii) his name and signature,

and he shall retain this written record for a period of at least two years from the date of selling the drug.

14.13.10.4 When a pharmacist prescribes and sells a Schedule I drug pursuant to section 14.13.10.2, he shall, with consent of the patient, communicate his decision to the medical practitioner at the earliest possible opportunity.

EPC Assessment / Counselling

Date:

Name:		Minor? <input type="checkbox"/> Yes <input type="checkbox"/> No	Time since coitus:	LMP:
Additional episodes of unprotected coitus since LMP: <input type="checkbox"/> Yes <input type="checkbox"/> No	Current form of regular birth control <input type="checkbox"/> OCP <input type="checkbox"/> Depo-provera <input type="checkbox"/> Diaphragm <input type="checkbox"/> Condoms <input type="checkbox"/> IUD <input type="checkbox"/> Other <input type="checkbox"/> None		Circumstance of the unprotected coitus	
Current Medications / Herbals				
EPC Provided? <input type="checkbox"/> Yes <input type="checkbox"/> No	Product Recommended <input type="checkbox"/> Levonorgestrel (0.75 mg iipo 0D) <input type="checkbox"/> Yuzpe – Ovral (ii q12h) <input type="checkbox"/> Yuzpe – OCP (___ q12h)			
Education Provided		Other Issues (check relevant ones only)		
<input type="checkbox"/> Name of product		<input type="checkbox"/> Ongoing contraception		
<input type="checkbox"/> Mechanism of action		<input type="checkbox"/> STD counselling		
<input type="checkbox"/> Directions for correct use		<input type="checkbox"/> Sexual assault		
<input type="checkbox"/> Efficacy				
<input type="checkbox"/> How to know if product is effective				
<input type="checkbox"/> What to do if it is not				
<input type="checkbox"/> Side effect information				
Follow up Planned				
<input type="checkbox"/> None <input type="checkbox"/> With patient <input type="checkbox"/> With MD <input type="checkbox"/> Referral to another HCP / agency				

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