

JP Refresher Seminar

Pharmacy Legislation

Pharmacy Practice Ontario College of Pharmacists



Useful Websites

www.ocpinfo.com

Ontario College of Pharmacists
➤ can find links to all legislation

www.napra.ca

National Association of Pharmacy Regulatory Authorities
➤ Can find links to national drug schedules and federal legislation



Legislation

Laws, Legislation = Act + Regulations
- made by a government (Provincial or Federal)

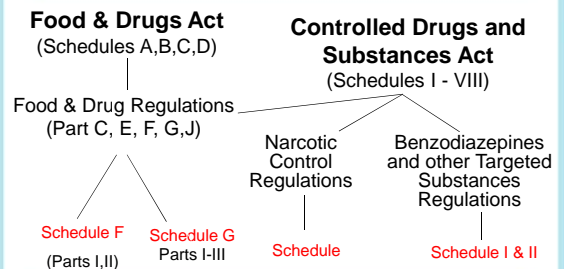
Act = Overview document, outlines 'what' is to be done (or not done), 'more difficult' to make changes.

Regulations = supporting, more detailed 'rules' to be followed ('how to...'), 'more easily' changed.

Schedule = a list; may be found in an Act, or in Regulations.



Federal Legislation



Provincial Legislation

- Regulated Health Professions Act (RHPA)
- Pharmacy Act (PA)
- Narcotic Safety & Awareness Act (NSSA)
- Drugs and Pharmacies Regulation Act (DPRA)
- Drug Interchangeability and Dispensing Fees Act (DIDFA)
- Ontario Drug Benefit Act (ODBA)



Regulated Health Professions Act

- Regulates and coordinates health professions in the public interest
- Requires all regulated professions to have Standards of Practice
- 26 regulated health professions
- 'Controlled Acts' outlined
- Regulates the members



Pharmacy Act

- Classes of registered members
 - Pharmacist
 - Intern
 - Registered Pharmacy Student
 - Registered Pharmacy Technician (these are protected titles)
- Pharmacy advertising
- Quality Assurance Program
- Definition of Professional Misconduct



Drug and Pharmacies Regulation Act

Section 117

“DRUG” means any substance or preparation containing any substance

- Manufactured, sold or represented for use in, (diagnosis, treatment, prevention of disease...) (restoring, correcting, modifying...)
- referred to in Schedule I, II or III (provincial/NAPRA schedules)
- named in the regulations



Drug and Pharmacies Regulation Act

“DRUG” does not include

- any substance .. food, drink (“Ensure”) or cosmetic (toothpaste)
- any substance listed as ‘U’ in NAPRA schedules
- a substance as defined by the ‘Natural Health Products Regulations’ unless it can be found in NAPRA schedules I, II or III
 - Eg. Quinine sulfate or ferrous gluconate



Drug and Pharmacies Regulation Act

What is the consequence of a substance being legally classified as a “DRUG”???

- It's sale is restricted in some way
- Sold in pharmacies
- Further subdivided into schedules



National Drug Schedules

- Adopted by Ontario and referenced in the DPRA
- Harmonization nationally
- National Drug Schedule Advisory Committee (NDSAC) determines the schedules
- Cascading model - I, II, III
- Based on risk to the public, and supervision needed for use.



National Drug Schedules

Schedule I Drugs

- require a prescription for sale
- provided to the public by the **pharmacist** following the **diagnosis** and professional **intervention** of a **practitioner**
- sale is controlled in a regulated environment as defined by provincial pharmacy legislation
- In Ontario, Sch I drugs include those found in:
 - Sch I of NAPRA schedules
 - parts I & II of Sch F to FDA
 - Sch I to VIII of CDSA**This definition is found in DPRA regulations**



National Drug Schedules

Schedule II Drugs

- less strictly regulated
- require professional intervention from a pharmacist, intern or pharmacy student (under the direct supervision of a pharmacist at the point of sale)
- prescription is not required
- must be retained within an area of the pharmacy where there is no public access and no opportunity for patient self-selection



National Drug Schedules

Schedule III Drugs

- available without a prescription
- Pharmacist must be physically present in the pharmacy
- sold from the self-selection area of the pharmacy from within 10 metres of the dispensary
- subject to any local professional discretionary requirements which may increase the degree of control (eg. – Graval/dimenhydrinate)



National Drug Schedules

Schedule III Drugs (cont.)

- pharmacist or intern should be available, accessible and approachable to assist the patient in making an appropriate self-medication selection.
- Examples: clotrimazole vaginal (internal) products, hydrocortisone 0.5% cream, asa 81mg tablets



National Drug Schedules

Unscheduled items

- can be sold without professional supervision
- adequate information is available for the patient to make a safe and effective choice
- labeling is deemed sufficient to ensure the appropriate use of the medication
- may be sold from any retail outlet

(not a 'drug' by the definition)



Drug Name	Regulation
Acetazolamide ⁽¹⁾	I 9/98
Acetaminophen ⁽¹⁾	I 9/98
Acetophenone ⁽¹⁾	I 9/02
Acetyl-a-methylthioamyl ⁽¹⁾	I 9/02
Acetylarsinous ⁽¹⁾	I 9/98
Acetylcholine Chloride ⁽¹⁾	I 9/98
Acetylsalicylic acid ⁽¹⁾	I 9/98
Acetylsalicylic acid and its salts oral preparations containing 30 mg or less per dosage unit and intended for pediatric use or rectal preparations containing 100 mg or less per dosage unit, in package sizes containing no more than 1.50 g of acetylsalicylic acid.	II 2/02
Acetylsalicylic acid and its salts, in products for oral use in strengths of 325mg and 500mg per dosage unit.	III 10/00
Acetylsalicylic acid and its salts, in products intended for oral adult use in strengths of 80 mg per dosage unit and 100 mg or greater per dosage unit, and in rectal preparations containing more than 100 mg per dosage unit.	III 10/00
Adrelin and its salts and derivatives ⁽¹⁾	I 9/98
Acetamide and its salts ⁽¹⁾	I 9/98
Acrylonitrile and its salts ⁽¹⁾	I 9/98
Adifenone ⁽¹⁾	I 2/07
Adiphenone and its salts and derivatives ⁽¹⁾	I 9/98
Adiponitrile and its salts ⁽¹⁾ for personal use	I 9/98
Adiponitrile and its salts for professional use	II 9/98

Federal Legislation

- ❖ Food & Drugs Act
 - FDA
- ❖ Controlled Drugs & Substances Act
 - CDSA

Food and Drugs Act - Schedules

Schedule A

- [List of diseases](#) for which treatments may not be promoted to the public
- Advertising to consumers restricted

Schedule B

- refer to [publications](#) describing official drug standards

Food and Drugs Act - Schedules

Schedule C

[radiopharmaceuticals](#)

Schedule D

allergenic substances, blood derivatives, drugs obtained by recombinant DNA procedures, immunizing agents (vaccines), insulin, and others

Food and Drugs Act - Regulations

Part C

- drugs - [Schedule F](#) (2 parts)

Part E

- cyclamate, saccharin

Part G

- controlled drugs – [Schedule G](#) (regulations to the CDSA)

Food and Drugs Regulations Schedule F Part I

- Prescription required across Canada
- has **Pr** symbol on package
- no additional sales reporting required (but must maintain prescription file for two (2) years)
- examples:
 - amoxicillin
 - blood pressure meds
 - thyroid replacement

(Schedule I – NAPRA)

Food and Drugs Regulations Schedule F Part II

- Drugs may be sold without prescription if drug is in a form not suitable for human use, OR is labeled "**FOR VETERINARY USE ONLY**" by manufacturer
- Otherwise, a prescription is required
examples: penicillin
tetracycline
adrenocortical hormones
furosemide

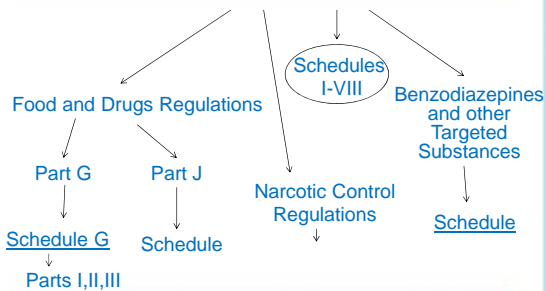


Controlled Drugs and Substances Act

- provides a framework for the control of import, export, production, distribution and use of substances that can alter mental processes and that may produce harm to health and to society when distributed or used without supervision.
- Controlled Substance – anything scheduled under CDSA
- Controlled Drug = Schedule G items (in the Food & Drug Regulations)



Controlled Drugs and Substances Act



Schedules...

Schedules I to VIII under CDSA

- Not currently used in pharmacy practice
- For assigning penalties for possession, trafficking, manufacturing...
- See reference article in *Pharmacy Connection* (March/April 1998)



Summary of Laws

Summary of Federal and Provincial Laws Governing Prescription Requirements,
Transfers, Refills, Prescription Drug Ordering and Records

Province	Prescription Requirements	Transfers	Refills	Prescription Drug Ordering	Records
Alberta
British Columbia
Manitoba
Ontario
Quebec
Saskatchewan
Yukon

From: www.ocpinfo.com

Page 1 of 2

Narcotic - Definition

- any substance included in or anything that contains any substance in the schedule to the Narcotic Control Regulations
- Symbol on stock bottle label (N)

Eg. codeine, morphine, meperidine, oxycodone



Narcotic Medications

Subdivided into 3 groups:

- **Straight** = single ingredient narcotic, injectables, multiple narcotic ingredients, narcotic compounds with 1 non-narcotic ingredient or 1 of "5" narcotics
- **Verbal Prescription Narcotic** = combinations containing 1 narcotic only and two or more medicinal ingredients
- **Exempted Codeine Preparations** = can be purchased without a Rx



Verbal Prescription Narcotic

- Defined
- contains in addition to a narcotic **two or more** medicinal ingredients other than a narcotic in a recognized therapeutic dose
- is **not** intended for parenteral use;
- does **not** contain diacetylmorphine (heroin), hydrocodone, methadone, oxycodone or pentazocine (the "5" narcotics)
- Prescription can be written (faxed) or given verbally
- Examples: Tylenol #3, Dimetapp C



Straight Narcotic

No direct definition in the legislation...

Must apply the previous definition 'backwards'

- single narcotic
- more than 1 narcotic ingredient
- injectable
- 1 narcotic + 1 medicinal ingredient
- contains oxycodone, hydrocodone, methadone, heroin or pentazocine
- requires a written (or faxed) prescription



Verbal or Written Rx ??

Tylenol #2 tabs
Tylenol elixir with codeine
Novahistex DH Expectorant
Fiorinal C ½ caps
Tylenol #4 tabs
Duragesic
Oxycontin



Exempted Codeine Preparations

OTC, non prescription Narcotics

maximum 8mg *codeine* per tablet/capsule, or 20mg per 30ml of liquid

PLUS

two other medicinal ingredients in a quantity of not less than the regular minimum single dose for one ingredient, or one half the regular minimum single dose for each such ingredient



Exempted Codeine Products

Must have warning on label by manufacturer:

"This preparation contains codeine and should not be administered to children except on advice of physician or dentist"

- **Shall not supply** if there are reasonable grounds for believing that the preparation will be used by a person for other than recognized medical or dental purposes



Exempted Codeine Products

Examples:

Tylenol #1
222 / A.C. & C. 8mg
Benylin with Codeine

(Schedule II)



Practitioner (Definition) - CDSA

A person registered and entitled under the laws of a province to practice medicine, dentistry or veterinary medicine

(compare with DPRA definition of a 'prescriber')



Double Doctoring (Definition)

No person shall seek or obtain

- a substance included in schedule I, II, III or IV, or
- an authorization to obtain a substance included in schedule I, II, III or IV from a practitioner, unless ...

(note: I,II,III,IV = 'all CDSA drugs')



Double Doctoring (Definition)

... the person discloses to the practitioner relating to the acquisition by the person of every substance in those schedules, and of every authorization to obtain such substances, from any other practitioner within the preceding thirty (30) days.

(patient needs to inform MD of past prescriptions)



Advertisement

- Any representation for the purpose of promoting directly or indirectly the sale of a narcotic
- Not allowed

(could include visibility and display of items in the dispensary)



Narcotic Control Regulations

Definition of a prescription

- a direction given by a **practitioner** that a **stated amount** of a **narcotic (or controlled drug)** be dispensed for the **person named**
- Eg. the quantity to dispense must be directly stated (50 tabs, 75ml) or can be calculated (i tid x 7 days)

These are not quantities for N/G:

i tid prn x 7 days

i-ii tid x 7 days i q4-6h x 7 days



Narcotic Control Regulations

- Pharmacist may supply if has received an order signed and dated by a practitioner and if signature is not known to the pharmacist, must be verified
- With verbal narcotic order, pharmacist must take reasonable steps to determine validity of prescription
- May supply **methadone** to dealer, hospital or pharmacist or patient if **physician is authorized (by the O.C.S and C.P.S.O.)** – CDSA sec.56



Narcotic Control Regulations

“A pharmacist shall not use a written or verbal prescription order to dispense a narcotic after the quantity specified has been dispensed”

TYLENOL #3
M:100 ← qty specified
SIG: i TID PRN
RPT X 4

WRONG!! No repeats allowed on Narcotics!!



Narcotic Control Regulations

policy does permit narcotic “part-fills”

- total quantity is prescribed, and amount for each part fill is specified (interval is optional)

TYLENOL #3
M: 500
SIG: i TID PRN

OK! → DISPENSE IN 100's

optional (q 30 DAYS)



Narcotic Control Regulations Sect. 43

“Pharmacist must take all reasonable steps that are necessary to protect narcotics on premises against loss or theft”

- Proper storage
- Inventory counts vs reconciliation
- Alarms
- Cameras
- Etc




Narcotic Control Regulations Sect. 45

EMERGENCY SUPPLY:

A pharmacist may supply another pharmacist with a quantity of a narcotic for emergency purposes (enough to fill one prescription) upon receipt of a written order signed and dated by that other pharmacist



Controlled Drugs

- Found in Schedule G to the Food and Drug REGULATIONS (Part G)
- Subdivided into Parts I, II and III
- Symbol on product label (stock bottle) 
- Eg. secobarbital, methylphenidate, d-amphetamine, phenobarbital, anabolic steroids



Food and Drug Regulations G.03.006

A pharmacist shall not refill a prescription for a controlled drug unless

- (a) the practitioner, at the time that he issued the prescription, [is] directed **in writing**, in the case of a controlled drug listed in **Part I** of the schedule to this Part ...
...that the prescription be refilled, the number of times that it may be refilled and the dates or the intervals between refills;



Part I Controlled Drug

Example of a written prescription:

Ritalin (methylphenidate) 10mg tabs

M: 100

S: i tid prn

Rep x 3 q 45 days

-what if this was a verbal prescription?
-what if the interval was missing?

Some examples of Part I CDs: Methylphenidate, dextroamphetamine



Food and Drug Regulations G.03.006

A pharmacist shall not refill a prescription for a controlled drug unless

- (a) the practitioner, at the time that he issued the prescription, [is] directed **in writing or orally**, in the case of a controlled drug listed in **Part II or III** of the schedule to this Part ...

that the prescription be refilled, the number of times that it may be refilled and the dates for or the intervals between refills;



Part II/III Controlled Drug

(written OR verbal Rx)

phenobarbital 30mg

M: 100

S: i qid

Rep x 3 q 25 days

(what if interval missing?)

Examples

Part II: phenobarbital, butorphanol

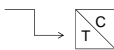
Part III: testosterone



Targeted Substances

- Schedule **IV** to the CDSA

- Symbol on stock bottle



- File Rx records with either N/CD or regular (doesn't matter, as long as consistent)



Benzodiazepines & Other Targeted Substances Regulations

s. 55 (b) A quantity may be sold to another pharmacy if the other pharmacist states that the targeted substance is required because of a delay or shortfall in an order for the targeted substance.

('Emergency supply')



Benzodiazepines & Other Targeted Substances Regulations

s. 52 **Refills** are permitted if number of refills are specified, a record is kept of each refill, less than one year has elapsed since the day on which the prescription was issued by the practitioner.

Must abide by any intervals noted by the prescriber.



'Notification'

- Relates to a pharmacist or prescriber
- Issued by Health Canada
- Specifically restricts the individual named from prescribing (or ordering) the Narcotic or Controlled Drugs or benzodiazepines as listed

(Must read the Notification letter carefully)



Ordering Supplies of Controlled Substances

Only by an authorized pharmacist ('narcotic signer' – notification of OCP by pharmacy owner)

- by written order
- through computer from **remote input device**
- by verbal order for verbal prescription narcotic that specifies **name and quantity** of narcotic



Narcotic Control Regulations Sect. 27

For order from remote input device or verbal order, licensed dealer must receive receipt a within five (5) working days stating:

- name and quantity of narcotic
- date received
- signature of pharmacist (who received order)

** (applies to all narcotics, controlled drugs & targeted substances)



Narcotic Control Regulations Sect. 27

For order from remote input device or verbal order, licensed dealer must receive receipt within five (5) working days.

If receipt is not received, licensed dealer shall not supply any further orders by remote to input device or telephone



CDSA- Narcotic Control Regs Sec.30

Upon receipt, pharmacist must forthwith enter in a book, register or other record

- name and quantity of narcotic, controlled drug, or targeted substance
- date received
- name and address of supplier

(see also FDA Part G.03.001)



CDSA- Narcotic Control Regs Sec.38

Except for verbal narcotics & propoxyphene, must enter in the sales record
(may be computer generated, or manual)

- patient name and address
 - name, quantity and dosage form
 - name, initials and address of prescriber
 - name of pharmacist
 - date supplied
 - prescription number
- (Part I Controlled Drugs are also to be recorded)



CDSA - Narcotic Control Regs Sec.38

If a prescriber writes any narcotic for **office** or **personal use**, this must be included in sales report (policy).

(This may be done manually, if the sale is of a non-reportable substance eg. Tylenol #3, phenobarbital)



CDSA - Narcotic Control Regs Sec.40

Must maintain special narcotic prescription file in sequence as to date and number for two (2) years

(Controlled Drug Rx records filed together with narcotic Rx)



CDSA - Narcotic Control Regs Sec.42

Pharmacist must report any loss or theft of narcotic within ten (10) days of discovery

Eg. Break in, grab theft, inventory shortage, spillage, breakage, forgery.



Destructions

- For damaged, outdated, unserviceable drugs (N, G, Targeted Substance)
- Letter (or Fax) to **Office of Controlled Substances** (Ottawa)
- Outline product name, exact quantity, lot number/expiry date and reason
- Reply will be MAILED back



Drug Control Unit, Compliance, Monitoring and Liaison Division

Office of Controlled Substances
Drug Strategy & Controlled Substance Programme
HEALTH CANADA
Address Locator: 3502B
Ottawa, Ontario
K1A 1B9

(613)957-0110 FAX
(613)954-1541 PHONE



Narcotic Safety and Awareness Act, 2010

Why create this legislation?

- promote appropriate prescribing and dispensing practices for monitored drugs
- identify and reduce the abuse, misuse and diversion of monitored drugs, and
- reduce the risk of addiction and death resulting from the abuse or misuse of monitored drugs
- collect, use and disclose information, including personal information, that relates to the prescribing and dispensing of narcotics and controlled substances ("monitored drugs") in Ontario



Narcotic Safety and Awareness Act, 2010

A prescriber who prescribes a monitored drug shall record the following information on the prescription:

1. The registration number on the certificate of registration issued to the prescriber by the College of which he or she is a member.
2. The patient's identifying number & type of ID on the prescription.
3. All of the other information which would be required on a prescription



Narcotic Safety and Awareness Act, 2010

A dispenser who dispenses a monitored drug shall keep a record of the following information with respect to the prescription:

1. The address, date of birth and gender of the person for whom the monitored drug is prescribed.
2. The patient's identifying number & type of ID
3. The prescriber's registration number
4. If the patient is not picking up the prescription him/herself, the name & address of the agent picking it up along with their identifying number and type of ID checked



Narcotic Safety and Awareness Act, 2010

Identity Verification

11. (2) A dispenser shall ensure that any identity verification requirements that are required by the regulations are met before dispensing a monitored drug. 2010, c. 22, s. 11 (2).

- The regulations require that the dispenser keep a record of the identifying number of the patient and type of ID that was used (the dispenser should not be the one recording the ID number on the prescription itself only in the prescription record)



Narcotic Safety and Awareness Act

NSSA – Regulations Section 5

- The prescriber must record the patient's identifying number & type of ID on the prescription
- The dispenser must keep a record of the patient's identifying number & type of ID
- If the prescription is called in verbally or the ID information is missing on the prescription, the pharmacist may document the information after confirming with the prescriber the patient ID type & number



Narcotic Safety & Awareness Act

NSSA – Regulations Section 7

- Specifies the type of identifying number that is acceptable i.e., government issued identification that bears the name of an individual and provides an acceptable level of certainty of the identity of the person – not necessarily photo ID
- List of approved forms of patient identification are on the Ministry website (subject to change occasionally)
- Requires dispensers to record the name, address, form of ID and number for persons who pick up a narcotic or controlled substance from the pharmacy (if someone other than the patient is picking up – agent/third party)
- Same rule would apply for monitored drugs being delivered to patients – if the person receiving the delivery is not the patient their name, address & ID number must be recorded



Narcotic Safety & Awareness Act

Some examples of acceptable forms of patient ID

- Ontario Health Card or other health card issued by a Province or Territory in Canada
- Valid Driver's License or Temporary Driver's License (issued by Ontario or other jurisdiction)
- Ontario Photo Card
- Birth Certificate from a Canadian province or territory
- Valid Passport – Canadian or other country
- Certificate of Canadian Citizenship

http://www.health.gov.on.ca/en/public/programs/drugs/ons/public_office/identification_list.aspx (link to full list – may change periodically)



Narcotic Safety & Awareness Act

NSSA Regulations

- provides exemptions to allow a prescription to be prescribed and dispensed if patients do not have appropriate identification – only the patient can pick up/accept a delivery, not an agent
- ensures that all opioids (including those not currently listed in the Controlled Drug and Substances Act – such as tramadol and tapentadol) are monitored drugs in Ontario
- exempts prescribers in certain settings such as a hospitals or prisons from the requirements of the NSAA



SUMMARY – WHAT IS A DRUG?

NAPRA Schedule I

- NCR Schedule I
- Benzodiazepine & Other Targeted substances Regulations Schedule
- FDA Schedule G (I, II, III)
- FD Reg Schedule F (I, II)
- Others as listed (eg. Muciprocin)

NAPRA Schedule II

- Exempted Codeine Preparations
- Others as listed

NAPRA Schedule III

- as listed

❖ Remember: the strictest rule always takes priority



Summary – What is NOT a Drug

NAPRA Schedule U (Unscheduled)

- Cosmetics
- Food products
- Natural Health Products**
- Homeopathic products



Practice, practice, practice...

Determine the Schedule that these products belong to, and describe how they would be sold (where, and by whom)

ibuprofen 600mg, 200mg tablets
ferrous fumarate 300mg (=100mg Fe)
pseudoephedrine 60mg tablets
digoxin 0.125mg tablets
Typhoid vaccine
ASA 80mg tablets, 81mg tablets



Provincial Legislation

Drug and Pharmacies Regulation Act (DPRA)



Drug and Pharmacies Regulation Act

- Provincial legislation
- Governs pharmacies (opening, closing, operation, ownership), sale of 'drugs', College committees, bylaws and enforcement
- Works in harmony with other legislation
- Definitions provided



Drug and Pharmacies Regulation Act

Definitions:

Certificate of registration - for pharmacist or pharmacy technician

Pharmacist - person registered as a pharmacist

Pharmacy technician – person registered as a pharmacy technician

Pharmacy – premises

Prescriber - authorized by laws/regulation to give Rx within their scope of practice of a health discipline

Prescription - direction from prescriber

Drug - item restricted in its sale to the public



Drug and Pharmacies Regulation Act

Section 118

- Does not apply to drugs compounded, dispensed, or supplied by a hospital or a health or custodial institution
- Allows practitioners who have the Controlled Act of dispensing to dispense to their own patients.
(This is the example of a drug being sold from a place other than a pharmacy)



Drug and Pharmacies Regulation Act

Who may prescribe drugs in Ontario

- Physicians (MD)
- Dentists (DDS)
- Veterinarians (DVM)
- Nurse Practitioners (RN(EC))
- Midwives (list of items)
- Chiropodists (DC) and Podiatrists (DPM)
- Optometrist (list of items)
(Scope of Practice)

Links to the different College's website are provided on the OCP website



Related Health Colleges

- [College of Physicians and Surgeons of Ontario \(CPSO\)](http://www.cpso.on.ca)
- [College of Nurses of Ontario \(CNO\)](http://www.cno.org)
- [Royal College of Dental Surgeons \(RCDS\)](http://www.rcdso.org)
- [College of Midwives of Ontario](http://www.cmo.on.ca)
- [College of Veterinarians of Ontario \(CVO\)](http://www.cvo.org)
- [College of Chiropodists of Ontario](http://www.cocoo.on.ca)
- [College of Optometrists of Ontario](http://www.collegeoptom.on.ca)



Prescription

- An order for a specific individual (patient)
- Ordered by an appropriate 'prescriber', after a diagnosis is made
- May be for a treatment, device, or medication (within the prescribers scope of practice)
- May be verbal or written (faxed)
- Written prescriptions must include a signature of the prescriber (...supported by CPSO policy)



Prescription (Written/Verbal/Faxed)



Dr. M. Smith
101 University Avenue Toronto, M5R 2R4
(416) 555-1212

Patient Name: Jane Doe
Address: 483 Huron Street, Toronto
Phone: (416) 962-4861
Date: June 17, 2010

amoxicillin 250mg
i tid
M: 30

Dr. M. Smith's Signature

Drug and Pharmacies Regulation Act Section 156

(1) Every person who dispenses a drug pursuant to a prescription shall ensure that the following information is recorded on the prescription

- the name and address of the person for whom the drug is prescribed;
- the name, strength (where applicable) and quantity of the prescribed drug;
- the directions for use, as prescribed;
- the name and address of the prescriber;



Drug and Pharmacies Regulation Act Section 156 (cont.)

- the identity of the manufacturer of the drug dispensed;
- the signature of the person dispensing the drug and, where different, also the signature of the person receiving a verbal prescription;
- an identification or other designation;
- the date on which the drug is dispensed;
- the price charged. (TOTAL)

(2) The records required under subsection (1) shall be retained for not less than two years.



Drug and Pharmacies Regulation Act

Part X Sect. 54-56 of the Regulations

– Record keeping

- Refers to making scanned electronic copies of prescriptions, hardcopies and other records/documents and retaining them as part of the patient record
- Must be kept for a period of 10 years from the last recorded professional pharmacy service or, if the patient is under 18, for 10 years after the patient turns 18
- Records must be readily retrievable and stored securely to ensure that patient confidentiality and privacy are protected



Record of Dispensing

Rx 1234 Doe, Jane 2 Jan 2012
483 Huron Street, Toronto (416)962-4861
Take 1 capsule 3 times daily.
Amoxicillin 250mg APX
30
Dr. M. Smith
101 University Ave, Toronto (416)555-1212
\$11.82
(signature of pharmacist)



“Signature”

- More than a mark or initials
- Not easily reproducible
- Distinctive
- Not a rubber stamp
- Should not be in pencil (erasable)
- Electronic signatures??

← must be unique, 'single use' signatures



Drug and Pharmacies Regulation Act Section 156 (Prescription Label)

(3) The container in which the drug is dispensed shall be marked with

- the identification number that is on the prescription;
- the name, address and telephone number of the pharmacy in which the prescription is dispensed;
- the identification of the drug as to its name, its strength and its manufacturer, unless directed otherwise by the prescriber;




Prescription Label (cont.)

- the quantity where the drug dispensed
- the name of the owner of the pharmacy;
- the date the prescription is dispensed;
- the name of the prescriber;
- the name of the person for whom it is prescribed;
- the directions for use as prescribed.



Prescription Label

 ANYTOWN PHARMACY (1235891 Ontario Ltd)
222 Main Street, TORONTO, ON
(416)595-1119

Rx 1234 Jane Doe

Take 1 capsule 3 times daily.

21 Amoxicillin 250mg APX

Dr. M. Smith 2 January 2012

(auxiliary label use?) (OCP Policy re: non-proprietary name use)



Misrepresentation

s.150 No person shall knowingly sell any drug under the representation or pretense that it is a particular drug that it is not, or contains any substance that it does not.

- Do not use Patented name if it is not the brand that was dispensed.
- Proper disclosure of brand used
- identification of ingredients in extemporaneous preps
- (placebo dispensing is allowed as prescribed)



DPRA Regulations Sec.44 & 45

"Child resistant package" means a container or a package that meets the standards for child resistant packages approved by the Minister.

Every person who fills a prescription shall dispense the drug in a child resistant package that is certified and designated by the Canadian Standards Association.



DPRA Regulations Sec.44 & 45

This requirement does not apply where

- the prescriber or the person who presents the prescription to be filled directs otherwise;
- in the professional judgement of the pharmaceutical chemist in the particular circumstances or the particular situation it is advisable not to use a child resistant package;
- a child resistant package is not suitable because of the physical form of the drug; or
- the person who fills the prescription is unable to obtain a child resistant package because supplies of such packages are unavailable on the market



DPRA Regulations Sec. 40

Verbal orders

3. The member receiving the verbal direction recorded,
 - i. the date the verbal direction was received,
 - ii. the number of refills authorized by the verbal direction, and
 - iii. the name of the member who received the verbal direction.
4. The prescription was recorded and signed by the member receiving the verbal direction.



Refill Authorization – DPRA Reg Sec.42

Pharmacists now have the authority to authorize refills of existing prescriptions under specific criteria (**ALL 4** must be met):

- reasonable efforts to contact the prescriber have been made and were unsuccessful;
- the prescriber of the prescription to be refilled, if available, would have authorized the refill;
- the patient for whom the drug is to be refilled has been prescribed the drug for a chronic or long term condition; **AND**
- the patient for whom the drug is to be refilled has a stable history with that drug



Refill Authorization – DPRA Reg Sec.42

- Cannot authorize the refilling of a narcotic, verbal prescription narcotic or controlled drug
- The total amount of the drug dispensed cannot be more than the amount previously dispensed or a three month supply, whichever is less
- A unique prescription identification number must be assigned to the authorized refill and the name of the original prescriber must be recorded in the patient record as well as the name of the authorizing pharmacist
- the prescriber and the patient's primary health care provider, if known, **must** be notified within 7 days of the authorization/dispensing date, name of drug and quantity dispensed



Drug and Pharmacies Regulation Act Section 157 (Rx Copy)

- (1) Every person in respect of whom a prescription is presented to a pharmacist to be dispensed, unless otherwise directed by the prescriber, is entitled to have a copy of it *marked as such*, furnished to the person, his or her agent, or a pharmacist acting on behalf of such person or agent.
 - is not valid as authorization
 - a pharmacist must provide a copy on request to patient, agent or pharmacist acting on behalf of patient or agent



DPRA Regulation Sec.43

A pharmacy may transfer a prescription to another pharmacy **EXCEPT**

- Schedule G or N (Controlled Drugs or Narcotics (NO TRANSFERS))
- All of the drugs authorized to be dispensed by the prescription have already been dispensed
- If that prescription has been previously transferred by that pharmacy



DPRA Regulation Sec.43

Prescription Transfers Cont.

The following information shall be provided to the pharmacy receiving the transfer:

- the name and address of the person for whom the drug is prescribed,
- the name and quantity of the drug prescribed and where applicable the strength of the drug,
- the directions for use as prescribed,
- the name and address of the prescriber,



DPRA Regulation Sec.43

Prescription Transfers (cont.)

- the identity of the manufacturer of the drug dispensed,
- the identification number of the prescription, ,
- the date the prescription was first filled and the date of the last refill,
- the total quantity of drug remaining to be dispensed under the prescription
- the quantity most recently dispensed if different from quantity prescribed
- the name of the member who is responsible for the transfer of the prescription



DPRA Regulation Sec.43

Prescription Transfers Cont.

A prescription shall not be transferred from a pharmacy unless a record is made in that pharmacy containing,

- (a) the date of the transfer of the prescription;
- (b) the identity of the pharmacy to which the prescription was transferred;
- (c) the name of the member who was responsible for the transfer of the prescription by the pharmacy; and
- (d) where the prescription was transferred verbally, the name of the person to whom the transfer was made.



DPRA Regulation Sec.43

Prescription Transfers cont.

- Authority to refill now transferred and cannot be filled in the originating pharmacy
 - Member cannot fill transferred prescription
 - Until all information is received and recorded by a member practising at the pharmacy
- Can be transferred into or out of Province (within Canada)



DPRA Regulation Sec.43

Prescription Transfers Cont.

Targeted Substances (CDSA)

Examples – lorazepam, clonazepam, diazepam

- Can only be transferred once
- Cannot be transferred further
- Cannot be refilled beyond 12 months from the date the original Rx was issued (must check the original prescription to verify date)



Drug and Pharmacies Regulation Act

Section 158 (out of province Rx)

A pharmacist may dispense a drug pursuant to a prescription authorized by a prescriber licensed to practise in a province or territory of Canada other than Ontario, if in the professional judgment of the pharmacist the patient requires the drug.

No allowances for prescriptions from US/international prescribers



OCP Policies And Guidelines



OCP Policies/Guidelines

Why Create Policies and Guidelines?

- Subjects not addressed in legislation
- Need for consistency
- Public protection



OCP Policies/Guidelines

Examples:

- Fax transmission of prescriptions
- Compliance Aids
- Dispensing components included in the U&C fee
- Designated Manager (3 different policies)
- Methadone Maintenance & Dispensing

Can be found on OCP website Professional Practice tab



Ontario Drug Benefit Formulary Comparative Drug Index (CDI)



Ontario Drug Benefit Formulary Comparative Drug Index

The Formulary / CDI serves as:

- a **guide to prescribers** and pharmacists to confirm a product is an eligible benefit
- a **guide for pharmacists** in stocking interchangeable products for dispensing
- a **guide to professional committees** in hospitals and institutions in the selection of pharmaceutical preparations



Ontario Drug Benefit Formulary Comparative Drug Index

The Formulary / CDI serves as:

- confirmation of the designation of drug products as **interchangeable** in the under Ontario legislation
- a **comparative pricing guide** for drug products



Ontario Drug Benefit Formulary Comparative Drug Index

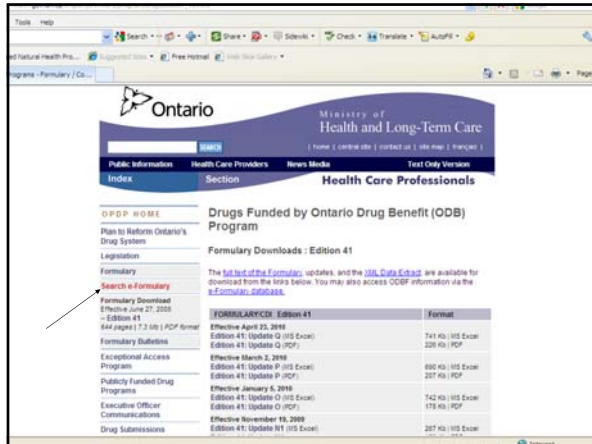
www.gov.on.ca/health/ MAIN WEBSITE

- "Drug Programs"
- "Drug Benefit Formulary and Comparative Drug Index"
- "Edition 41" (+ updates)

Direct link:

http://www.health.gov.on.ca/english/providers/program/drugs/odbf_mn.html





Ontario Drug Benefit Formulary Comparative Drug Index

12 "Parts" or sections

- Part I – Introduction
 - Background, How to Use, Dispensary Reimbursement/Procedures, Information/Contacts
- Part II – Preamble
- Part III A – Formulary/Comparative Drug Index (CDI)
 - Part III B – OFI listing
- Part IV – Alphabetical Index for Part IIIA and B



Ontario Drug Benefit Formulary Comparative Drug Index

- Part V – Pharmacotherapeutic Classification Index
- Part VI A – Facilitated Access Program and eligible drugs e.g. HIV/AIDS
 - Part VI B - Palliative care drugs
- Part VII – Trillium Program
- Part VIII – Exceptional Access Program EAP - (formerly Individual Clinical Review Program (ICR) formerly "s. 8 drugs")

Cont'd...



Ontario Drug Benefit Formulary Comparative Drug Index

- Part IX – Additional Benefits; nutritional/diabetic testing agents
- Part X – Abbreviations, Tables, Sample forms
- Part XI – (currently not used)
- Part XII – Limited Use Products, (consolidation of LU from Part III)



Provincial Legislation

Drug Interchangeability and Dispensing Fee Act (DIDFA)



DIDFA

- Provincial legislation
- Interchangeable Product (as defined) = products **listed** in the ODB Formulary/CDI (includes OFI items)
- The purpose of this law is to make it mandatory to offer the patient a lower priced medication alternative (interchangeable) if available. (PARCOST)
- Does **not** apply to the dispensing of a drug to a patient in a hospital.



DIDFA

Interchangeable Products

- a drug or combination of drugs identified by a specific product name or manufacturer and **designated** as interchangeable with one or more other such products
- **onus on the manufacturer** to provide evidence of interchangeability
- as per the **Committee to Evaluate Drugs (CED)**
- **Executive Officer** designates or removes interchangeable status



DIDFA Sec.4

- (1) If a prescription directs the dispensing of a **specific** interchangeable product,
the dispenser **may** dispense in its place another product that is designated as interchangeable with it.



Example

Rx written for:
PROZAC® 20mg

May dispense:
APO-Fluoxetine® 20mg
(check formulary)

(the ® symbol denotes 'patented' trade name of a product)



Formulary Search
Search the Ontario Drug Benefit Formulary/Comparative Drug Index, effective from **September 30, 2009**, using any or all of the criteria below.

Coverage Status: All Benefits
Therapeutic Classifications: All Therapeutic Classifications
Manufacturer: All Manufacturers
Keyword: PROZAC
 Generic Name Brand Name DRUGS
 Search for Products that begin with keyword entered Generic Brand name Summary List
[Search] [Reset]

is provided as a convenience only and should not be relied on as authoritative. The Ministry endeavours to update the information on this web site periodically, but does not guarantee that the information is the authoritative list of the Ontario Drug Benefit Formulary / Comparative Drug Index (Formulary / CDI). See the latest version of the Formulary published by the Ministry of Health and Long-Term Care.
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Search Results
You can sort your results in ascending / descending order by clicking on the column headings, with the exception of Therapeutic Notes.

Products found: 2

DRUGPN	Generic Name	Brand Name, Strength & Storage Form	EBR	Drug Benefits Price	Amount BCH/TC Pays	Inter-changeability	Limited Use	Therapeutic Notes
02018895	FLVOIETRIE HCL	Prozac (not a Benefit): 10mg Cap	LL	714	NA	YES	NO	YES
00536622	FLVOIETRIE HCL	Prozac 20mg Cap	LL	1.6393	0.8025	YES	NO	YES

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FLUOXETINE HCL
20mg Cap
Amount MOH/TC Pays: 0.4598

Interchangeables found: 11

DRUGPN	Brand Name	Drug Benefit Price
02215081	Apo-Fluoxetine	0.4598
02462278	Co-Fluoxetine	0.4598
02286079	Fluoxetine	0.4598
02272934	Mylan-Fluoxetine	0.4598
02218098	Novo-Fluoxetine	0.4598
02502364	Ro-Fluoxetine	0.4598
02177382	PMS-Fluoxetine	0.4598
02222860	PMS-Fluoxetine	0.4598
08536622	Prozac	1.6393
02481374	Ratio-Fluoxetine	0.4598
02481487	Sandoz-Fluoxetine	0.4598
02820002	Zim-Fluoxetine	0.4598

is provided as a convenience only and should not be relied on as authoritative. The Ministry endeavours to update the information on this web site periodically, but does not guarantee that the information is the authoritative list of the Ontario Drug Benefit Formulary / Comparative Drug Index (Formulary / CDI). See the latest version of the Formulary published by the Ministry of Health and Long-Term Care.
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DIDFA Sec.4

(2) If a prescription directs the dispensing of a **specific** interchangeable product,
the dispenser, on the request of the person for whom the product was prescribed or the person presenting the prescription **shall** dispense in its place another product that is designated as interchangeable with it.



Example

Rx written for:
PROZAC ® 20mg

Patient requests:

“A generic brand”

(check in Formulary for brand to dispense)



Interchangeables found: 12	Brand Name	Single Source Price
02153811	Apo-Fluoxetine	0.4598
02424178	Cu-Fluoxetine	0.4598
02286076	Fluoxetine	0.4598
02223114	Mylan-Fluoxetine	0.4598
02155596	Nivo-Fluoxetine	0.4598
02182734	Nu-Fluoxetine	0.4598
02172387	PHS-Fluoxetine	0.4598
02222593	Phl-Fluoxetine	0.4598
09036932	Prozac	1.8393
02451374	Rabo-Fluoxetine	0.4598
02454887	Sandoz-Fluoxetine	0.4598
02303897	Zim-Fluoxetine	0.4598

DIDFA Sec.4

(3) If a prescription directs the dispensing of a **specific** interchangeable product,

the dispenser shall not supply that product without informing the person for whom the product was prescribed or the person presenting the prescription, in the manner prescribed by the regulations, of the right to request an interchangeable product.



DIDFA Sec.4(3)

Using the previous example:

- Rx written for 'Prozac'
- **Must** inform patient that there is an interchangeable product available.
- Brand decision is the patient's choice.
- Use formulary for brands to choose from
- Interchangeable brands are all approved by CED



DIDFA Sec.4

(4) Subsection (3) does not apply if,

- the amount to be charged for supplying the product specified in the prescription is not more than the least amount that would have been charged for supplying a product that is interchangeable with it and available in the dispenser's inventory; or

Eg. Can dispense 'Name Brand' without notifying patient if you charge the price of the generic product.



DIDFA Sec.4

- (4) Subsection (3) does not apply if,
- the product is being supplied pursuant to a repeat of the prescription.

Eg. If 'Brand Name' product was used in first fill, may continue to use it



DIDFA Sec.4

- (5) If a prescription directs the dispensing of a product that is **not** designated as an interchangeable product and there is an interchangeable product that contains a drug or drugs in the same amounts of the same active ingredients in the same dosage form ... the dispenser may dispense the interchangeable product.

'Substitution **into** the formulary'



Example

Rx written for:
Tylenol ® 325mg tabs

May dispense:
Tylenol ® 325mg tabs
or acetaminophen 325mg tabs
➢ a brand listed in the formulary
➢ cannot just dispense 'any' brand...



Interchangeable brand #	Brand name	MOH/TC Paye
000000	Acetaminophen	0.0114
000001	Apix-Acetaminophen	0.0245
000002	Alaxon (not a brand)	N/A
000003	Novoclon	0.0114



DIDFA Sec.4

- (6) Subsections (1), (2), (3), and (5) do not apply to a prescription that includes,

- in the case of a written prescription, the handwritten "no sub", "pas de rempl.", "no substitution" or "pas de remplacement"; or
- in any other case, a direction recorded by the dispenser that there be no substitution. (eg: patient request)



DIDFA Sec.4

- (7) If a prescription directs the dispensing of a drug for which there are interchangeable products **without identifying a specific product name or manufacturer**, the dispenser shall dispense an interchangeable product of that drug.



Example

Rx written for:
furosemide 40mg

May dispense:
Any brand listed in the formulary
(not just ANY brand on the market)



Interchangeable Grouping

You can sort your results in ascending/descending order by clicking on the column headings.

40.00 ELECTROLYTIC CALOREIC AND WATER-BALANCE
40.20.00 DIURETICS

FUROSEMIDE
40mg Tab
Amount MOHLTC Pays: 0.0558

Interchangeable Brand #	Brand Name	Drug Strength Price
0026255	Apix-Furosemide	0.0558
0228256	Lasix	0.1307
0020259	Neon-Semide	0.0558

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DIDFA Sec.4

(8) If an interchangeable product is dispensed in accordance with this Act, no action or other proceeding lies or shall be instituted against ... the dispenser ... on the grounds that an interchangeable product other than the one prescribed was dispensed.



DIDFA Sec.4 - Examples

Rx

Zestril®
10mg
tabs

- Listed in CDI / ODB formulary
- = interchangeable
- can dispense:
 - Zestril
 - a brand listed in the Formulary
- must inform patient of option to substitute



24.00 HYPOTENSIVE DRUGS FOR DIURETICS SEE 40.20

LISINAPRIL
10mg Tab
Amount MOHLTC Pays: 0.1619

Interchangeable Brand #	Brand Name	Drug Strength Price
0021263	Apix-Lisinopril	0.1619
0021261	Cil-Lisinopril	0.1619
0026650	Lisinopril	0.1619
0023265	Lisinopril Tablets	0.1619
0021661	Mylan-Lisinopril	0.1619
0028326	Neon-Lisinopril (Part 2)	0.1619
0026271	PH-Lisinopril	0.1619
0026269	Rap-Lisinopril	0.1619
0028882	Rapex-Lisinopril Z	0.1619
0028262	Sandoz-Lisinopril	0.1619
0026270	Zestril	0.1619



DIDFA Sec.4 - Examples

Rx

lisinopril
10mg
tabs

- Listed in CDI / ODB formulary
- = interchangeable
- can dispense:
 - any brand listed



DIDFA Sec.4 - Examples



- not listed in CDI / ODB formulary
- not interchangeable (BUT: interchangeable ingredient)
- can dispense:
 - Acme Brand
 - any brand listed (ie: sub into formulary)



DIDFA Sec.4 - Examples



- NOW in CDI / ODB formulary (OFI section)
- interchangeable
- can dispense:
 - Minocin brand
 - OR: another brand listed as interchangeable can be offered to patient



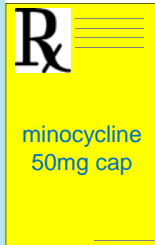
Interchangeable Grouping

MINOCYCLINE HCL
50mg Cap
Amount MOHLTC Pay: 0.0000

Interchangeable Brand #	Brand Name	Drug Benefits Status	New Search
02054050	Apo-Minocycline (Pat & Benefit)	N/A	
02120214	Minocin (Pat & Benefit)	N/A	
02202233	Mylan-Minocycline (Pat & Benefit)	N/A	
02308443	Novo-Minocycline (Pat & Benefit)	N/A	
02204419	PMS-Minocycline (Pat & Benefit)	N/A	
02384538	Rabe-Minocycline (Pat & Benefit)	N/A	
02321233	Sandoz-Minocycline (Pat & Benefit)	N/A	



DIDFA Sec.4 – Examples



- NOW in CDI / ODB formulary
- interchangeable
- can dispense:
 - any brand listed in OFI section
 - Dialogue with patient as to which brand they would prefer



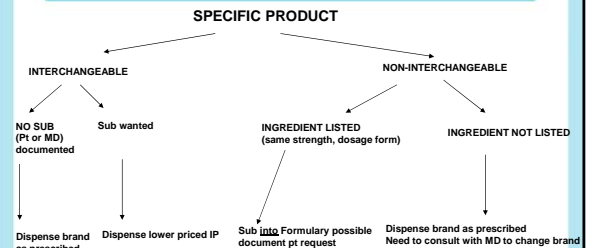
DIDFA Sec.4 – Examples

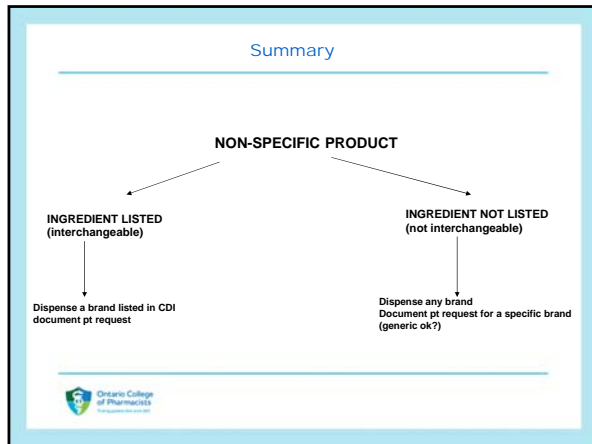


- NOW in CDI / ODB formulary
- interchangeable
- can dispense:
 - Apo brand
 - another brand listed as interchangeable



Summary





DIDFA Sec.9

(1) Every person who dispenses a drug pursuant to a prescription shall dispense the **entire quantity** of the drug prescribed at one time unless before the drug is dispensed the person presenting the prescription in writing authorized the dispensing of the drug in smaller quantities

Example

Rx written for:
 Losec 20mg
 M: 100 tabs

Dispense 100 tablets
 (unless request for less is documented)

DIDFA Reg 936

3. A drug may be dispensed in less than the entire quantity prescribed,

- if the proper exercise of professional judgment by the dispenser so requires;
- when a lesser quantity is being paid for under an agreement between an insurer or other person and a beneficiary or subscriber to provide payment for health care services upon the payment of an agreed amount of money

DIDFA Reg.936

4. (1) A person who dispenses a drug pursuant to a prescription shall provide a **receipt** ... at the same time that the drug is supplied that sets out the amount being charged in respect of,

- a dispensing fee;
- the cost of the drug; and
- the total price of the prescription.

DIDFA Reg.936

4. (2) Subsection (1) does not apply to a drug that does not require a prescription.

(eg. A Schedule II or III item)

DIDFA Reg.936

5. (1) Every operator of a pharmacy shall retain each invoice and purchase record, including any record of price reductions ... in the form of rebates, discounts, refunds or free goods, ... received ... that relates to the purchase by the pharmacy of drug products to which the Act applies.



DIDFA Reg.936

5. (2) An invoice or record referred to in subsection (1) shall be retained by the operator in the pharmacy or readily available to the pharmacy to which it relates for at least two years from the receipt of the invoice or record.

(note: Canada Revenue Agency requires longer retention period)



DIDFA Reg.936

1. For the purposes of section 4(3) of the Act, the posting of the following notice clearly and prominently in or adjacent to the dispensary area so that it is readable by the person presenting the prescription is prescribed in the manner in which persons shall be informed of the right to request an interchangeable product.

(Yellow OCP 'Notice to Patients' sign)



DIDFA Reg.936

2. For the purposes of section 6(4) of the Act, the posting of the following notice clearly and prominently in or adjacent to the dispensary area so that it is readable by the person presenting the prescription is prescribed in the manner in which persons shall be informed of the usual customary dispensing fee.

(Yellow OCP 'Fee posting sign')



DIDFA Reg.935

5. A person may charge more than the person's usual and customary dispensing fee for a product that is supplied pursuant to a prescription if the person explains why a fee in excess of the usual and customary fee is being charged prior to the dispensing of the prescription and the charging of the additional fee is not an act of professional misconduct



Any questions?

nsutcliffe@ocpinfo.com

And check the OCP website for many FAQs

