Prescribing Drugs

APPROVED BY COUNCIL: December 2012
REVIEWED AND UPDATED: February 2016
KEY WORDS: Prescribing, Electronic Prescribing (ePrescribing), Drug, Drug Sample, Narcotic, Opioid, Controlled Substance, Monitored Drug, Electronic Medical Record (EMR), Physician-Patient Relationship, Clinical Assessment, Consent, Medical Record, Audit, Refill, Circle of Care, Unapproved Drugs, Preventing Medication Errors, Prescription Drug Abuse, Treatment Agreement

RELATED TOPICS: The Practice Guide: Medical Professionalism and College Policies, Medical Records, Confidentiality of Personal Health Information, Consent to Medical Treatment, MD Relations with Drug Companies, Dispensing Drugs, Delegation of Controlled Acts, Treating Self and Family Members, Mandatory and Permissive Reporting, Disclosure of Harm, Ending the Physician-Patient Relationship

Narcotic Control Regulations, C.R.C. c. 1041.
Food and Drugs Act, R.S.C, 1985, c. F-27.
General, O. Reg., 114/94.
General, O. Reg., 58/11.
Drug Interchangeability and Dispensing Fee Act, R.S.O. 1990, c. P.23.
General, O. Reg., 381/11.
Personal Health Information Protection Act, 2004, S.O. 2004, c. 3, Schedule A.

REFERENCE MATERIALS: See Back Page

COLLEGE CONTACT: Public and Physician Advisory Service
INTRODUCTION
Prescribing drugs is a standard component of most physicians’ practices. It is an important area of practice that requires appropriate knowledge, skill and professional judgment. To improve patient safety when prescribing, this policy sets out expectations for physicians who prescribe drugs.

Prescribing is also governed by a complex legislative framework. In addition to the expectations set out in this policy, physicians must be aware of, and comply with, relevant requirements for drugs and prescribing set out in law. This includes, but is not limited to, requirements contained in the Food and Drugs Act,1 Controlled Drugs and Substances Act,2 Narcotics Safety and Awareness Act, 2010,3 and Drug and Pharmacies Regulation Act.4

The first section of this policy contains general expectations for prescribing that always apply when physicians prescribe a drug. The second section highlights issues and expectations for specific prescribing circumstances that apply when such circumstances exist. The last section of the policy contains guidelines for physicians who prescribe drugs.

PRINCIPLES
The key values of professionalism – compassion, service, altruism and trustworthiness – form the basis for the expectations set out in this policy. Physicians embody these values and uphold the reputation of the profession by:

1. Acting in patients’ best interests;
2. Demonstrating professional competence, which includes maintaining the medical knowledge and clinical skills necessary to prescribe appropriately. This involves keeping abreast of current developments in:
   a. applicable legislation;
   b. CPSO expectations and guidelines regarding prescribing;
   c. prescribing practices, including technology related to medication management, electronic prescribing and associated information systems;
   d. relevant practice guidelines and tools; and
   e. implementing these expectations and best practices, as appropriate.
3. Maintaining patients’ confidentiality and privacy when collecting, using or disclosing (e.g., transmitting) prescription information;
4. Collaborating effectively with patients, physicians and other health-care providers;
5. Communicating with patients and other health-care providers with civility and professionalism; and
6. Not pursuing personal advantage, whether financial or otherwise, at the expense of the patient, when prescribing drugs, so as not to compromise their duty to their patients.5

PURPOSE AND SCOPE
This policy sets out the College’s expectations for all physicians who prescribe drugs or provide drug samples to patients.

DEFINITIONS
Drug: As defined in the Drug and Pharmacies Regulation Act (DPRA).6 Drugs are also known as ‘medications’.

Prescribing Drugs: Is a controlled act as set out in the Regulated Health Professions Act, 1991.7 The controlled act of prescribing is comprised of the generation and authorization of prescriptions.

A drug is prescribed when a prescriber provides a direction that authorizes the dispensing of a drug or mixture of drugs.8 The direction may be communicated verbally, in writing or electronically.

Electronic Prescribing (ePrescribing): Electronic prescribing encompasses the electronic generation, authoriza-

---

5. For more information on conflicts of interest, please see Part IV of the General, O. Reg., 114/94, enacted under the Medicine Act, 1991, S.O. 1991, c. 30 (hereinafter Medicine Act, General Regulation) and the CPSO’s MD Relations with Drug Companies policy.
5a. Specific additional expectations for prescribing dried marijuana for medical purposes are contained in the College’s Marijuana for Medical Purposes policy.
6. Section 1(1) of the DPRA.
8. Physicians may both prescribe and dispense the drug. For more information on dispensing, please see the CPSO’s Dispensing Drugs policy.
tion and transmission of dispensing directions for a drug or mixture of drugs.

Electronic prescriptions are generated electronically (using a system or tool) in a format that can be understood by a computer, authorized electronically (with an electronic signature or other process), and transmitted electronically to another system or repository that can only be accessed by an authorized dispenser. All three stages must be electronic before a prescription is a true ‘electronic prescription’.

**Drug Sample:** A package of medication distributed by pharmaceutical companies to physicians or others free of charge. Drug samples are also known as ‘clinical evaluation packages’.

**Narcotics and Controlled Substances:** As defined in the *Controlled Drugs and Substances Act (CDSA)*, and the *Narcotic Control Regulations*. The term ‘narcotics’ includes opioids.

**POLICY**
Physicians must comply with the expectations set out in this policy when prescribing drugs or providing drug samples.

### 1. General Expectations

#### Before Prescribing

**Physician-Patient Relationship**
Physicians typically prescribe drugs within the context of a physician-patient relationship. In most cases, this means that an appropriate clinical assessment of the patient has been conducted, the physician has made a diagnosis or differential diagnosis and/or has a clinical indication based on the clinical assessment and other relevant information, informed consent has been obtained, and the physician prescribes a drug.

**Assessment**

Before prescribing a drug, physicians must have current knowledge of the patient’s clinical status. This can only be accomplished through an appropriate clinical assessment of the patient. An assessment must include:

a) An appropriate patient history, including the most complete and accurate list possible of drugs the patient is taking and any previous adverse reactions to drugs. A physician may obtain and/or verify this information by checking previous records and databases, when available, to obtain prescription and/or other relevant medical information; and if necessary,

b) An appropriate physical examination and/or any other examinations or investigations.

In many cases, physicians conduct all or part of the assessment themselves; however, the College recognizes that this may not always be in the best interests of the patient. Physicians are permitted to rely on an assessment conducted by someone else if:

a) they have reasonable grounds to believe that the person conducting the assessment has the appropriate knowledge, skill and judgment to do so. In most circumstances, this will require that the physician know the person conducting the assessment and be aware of his or her qualifications and training. In some limited circumstances, such as large health institutional settings (e.g., hospital or long-term care home), the physician may be able to rely upon his or her knowledge of the institution’s practices to satisfy him or herself that the person conducting the assessment has the appropriate knowledge, skill and judgment to do so; and

b) they obtain the assessment information from the person conducting the assessment and make an evaluation that it is appropriate.

If these conditions cannot be met, the physician must conduct his or her own clinical assessment. The prescribing physician is ultimately responsible for how they use the assessment information, regardless of who conducted the assessment.

---

9. Section 2(1) of the CDSA.
10. Section 2 of the Narcotic Control Regulations, C.R.C. c. 1041, enacted under the CDSA (hereinafter CDSA, Narcotic Control Regulations).
11. A physician-patient relationship may not be established when physicians provide episodic care for minor conditions to a family member, or incidental medical care to their spouse. For more information on treating family members, please see the CPSO’s *Treating Self and Family Members* policy.
12. Physicians may obtain information from records or databases unless the physician is aware that the patient has expressly withheld or withdrawn consent for the use or disclosure of this information. If a patient has expressly restricted disclosure of their information, it is advisable to note this in the patient’s medical record.
Prescribing Drugs

Exceptions
The circumstances in which physicians are permitted to prescribe without a prior assessment of the patient can include:

a) Prescribing for the sexual partner of a patient with a sexually transmitted infection (STI) who, in the physician's determination, would not otherwise receive treatment and where there is a risk of further transmission of the STI;

b) Prescribing prophylaxis (e.g., oseltamivir) as part of public health programs operated under the authority of a Medical Officer of Health; and

c) Prescribing post-exposure prophylaxis for a health-care professional following potential exposure to a blood borne pathogen.

d) Prescribing naloxone for inclusion in an opioid overdose emergency kit.12a

Diagnosis
If physicians intend to prescribe a drug, they are required to make a diagnosis or differential diagnosis and/or have a clinical indication based on the clinical assessment and other relevant information.13 There must be a logical connection between the drug prescribed and the diagnosis or differential diagnosis and/or clinical indication.

Physicians must consider the risk/benefit ratio for prescribing that particular drug for that patient. In addition, physicians must consider the combined risk/benefit ratio when prescribing multiple drugs. If using technology to prescribe (e.g., Electronic Medical Record), clinical decision support tools may be helpful in assisting physicians determine whether the drug(s) are appropriate for the patient.

Physicians are also required to consider the risk/benefit ratio when providing long-term prescriptions. The duration of the prescription must be balanced with the need to re-assess the patient and the potential harm that may result if the patient runs out of the medication.14

Informed Consent
As with the usual requirements for informed consent when considering any treatment,15 physicians are required to advise the patient about the material risks16 and benefits of the drug being prescribed, including the drug's effects and interactions, material side effects, contraindications, precautions, and any other information pertinent to the use of the drug.

When Prescribing

Content of Prescriptions
Physicians must include the following information on a prescription:

- Name of patient;
- Name of the drug, drug strength and quantity or duration of therapy;
- Full instructions for use of the drug;
- Full date (day, month and year);
- Refill instructions, if any;
- Printed name and signature of prescriber (if outside of an institution, include address and telephone number of location where medical records are kept);
- CPSO registration number;17 and
- Any additional information required by law.

If the prescription is for a monitored drug,18 physicians must also include an identifying number for the patient (e.g., health card number)19 and indicate the type of identifying number it is (e.g., health card), unless certain conditions set out in regulation are met.20

It is recommended that physicians consider, on a case-by-case basis,21 whether it is appropriate to include the following information on the prescription:

- Address and/or date of birth of patient

---

12a Where a physician prescribes naloxone for inclusion in an emergency kit, they must be satisfied that the kit will only be distributed to those who have received appropriate instruction in its use, and that measures will be in place to identify and replace expired medication. Physicians must also be satisfied that every recipient of the kit will be informed of the complications and risks that can arise following administration of naloxone, and be advised that emergency care must always be sought in the event of an overdose, even where naloxone has been administered. This advice must also be communicated in the written instructions contained in the kit.

13. Other information relevant to the patient’s condition or medication usage e.g., information from family, other health-care providers and other sources.

14. For more information on refills, please see the ‘Refills’ section of this policy.

15. For more information on consent, please refer to the CPSO’s Consent to Medical Treatment policy.

16. The material risks that must be disclosed are risks that are common and significant, even though not necessarily grave, and those that are rare, but particularly significant. In determining which risks are material, physicians must consider the specific circumstances of the patient and use their clinical judgment to determine the material risks.

17. Although this is only required in legislation for monitored drugs as defined in the NSAA, the College requires physicians to include their CPSO number on all prescriptions for all drugs.


20. See Sections 3 and 6 of the General, O. Reg., 381/11, enacted under the NSAA.

21. Physicians must not have blanket policies to write “no substitutions”, “do not adapt”, “do not extend” or “do not refill” notations on all prescriptions. For more information about blanket ‘no refill’ policies, see the ‘Refills’ section of this policy.
• Indication for use, if prescribed p.r.n.
• “No substitutions”, if applicable and clinically appropriate\(^{22,23}\)
• “Do not adapt”, “do not extend” or “do not refill”, when prudent or advisable\(^{24}\)
• The patient’s weight and/or age (e.g., where the patient is a child and this information would affect dosage)

**Clarity of Prescriptions**

Physicians must ensure that all prescriptions are clearly understandable and that written prescriptions are legible. It is recommended that physicians use the generic name of the drug to ensure prescriptions are clear.

a) Verbal Prescriptions

Medication safety literature highlights that the use of verbal prescriptions is error-prone. Physicians must have protocols in place to ensure verbal prescriptions are communicated in a clear manner.\(^{25}\)

b) Handwritten or Electronic Prescriptions

To improve legibility, among other things, the College recommends that physicians take advantage of technology, for example, by generating prescriptions via their Electronic Medical Record (EMR) system. When generating prescriptions, physicians must pay particular attention to the use of abbreviations, symbols and dose designations, and must avoid using the abbreviations, symbols, and dose designations that have been associated with serious, even fatal, medication errors.\(^{26}\) It is recommended that physicians use TALLman lettering\(^{27}\) for drug names that may look-alike and/or sound-alike.\(^{28}\)

When generating prescriptions electronically, physicians must ensure the proper drug, dose and dosage form are chosen when selecting from a list of drugs and doses.

**Authorization**

Every prescription must be authorized by a prescriber before it can be filled and dispensed. A prescriber can authorize a prescription verbally, with a signature, or electronically. Regardless of the method of authorization, each prescription must only be authorized once.\(^{29}\)

a) Verbal

A prescription can be authorized by a physician verbally; however, there are some limitations on the use of verbal prescriptions.\(^{30}\) For example, Section 40(3) of General, O. Reg., 58/11, enacted under the DPRA states that a drug shall not be dispensed in a pharmacy pursuant to a prescription given verbally unless several conditions have been met, including that the drug is not a narcotic drug.\(^{31}\)

b) Signature

A prescription can be authorized by a physician’s signature. The signature must be authentic and unaltered.\(^{32}\) Electronic signatures may be acceptable if they meet the College of Pharmacists of Ontario (COP) Guidelines for Prescriptions Transmitted to Pharmacists by Fax or in Digitized Image Files. For example, the electronic signature must be a unique, clearly identifiable, life-size image.\(^{33}\) Before physicians begin signing prescriptions electronically, it is recommended that they communicate with the pharmacist...

---

\(^{22}\) Section 4(3) of the Drug Interchangeability and Dispensing Fee Act, R.S.O. 1990, c. P.23 requires that this notation be handwritten on the prescription.

\(^{23}\) If there are no clinical reasons not to use a generic drug, physicians are encouraged to consider prescribing the generic in order to save costs to the public health-care system.

\(^{24}\) However, physicians are advised that there may be occasions where pharmacists use their professional judgment to adapt, extend or refill prescriptions to ensure continuity of patient care.

\(^{25}\) For guidelines on verbal prescribing, please see the ‘Preventing Medication Errors’ section of this policy.

\(^{26}\) Physicians may wish to review the following documents for more information: the Institute for Safe Medication Practices (ISMP) Canada Safety Bulletin: Eliminate Use of Dangerous Abbreviations, Symbols, and Dose Designations at: http://www.ismp-canada.org/download/ISMPCanadaListOfDangerousAbbreviations.pdf; the ISMP Canada list at: http://www.ismp-canada.org/download/ISMPCanadaListOfDangerousAbbreviations.pdf; and the CPSO’s Dialogue article “Eliminate Use of Dangerous Abbreviations, Symbols, and Dose Designations.”

\(^{27}\) For example, prednisone or prednisolone, and hydrocodone or oxycodeine. For more information, please see the ‘Preventing Medication Errors’ section of this policy, and the following documents: the ISMP FDA and ISMP Lists of Look-Alike Drug Names with Recommended Tall Man Letters (available at: https://www.ismp.org/tools/tallmanletters.pdf), and the ISMP Canada Safety Bulletin: Application of TALLman Lettering for Drugs Used in Oncology.

\(^{28}\) For a list of easily confused drug names, see the following ISMP document, available at: http://www.ismp.org/tools/confuseddrugnames.pdf.

\(^{29}\) Duplicate copies of the prescription must not be created. If physicians wish to provide a copy of the prescription to their patients for information purposes, they may provide them with the prescription information in a format that does not resemble a prescription (e.g., paper receipt).

\(^{30}\) The Ontario College of Pharmacists (OCP) created a summary of federal and provincial laws governing verbal prescription requirements, which can be found here: http://www.ocpinfo.com/client/ocp/OCPHome.nsf/object?Summary+of+Laws/$file/Summary+of+Laws.pdf.

\(^{31}\) However, “verbal prescription narcotics,” as defined in Section 1(1) of the General, O. Reg., 58/11, enacted under the DPRA may be dispensed. The rules regarding when verbal prescriptions can be dispensed are complex, and physicians are encouraged to contact the pharmacist if they are uncertain about whether a particular verbal prescription is permitted.

\(^{32}\) Section 40(4) a) of the DPRA.

\(^{33}\) For more information, see the OCP Guidelines at: http://www.ocpinfo.com/client/ocp/OCPHome.nsf/web/Fax+or+Digitized+Guidelines.
Prescribing Drugs

regarding the process they are using to sign the prescriptions, to ensure the pharmacists’ requirements are being met.

d) Electronic
Electronic prescriptions can only be authorized by an authorized prescriber.36 There must be a mechanism that prevents duplicate prescription authorization and the prescription authorization mechanism37 must be:

- Secure;36 and
- Acceptable for the purposes of authentication to pharmacists.37

After Prescribing
Transmitting a Prescription
In an ePrescribing context, authorization and transmission of a prescription are often combined. However, regardless of the method of transmission (e.g., paper, verbal, fax,38 digitized image files39 or electronic), physicians must comply with the following requirements:

1. All prescriptions transmitted must originate with the prescriber;40
2. The process of transmitting prescriptions must maintain patient confidentiality;
3. Transmission of the prescription must employ reasonable security measures (e.g., password protection, encryption, etc.).39 This includes transmission to or from the EMR (i.e., from a stand-alone application to the EMR or from the EMR to the dispenser); and
4. Patient choice must be protected; that is, the patient must have a choice of pharmacy where the prescription is to be filled.42

Physicians must respond in a timely and professional manner when contacted by a pharmacist40 or other health-care provider to verify a prescription or respond to a request for information about the drug prescribed.

Documentation
In addition to complying with the general requirements for medical records,44 physicians must specifically document the following information regarding the drugs they prescribe in a patient’s medical record:

- The date the drug is prescribed;
- The type of prescription (verbal, handwritten, electronic);
- The name of the drug, drug strength and quantity or duration of therapy;
- Full instructions for use of the drug;
- The fact that the drug’s material risks, including material side effects, contraindications or precautions were discussed with the patient;45
- Refill information; and

34. No other members of staff can authorize a prescription unless there is a direct order or medical directive from the physician.
35. Mechanisms could include such things as strong passwords, tokens, biological markers, or any combination of these.
36. Secure means there are reasonable safeguards in place to prevent prescriptions from being generated by people inside or outside of the system who are not authorized to prescribe.
37. The capability for true ePrescribing outside of a closed environment (e.g., hospital) is currently being developed. As such, there are currently no guidelines regarding security and which electronic prescription authorization mechanisms, other than an electronic signature, are acceptable. As discussed above, electronic signatures must be unique, clearly identifiable, life-size images, and it is advisable to discuss arrangements for their use with the pharmacist in advance.
38. Refer to the following OCP documents: Policy on Faxed Prescriptions; and Guidelines for Prescriptions Transmitted to Pharmacists by Fax or in Digitized Image Files.
39. Unless an EMR-generated, faxed prescription with an attached electronic signature meets the OCP Guidelines for Prescriptions Transmitted to Pharmacists by Fax or in Digitized Image Files, physicians must continue to print and sign all EMR-generated prescriptions before either transmitting them to pharmacies, or handing them to patients to carry into a pharmacy.
40. If a prescription written by a prescriber is faxed to the pharmacy by a patient or a patient’s agent, the original prescription must be provided to the pharmacist before dispensing is completed and the medication is released.
41. Obligations with respect to the security of personal health information are set out in Sections 12 and 13 of PHIPA. For more information on the security of faxed prescriptions, see the Information and Privacy Commissioner of Ontario’s Guidelines on Facsimile Transmission Security.
42. If physicians are ePrescribing, they must give patients a choice as to whether they would like the prescription transmitted to the pharmacy electronically, or whether they would like a paper prescription. This is to ensure that patients are able to fill their prescription at a pharmacy of their choosing, until such time that all pharmacies can accept electronic prescriptions and paper prescriptions are phased out.
43. For more information on strengthening protocols between physicians and pharmacists, please see the Dialogue article “Recommended Protocols can Strengthen Physician/Pharmacist Working Relations”.
44. Sections 18-21 of the Medicine Act, General Regulation. For more details of the requirements concerning medical records, see the CPSO’s Medical Records policy.
45. The College recommends that physicians consider documenting which risks were discussed with the patient, as this information may be helpful for future reference.
• Other relevant information (e.g., drug cannot be substituted; prescription cannot be adapted, extended or refilled, as applicable).

The College recommends that entries be recorded as soon as possible after the encounter. This is important to ensure safe delivery of care, especially in a shared care environment.46

The documentation requirements set out above apply to physicians even if they are verbally prescribing, refilling prescriptions, or providing a patient with a drug sample.

a) Audit
Physicians who have an EMR with ePrescribing capabilities must ensure that their system is able to track all electronic prescriptions, who authorized them, whether they were printed or authorized and transmitted, where they were sent and whether/by whom they were modified and when. The system must also be able to identify what additions or edits were made to the prescription record over time.47

Physicians must also ensure that their system is able to generate reports that contain the results of queried information (e.g., list of prescriptions issued to a particular patient, prescriptions issued by the prescriber, or prescriptions written for a particular drug, etc).

Monitoring
After prescribing, physicians must inform patients of the need for follow-up care to monitor whether any changes to the treatment plan (e.g., prescription) are required. It is recommended that patients are informed of their role in safe medication use and monitoring effectiveness. Patients must be monitored for any emerging risks or complications. Drug therapy must be stopped, following appropriate protocol, if it is not effective, or the risks outweigh the benefits.

Sharing Information
To ensure good patient care is provided, communication between physicians and health-care providers is recommended. If the patient has a primary care provider, it is important for that provider to have all relevant information about his or her patient. This includes information about drugs prescribed for the patient. Unless a patient has expressly withheld or withdrawn consent, health information can be shared within the ‘Circle of Care’46 in accordance with the Personal Health Information Protection Act, 2004 (PHIPA).

2. Specific Issues in Prescribing

Refills49
Physicians may write a prescription with a certain number of refills, if permitted by law.50 Prescribing with refills is often appropriate for patients with chronic conditions that are likely to remain stable for the duration of the dispensing period. Physicians must ensure procedures are in place to monitor the ongoing appropriateness of the drug when prescribing with refills. This includes conducting periodic re-assessments looking for any changes in the underlying chronic condition, as well as any new drug interactions or contraindications, and/or new side effects of the prescribed drug.

When physicians are contacted to authorize a refill on a prescription that has run out, they must consider whether the drug is still appropriate, and whether the patient’s condition is stable enough to warrant the prescription refill without further assessment. It is recommended that physicians also consider whether requests for prescription refills received earlier or later than expected may indicate poor adherence, possibly leading to inadequate therapy or

46. For full details of the requirements concerning medical records, see the CPSO’s Medical Records policy.
47. Audit requirements are set out in the CPSO’s Medical Records policy and in Section 20 of the Medicine Act, General Regulation.
48. ‘Circle of Care’ is a term commonly used to describe the ability of certain health information custodians (e.g., physicians and other regulated health professionals) to assume an individual’s implied consent to collect, use or disclose personal health information for the purpose of providing health care to that individual, in circumstances defined in PHIPA. For more information, see the Information and Privacy Commissioner of Ontario’s Circle of Care: Sharing Personal Health Information for Health-Care Purposes document. Sharing information in the context of prescribing narcotics and controlled substances is discussed in more detail in the ‘Narcotics and Controlled Substances’ section of this policy.
49. Also known as ‘prescribing with repeats’ or ‘renewing prescriptions’.
Prescribing Drugs

adverse events.

At times, the request to authorize a refill on a prescription may be communicated to the physician’s office staff. Physicians must ensure that there are protocols in place when they use office staff to facilitate the authorization of refills. Physicians must review and authorize all requests, unless physicians are delegating this responsibility to staff51 or their staff person is a regulated health professional who has the authority to prescribe. Physicians must ensure that all requests for refills and all refills that are authorized are documented in the patient’s medical record.

‘No Refill’ Policies

Some physicians have blanket ’no refill’ policies, meaning they will not authorize refills for any patient, for any drug, in any circumstance. The College prohibits the use of blanket ‘no refill’ policies because they are not consistent with patient-centered care and have no clinical basis. If there are situations where refills may not be advisable, the College recommends open discussion between physicians and dispensers, so that those involved in the patient’s care are best positioned to exercise judgment where necessary and appropriate.

Drug Samples

Many physicians receive drug samples from representatives of the pharmaceutical industry. Drug samples are one means of determining whether a drug is effective and useful for a particular patient. As well, drug samples can benefit patients with limited financial resources and who do not have other means to access the drug.

When physicians provide drug samples, some of the general requirements for prescribing a drug will apply. More specifically, physicians must:

• Conduct an appropriate clinical assessment, make a diagnosis or differential diagnosis and/or have a clinical indication, and obtain informed consent before providing drug samples;

• Document the drug samples given to patients, including the date provided, name of the drug, drug strength, quantity or duration of therapy, instructions for use, and the fact that the drug’s material risks, including material side effects, contraindications or precautions were discussed with the patient;52

• Communicate the need for follow-up to monitor whether any changes to the treatment plan are required; and

• Share information about drug samples provided with other health-care providers, as appropriate.

In addition, physicians who provide drug samples must meet or ensure that the following requirements are met:

• No form of material gain is obtained for the physician or for the practice with which he or she is associated.

• No trading, selling, or bartering of drug samples for cash or other goods or services occurs.

• Samples are securely and appropriately stored to prevent spoilage and theft/loss, and are given to patients with current expiry dates.

• Samples that are unfit to be provided to patients (expired or damaged) are safely and securely disposed of.53

Redistributing Unused Drugs

The College has become aware of circumstances in which physicians want to redistribute, to patients with limited resources, expensive drugs that have been returned to them by patients who are no longer able to use them. Redistributing unused drugs is inappropriate and strongly discouraged because the integrity of the drugs cannot be ensured. Returned drugs must be disposed of in a safe and secure manner.54

Narcotics and Controlled Substances

Narcotics and controlled substances are important tools in the safe, effective and compassionate treatment of acute or chronic pain, mental illness, and addiction. Physicians with the requisite knowledge and experience are advised to pre-

51. If physicians are delegating this responsibility to staff, they must do so in accordance with the CPSO’s Delegation of Controlled Acts policy.
52. The College recommends that physicians consider documenting which material risks were discussed with the patient, as this information may be helpful for future reference.
53. It is recommended that expired or damaged drugs be returned to a pharmacy for proper disposal.
54. It is recommended that the drugs be returned to a pharmacy for proper disposal.
Physicians may be able to reduce or impede the diversion,\textsuperscript{56} misuse and/or abuse of narcotics and controlled substances by: carefully considering whether these drugs are the most appropriate choice for the patient; recognizing patients who may be double-doctoring,\textsuperscript{57} diverting, misusing or abusing prescription drugs; sharing information with others, as appropriate; instituting measures to prevent prescription pad theft or tampering; taking measures to prevent the theft of drugs from their offices; and educating patients.

The purpose of this section of the policy, along with the related guidelines, is to clarify for physicians their obligations when prescribing narcotics and controlled substances and their role in preventing and addressing prescription drug abuse. This policy does not attempt to curb the prescribing of narcotics and controlled substances for legitimate reasons (i.e., acute or chronic pain, mental illness or addiction), but does reinforce the requirement that physicians prescribe these drugs in an appropriate manner.

Considerations

In addition to complying with the general requirements set out for prescribing any drug and any applicable legislation, physicians must carefully consider whether the narcotic or controlled substance is the most appropriate choice for the patient, even if the patient has been prescribed these drugs in the past.\textsuperscript{58} Special consideration is necessary given that narcotics and controlled substances are highly susceptible to diversion, misuse and/or abuse because of their psychoactive properties. These drugs are extremely harmful to patients and to society when they are diverted, misused and/or abused, so physicians must first consider whether an alternate treatment or drug is clinically appropriate. If there are no appropriate or reasonably available alternatives, physicians are advised to record this fact in the patient’s medical record. The benefits of prescribing narcotics and controlled substances must be weighed against their potential risks when used long-term.

Office Policies and Practices: Setting and Managing Patient Expectations

a) General Policies and Practices

It is recommended that physicians who prescribe narcotics and controlled substances consider implementing office policies and practices regarding the prescribing of these drugs, for example, a policy on the use of treatment agreements.\textsuperscript{59} Communicating these office policies and practices to patients can help manage patient expectations and help monitor whether the treatment is being used as prescribed.

b) ‘No Narcotics’ Prescribing Policy

When physicians are asked by patients to prescribe narcotics or controlled substances,\textsuperscript{60} they may feel obligated or pressured to prescribe them. In fact, some physicians have a general ‘no narcotics’ policy in order to avoid such situations. Having a blanket ‘no narcotics’ policy removes the physician’s ability to exercise his or her clinical discretion when considering whether or not to prescribe narcotics and controlled substances to a particular patient. Instead of having such a policy, it is advised that physicians use their professional judgment to determine whether prescribing narcotics and controlled substances is appropriate for each patient. Physicians have no obligation to prescribe any drug, including narcotics and controlled substances, if they do not feel it is clinically appropriate.

As such, the College recommends that physicians do not adopt a blanket policy refusing to prescribe narcotics and controlled substances, unless physicians have restrictions.

\textsuperscript{55} Canadian Centre on Substance Abuse, Prescription Drug Abuse FAQs (CCSA, 2007).
\textsuperscript{56} Drug diversion, broadly defined, is when the legal supply chain of prescription drugs is broken, and drugs are transferred from a licit to an illicit channel of distribution or use.
\textsuperscript{57} Obtaining multiple prescriptions from different physicians.
\textsuperscript{58} The College recommends that physicians refer to relevant guidelines and tools for prescribing narcotics and controlled substances. For example, physicians are advised to refer to the Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain when prescribing opioids for chronic non-cancer pain. Available at: http://nationalpaincentre.mcmaster.ca/opioid/. ‘Tools for appropriate patient screening may be particularly helpful in this regard. Physicians are advised to refer to the guidelines on ‘Narcotics and Controlled Substances’ in this policy for more information.
\textsuperscript{59} Physicians are advised to refer to the guidelines on ‘Narcotics and Controlled Substances’ in this policy for more information.
\textsuperscript{60} Some patients may seek prescriptions for narcotic and controlled substances for reasons that are not legitimate. It may be very difficult for physicians to determine this, so it is recommended that they use their professional judgment to determine whether prescribing narcotics or controlled substances is prudent. Physicians are advised to refer to the guidelines on ‘Narcotics and Controlled Substances’ in this policy for more information.
Preventing them from prescribing narcotics and controlled substances. Prescribing narcotics and controlled substances are part of good clinical care and refusing to prescribe these drugs altogether may lead to inadequate management of some clinical problems and may leave patients seeking treatment from other physicians, putting pressure on others to manage these cases, or otherwise leaving patients without appropriate treatment.

Monitoring Patients: Misuse, Abuse and Double-Doctoring

When prescribing narcotics and controlled substances, physicians must be alert for behaviour which suggests that patients are seeking drugs for diversion purposes, or are misusing or abusing prescription drugs.

One of the ways in which patients may access narcotics and controlled substances to misuse or abuse is by double-doctoring. Under the CDSA, a person who has received a prescription for a narcotic shall not seek or receive another prescription or narcotic from a different physician without telling that physician about every prescription or narcotic that he or she has obtained within the previous 30 days.

Sharing Information

If physicians suspect or discover that their patient is double-doctoring, or is otherwise misusing or abusing narcotics and controlled substances, they might be unsure as to what to do with that information. Physicians must keep patient health information confidential and private, unless they have consent to share the information or are permitted or required by law to do so.

The following sections outline the most relevant requirements in PHIPA regarding consent, along with the instances in which physicians are permitted by law to disclose information without consent. If physicians are uncertain of their obligations, or whether the sections set out below apply in the circumstances of specific cases, physicians are advised to seek legal advice.

a) Circle of Care

The majority of circumstances addressed in this policy contemplate that physicians will share a patient’s personal health information, including prescriptions, with other members of the patient’s health-care team for the purpose of providing or assisting in the provision of health care. Generally speaking, in these situations, physicians can assume they have a patient’s implied consent to share personal health information (including information regarding prescriptions) with other members of the patient’s health-care team, and they will not need to seek patient consent each time. Physicians cannot, however, assume patient consent if the patient has expressly stated that he or she does not want the information to be shared.

b) Permitted Disclosure

PHIPA contains a number of provisions which permit personal health information to be disclosed without patient consent. The decision to disclose information in these situations is at the physician’s discretion. Physicians must use their professional judgment to determine whether the circumstances of each case satisfy the requirements of the provision and disclosing the information is justified.

PHIPA contains a number of provisions which permit disclosure. These provisions that are most likely to be relevant to prescribing information are described below.

i) Disclosure for authorized investigations or inspections

• This provision enables information to be disclosed in the context of an investigation or inspection, for the purposes of facilitating that investigation.
• The investigation or inspection must be authorized by a warrant, or by an Act of Ontario or an Act of Canada.
• The disclosure must be made to the person who is authorized to do the investigation or inspection.

The Canadian Medical Protective Association (CMPA) has provided information regarding double-doctoring and responding to inquiries from law enforcement officials in...
responding to prescription fraud.66

ii) Disclosures related to risks

- This provision allows for information to be disclosed in order to prevent or reduce a risk of harm to others.
- To rely on this provision, health-care providers must believe on reasonable grounds that the disclosure is necessary for the purpose of eliminating or reducing a significant risk of serious bodily harm to a person or group of persons.67

Mandatory Reporting Obligation

Physicians are required to report the loss or theft of narcotics and controlled substances from their office to the Office of Controlled Drugs and Substances, Federal Minister of Health, within 10 days.68

Drugs that have not been Approved for Use in Canada (‘Unapproved Drugs’)

Physicians must not prescribe drugs that have not been approved for use in Canada, that is, drugs for which Health Canada has not issued a Notice of Compliance (NOC).69 However, there are two circumstances when access to an unapproved drug can be obtained for patient use. The first is when drugs have been authorized by Health Canada for research purposes as part of a clinical trial. The other is when drugs have been authorized under Health Canada’s Special Access Programme.70

If physicians consider obtaining access to drugs for patients under these circumstances, they must comply with Health Canada’s requirements.

GUIDELINES

Preventing Medication Errors

Medication errors can cause serious harm and even death. Often, medication errors are caused by underlying problems in the system. For example, problems such as look-alike labels and confusing equipment can lead to mistakes in health care.

Physicians can help reduce the occurrence of some medication errors by considering the following guidelines.

Verbal Prescriptions71

The use of verbal prescriptions (spoken aloud in person or by telephone) introduces a number of variables that can increase the risk of error. These variables include:

- Potential for misinterpretation of orders because of accent or pronunciation;
- Sound-alike drug names;
- Background noise;
- Unfamiliar terminology;
- Patients having the same or similar names;
- Potential for errors in drug dosages (e.g., sound-alike numbers); and
- Misinterpretation of abbreviations.

In addition, the use of intermediaries (e.g., office staff) has been identified as a prominent source of medication error. Medication safety literature recognizes that the more direct the communication between a prescriber and dispenser, the lower the risk of error. As such, if physicians wish to use verbal prescriptions, it is recommended that physicians communicate the verbal prescription themselves. If this is not possible, it is recommended that physicians consider

67. Section 40(1) of PHIPA. This provision is not specific to opioids; the threshold is ‘risk of serious bodily harm’. It doesn’t specify to whom the disclosure is to be made.
68. Section 55(g) of the CDSA, Narcotic Control Regulations; Sections 7(1) and 61(2) of the Benzodiazepines and Other Targeted Substances Regulations, S.O.R./2000-217, enacted under the CDSA. These obligations are also set out in the CPSO’s Mandatory and Permissive Reporting policy.
69. Federal legislation stipulates that no one can sell or advertise a new drug unless the Minister has issued an NOC to the manufacturer. The NOC indicates that the drug meets the required standards for use in humans or animals and is approved for sale in Canada. A manufacturer receives an NOC when it has met Health Canada’s regulatory requirements for the safety, efficacy and quality of a product. For more information, see Health Canada’s Notice of Compliance webpage.
70. The Special Access Programme (SAP) provides access to non-marketed drugs for practitioners treating patients with serious or life-threatening conditions when conventional therapies have failed, are unsuitable, or unavailable. The SAP authorizes a manufacturer to sell a drug that cannot otherwise be sold or distributed in Canada. For more information, see Health Canada’s Special Access Programme – Drugs document.
asking someone who has an understanding of the drug and indication to communicate the prescription information, unless the prescription is a refill.

When verbal prescriptions are used, it is recommended that the accuracy of the prescription be confirmed using strategies such as a ‘read back’ of the prescription and/or a review of the indication for the drug. It is recommended that the read back include:

• Spelling of the drug name;
• Spelling of the patient’s name; and
• Dose confirmation expressed as a single digit (e.g., “one-six” rather than “sixteen”).

In addition, to reduce the risk of error due to patients having the same (or similar) names, it is advisable to communicate at least one additional unique patient identifier to the dispenser.

**Look-alike/Sound-alike Drug Names**

Some drug names may look-alike and/or sound-alike. In order to avoid the potential for confusion, physicians may want to consider:

• writing prescriptions clearly by printing the name of the product in block letters or using TALLman lettering, by not using abbreviations, or by using electronic prescriptions;
• including more information about the drug (e.g., include both brand name and generic name, and the reason for prescribing the medication);
• ensuring that the strength, dosage and directions for use are clearly indicated on the prescription; and
• communicating to the patient (or a family member) the reason the medication has been prescribed and verifying that the patient can read the prescription.

**High-alert Medications**

High-alert medications are drugs that bear a heightened risk of causing significant patient harm when they are used in error. Although mistakes may or may not be more common with these drugs, the consequences of an error can be more serious. Physicians are advised to consider consulting the high-alert medications list to determine which medications require special safeguards to reduce the risk of errors.

**Vulnerable Populations/High-alert Environments**

Paediatric, geriatric, and medically complex patients are particularly vulnerable to medication incidents. In addition, high-alert environments and situations, such as emergency procedures, may contribute to a greater risk of error. It is recommended that the potential for harm in these circumstances be considered in advance, and systems and procedures be reviewed to mitigate the potential for error.

**Double-Checking**

A common cause of drug name mix-ups is what experts call confirmation bias, where a practitioner reads a poorly written drug name and is most likely to see in that name that which is most familiar to him or her, overlooking any disconfirming evidence. Physicians are advised to double-check all prescriptions they write to ensure they are clearly written for the drug they intended to prescribe.

**Patient Involvement**

Medication safety literature recognizes that patients represent an untapped resource for reducing the incidence of medication errors. It is recommended that physicians encourage their patients to: question why they are receiving a drug; verify that it is the appropriate drug, dose and route; and, alert the health-care provider involved in prescribing, dispensing, or administering a drug to potential problems, such as allergies or past drug-drug interactions, any new physical symptoms/side effects that occur, or any changes in their clinical status.

Physicians are encouraged to be alert to the possibility of an error in the dispensing of a drug when a patient expresses concern that the drug dispensed is different from that previously provided.

If a prescription is generated, authorized and transmitted

---

74. For more information, see the following documents: the ISMP FDA and ISMP Lists of Look-Alike Drug Names with Recommended Tall Man Letters (available at: https://www.ismp.org/tools/tallmanletters.pdf); and the ISMP Canada Safety Bulletin: Application of TALLman Lettering for Drugs Used in Oncology.
76. Alberta College of Pharmacists, College and Association of Registered Nurses of Alberta & College of Physicians and Surgeons of Alberta, Ensuring Safe & Efficient Communication of Medication Prescriptions in Community and Ambulatory Settings (ACP, CARNA & CPSA, 2007) at p.3.
electronically, the physician may wish to generate a record/receipt of the prescription for the patient. This would accomplish several things:

- Ensure the patient knows what they have been prescribed;
- Give the patient an opportunity to go home and look up the drug; and
- Avoid errors of dosing, etc.

**Reporting Adverse Drug Reactions or Medication Incidents**

It is recommended that physicians report any adverse drug reactions to the relevant organizations. It is advisable to report all suspected adverse drug reactions, especially those that are:

- Unexpected, regardless of their severity, i.e., not consistent with product information or labelling;
- Serious, whether expected or not; or
- Due to recently marketed health products (on the market for less than five years), regardless of their nature or severity.

Voluntary reporting by health-care providers and consumers of suspected reactions is the most common way to monitor the safety and effectiveness of marketed health products. These individual reports may be the only source of information concerning previously undetected adverse reactions or changes in product safety and effectiveness profiles to marketed health products. Adverse drug reactions can be reported to Health Canada’s Vigilance Program at:


It is recommended that physicians also report medication incidents to assist in identifying new or undetected safety issues. This can be done through the Institute for Safe Medication Practices (ISMP) Canada at:


It is recommended that physicians encourage their patients to report any medication incidents or near misses at:

http://www.safemedicationuse.ca.

In addition to reporting any adverse drug reactions or medication incidents physicians are advised to refer to the CPSO’s Disclosure of Harm policy for additional requirements that may apply.

**Narcotics and Controlled Substances**

**Responding to Requests for Narcotics and Controlled Substances**

Physicians can implement a number of practical steps to help prevent diversion, misuse and abuse:

- If the patient is not well known to you, ensure the patient’s identity has been verified; for example, by requesting two or three pieces of identification (e.g., driver’s licence, health card, social insurance number).
- Verify the presenting complaint and observe for aberrant drug-related behaviour.
- Screen for current and past alcohol, drugs (prescription and non-prescription) and illicit drug use.
- Consider using screening tools from the Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain.
- Consider whether patients may be diverting, misusing or abusing narcotics and controlled substances when they:
  - Request a specific drug by name and/or state that alternatives are not effective, or they are “allergic” to them.
  - Refuse appropriate confirmatory tests (e.g., blood tests, x-rays, etc.).
- Ask the patient if they have received any narcotics or controlled substances in the last 30 days from another practitioner, and look for any signs of evasiveness.
- Talk to the patient’s primary care provider, specialist and/or pharmacist.

---

77. Adverse drug reactions are unwanted effects that happen when drugs are used under normal conditions. Adverse drug reactions are also called side effects. Adverse drug reactions are not medication incidents. Unlike a medication incident, an adverse drug reaction generally doesn’t involve a mistake and typically can’t be prevented.

78. Health Canada’s Adverse Reaction Information webpage describes a serious adverse drug reaction as one that requires in-patient hospitalization or prolongation of existing hospitalization, causes congenital malformation, results in persistent or significant disability or incapacity, is life-threatening or results in death. Adverse reactions that require significant medical intervention to prevent one of these listed outcomes are also considered to be serious.

79. A medication incident is a mistake with medication, or a problem that could cause a mistake with medication. ‘Medication error’ is another name for one kind of medication incident. Medication incidents include obvious things like receiving the wrong medication or dose, but might also include problems like a confusing label that might lead to someone receiving the wrong medication.

80. Please see the next section on ‘Identifying Aberrant Drug-Related Behaviour’ for more information.
Identifying Aberrant Drug-Related Behaviour

It may be difficult to determine whether patients are seeking prescription drugs for diversion purposes, or are misusing or abusing these drugs. Common aberrant drug-related behaviours can be divided into three groups:

- Escalating the dose (e.g., requesting higher doses, running out early);
- Altering the route of delivery (e.g., biting, crushing controlled-release tablets, snorting or injecting oral tablets); and
- Engaging in illegal activities (e.g., double-doctoring, prescription fraud, buying, selling and stealing drugs).

The chart on this page lists aberrant drug-related behaviours potentially indicative of opioid misuse.

Office Practices and Policies: Setting and Managing Patient Expectations

When physicians prescribe narcotics and controlled substances, it is recommended that they clarify to patients under what conditions they will prescribe. It is advisable to outline the circumstances for prescribing and not prescribing in the policy. This can include information regarding the preconditions for prescribing generally, and more specific office policies such as:

- Aberrant drug-related behaviour will be monitored (e.g., urine drug screening); and
- Treatment agreements will be used.

Treatment Agreements

A treatment agreement is often an effective tool for ensuring proper utilization of the narcotic or controlled substance. They may especially be helpful for patients not well known to the physician, or at higher risk for prescription drug misuse or abuse.

Treatment agreements are formal and explicit written agreements between physicians and patients that delineate key aspects regarding adherence to the therapy. An agreement could state that:

- the physician will only prescribe if the patient agrees to stop all other narcotics and controlled substances;
- the patient will use the drug only as directed;
- the patient acknowledges that all risks of taking the drug have been fully explained to him or her; and
- the patient will use a single pharmacy of their choice to obtain the drug.

Having an agreement ensures patients are told what is expected of them when they receive a prescription and the circumstances in which prescribing will stop. The consequence for not meeting the terms of the agreement would also be clear: the physician may decide not to continue prescribing narcotics and controlled substances.

---

82. See the Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain for a sample treatment agreement, available at: http://nationalpaincentre.mcmaster.ca/opioid/cgop_b_app_b05.html.
83. For information on ending the physician-patient relationship, please see the CPSO’s Ending the Physician-Patient Relationship policy.
Monitoring Patients
Physicians may wish to keep a narcotics and controlled substances log84 for each patient. This would help physicians keep track of what was prescribed for each patient, to ensure patients are not over-prescribed narcotics and controlled substances.85 The use of technology could help in this regard (e.g., EMR).

Preventing Prescription Fraud86
In issuing prescriptions for narcotics and controlled substances physicians may want to consider taking the following precautions:

- If using a paper prescription pad:
  - Use carbon copies or numbered prescription pads;
  - Write the prescription in words and numbers;
  - Draw lines through unused portions of the prescription; and
  - Keep blank prescription pads secure.
- If using desk-top prescription printing:
  - Use EMR-enabled security features such as watermarks.
  - Write a clear signature and do not use a scribbled initial.
- Promote the patient’s use of a single dispensing pharmacy of their choice. Include the name of the pharmacy the patient would like to take the prescription to be dispensed, on the prescription.
- Fax (or electronically transmit when available) prescriptions directly to the pharmacy.
- If using fax or electronic transmission of the prescription (when permitted) ensure confidentiality,87 confirm destination, and retain copies.

Security of Drugs
Narcotics and controlled substances require greater storage security than other drugs. It is recommended that drugs stored in a physician’s office be in a locked cabinet, out of sight. Physicians are advised to avoid storing drugs in any other location, including their homes. Physicians are advised to never leave medical bags unattended or in plain view.

Advice for Patients88
It is recommended that physicians advise patients on safe use at home and storage of narcotics and controlled substances. It is recommended that physicians consider communicating the following:

- Read the label and take the drug exactly as directed. Take the right dose at the right time.
- Follow the other directions that may come with the drugs, such as not driving, and avoiding the use of alcohol.
- Store narcotics and controlled substances in a safe place, out of the reach of children and teenagers, and keep track of the amount of drugs.
- Never share prescription drugs with anyone else, as this is illegal and may cause serious harm to the other person.
- Return any unused drugs to the pharmacy for safe disposal, in order to prevent diversion for illegal use and to protect the environment. Drugs must not be disposed of in the home (e.g., in the sink, toilet or trash).

In addition, physicians may want to advise patients about what to do if they miss a dose, and remind them that crushing or cutting open a time-release pill destroys the slow release of the drug and can lead to an overdose with serious health effects.

---
85. It is recommended that physicians look for evidence of non-compliance, escalation of dose, early renewals, misrepresentation, or fraud.
87. For more information on the security of faxed prescriptions, see the Information and Privacy Commissioner of Ontario’s Guidelines on Facsimile Transmission Security.
REFERENCE MATERIALS:


Canadian Centre on Substance Abuse, Prescription Drug Abuse FAQs (CCSA, 2007).

Canadian Medical Protective Association, Responding to Prescription Fraud (CMPA, 2008).

College of Physicians and Surgeons of Newfoundland and Labrador, Sample Narcotic Flow Sheet (CPNSNL, 2004).


Health Canada, It’s Your Health: Opioid Pain Medications (HC, 2009).


Information and Privacy Commissioner of Ontario, Circle of Care: Sharing Personal Health Information for Health-Care Purposes (IPC, 2009).


Institute for Safe Medication Practices Canada, Application of TALLman Lettering for Drugs Used in Oncology (ISMPC, 2010).


Ministry of Health and Long-Term Care, Monitored Drugs List (MOHLTC, 2012).

Ministry of Health and Long-Term Care, Ontario’s Narcotics Strategy: List of Approved Forms of Identification (MOHLTC, 2012).


Ontario College of Pharmacists, Guidelines for Prescriptions Transmitted to Pharmacists by Fax or in Digitized Image Files (OCP, 2006).

Ontario College of Pharmacists, Policy on Faxed Prescriptions (OCP, 2007).

Ontario College of Pharmacists, Prescription Regulation Summary Chart (OCP, 2012).