

# PROVINCIAL LEGISLATION

## ONTARIO DRUG BENEFIT ACT AND REGULATIONS



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of Pharmacists  
Putting patients first since 1875

2011

Ministry of Health and Long Term Care Programs

[www.gov.on.ca/health/](http://www.gov.on.ca/health/) MAIN WEBSITE

- “Drug Programs”
- “Drug Benefit Formulary and Comparative Drug Index”
- “Edition 41” (+ updates)
- “MedsChek”

Direct link:

[http://www.health.gov.on.ca/english/providers/program/drugs/edition\\_41.html](http://www.health.gov.on.ca/english/providers/program/drugs/edition_41.html)



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The screenshot shows the Ontario Drug Benefit website interface. The 'Formulary' link is highlighted with a red arrow. The page title is 'Ontario Public Drug Program - Formulary / Comparative Drug Index'. The navigation menu includes 'Public Information', 'Health Care Providers', 'News Media', and 'Test Only Version'. The main content area is titled 'Health Core Professionals' and lists various sections such as 'Drugs Funded by Ontario Drug Benefit (ODB) Program', 'Formulary Downloads: Edition 41', 'Formulary', 'Formulary Download', 'Formulary Bulletin', 'Exceptional Access Program', 'Specialty Funded Drug Programs', 'Executive Officer Communications', 'Drug Submissions', 'New Drugs Are Approved', and 'Councils'. A table lists the effective dates and versions for various formulary components.

The ODB Formulary/CDI  
“The Formulary”

### 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



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The ODB Formulary/CDI  
“The Formulary”

- Part V – Pharmaco-Therapeutic 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

Cont’d...



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The ODB Formulary/CDI  
“The Formulary”

- Part VIII – Exceptional Access Program EAP - (formerly Individual Clinical Review Program (ICR) formerly “s. 8 drugs”)
- 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)



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### Ontario Drug Benefit Act Principles

- Meet needs of patients, consumers and taxpayers in Ontario
- Involve consumer and patients in a meaningful way - Accountability
- Operate transparently to fullest extent for all who have an interest in the system
- Ensure best use of resources, value for money and cost-effectiveness
- Utilize best clinical and economic evidence for funding decisions for drugs



### Ontario Drug Benefit Act

- ODB depends on DIDFA to achieve cost savings
  - Utilize principles of interchangeability (DIDFA)
- Don't confuse ODB and DIDFA
  - DIDFA applies to all prescriptions in Ontario
  - ODB only applies to ODB eligible drugs for ODB eligible recipients
- Definitions in both DIDFA and ODB crucial to understanding the Acts e.g. executive officer, interchangeable, listed drug product...



### Ontario Drug Benefit Act Executive Officer ODBA s. 1.1

- Executive Officer (EO) replaces the Minister of Health
- Perform any function or duty under both the ODBA and DIDFA
- Administer the Ontario public drug programs



### Ontario Drug Benefit Act Pharmacy Council

- Pharmacy Council advises EO and MoH on health and pharmaceutical policies
  - Ensures involvement of pharmacists
- Define and implement professional services
- Co-chaired by representatives of the Ministry and the Ontario Pharmacists Association



### Ontario Drug Benefit Act Eligible Persons: Section 2

#### Member of a "Designated Class"

- defined in the Regulations
  - Seniors, eligible Home Care recipients, Nursing Home residents, Homes for Special Care residents, Homes for the Aged and Rest Home residents, residents of approved "charitable homes"



### Ontario Drug Benefit Act Eligible Persons: Section 2

Also applies to "persons entitled to receive benefits" under - Family Benefits Act, Ontario Disability Support Program Act, Ontario Works Act"

- Social assistance
- Family benefits



Ontario Drug Benefit Act  
Application of the Act: Section 3

- **Only applies to**
  - supplying of 'listed drug products'
  - eligible persons
- **Does not apply to the cash or private sector\***

Health care sector divided into groups –

- 1) public funded by government or public sector
- 2) cash paying or people covered by private insurance or private sector



Ontario Drug Benefit Act  
Billing Restrictions: Section 4

- **No operator of a pharmacy or physicians can charge or accept payments from anyone except the EO for the purposes of this Act**
- **Co-payments permitted**
- **Regulations provide EO with authority to determine maximum amount**
- **Collection of co-payment is not mandatory – “...pharmacist may charge...”**



Ontario Drug Benefit Act  
Payment of Claims: s. 5

- **Executive officer obligated to pay for those claims where provisions of the Act and Regulations are met**
- **EO allowed to pay different amounts, subject to prescribed requirements, e.g. compliance packaging**



Ontario Drug Benefit Act  
Refusal to Dispense Prohibited: section 10

- **cannot refuse to dispense to an eligible person to avoid any provision of this Act**
  - e.g disagree with fee, holiday supply
- **can refuse for reasons of professional judgement**
  - document situation and reasons



Ontario Drug Benefit Act  
Dispensing Fees s.6(2)

**For Pharmacies:**

- **No dispensing fee where a listed drug product does not require a prescription for sale and to which this clause applies**
- **in all other cases, *the lesser of,***
  - (i) The dispensing fee prescribed by the regulations or
  - (ii) **the amount the operator sets under subsection 6(1) of the *Drug Interchangeability and Dispensing Fee Act. (i.e. usual and customary dispensing fee the operator of the pharmacy registers with the College)***



Ontario Drug Benefit Act  
Amount EO to pay: section 6

**s6(3) If the acquisition cost of a listed drug product for an operator of a pharmacy is greater than the sum of the drug benefit price...and the mark up on that price the EO shall also pay, under subsection 5(1), the difference between the acquisition cost for the drug product and that sum.**

*(must provide documentation, i.e. invoice to prove you purchased the drug at a higher price)*



## Ontario Drug Benefit Act Section 6

### Interchangeable Products

- Where interchangeable products are dispensed, you must charge for the lowest priced interchangeable product listed
- You can dispense a higher priced interchangeable product but you will only be paid for the lowest priced interchangeable product listed



## Ontario Drug Benefit Act "No substitution" by "physician"

s6(5) provides for the payment of eligible drugs where the Physician has indicated "no substitution"

- **Must meet conditions prescribed by the Regulations**
  - Physician must indicate in writing "no substitution" for a written Rx
  - Physician must provide a **Canada Vigilance Adverse Reaction Reporting Form** for the pharmacist
  - Verbal Rx – pharmacist must ensure that a **Canada Vigilance Adverse Reaction Reporting Form** is provided by the physician



## Ontario Drug Benefit Act "No Substitution" by "patient"

- Patient choice protected in the ODB Program, same principle as DIDFA
- If the 'brand' or more expensive listed interchangeable drug product is requested by patient, i.e. no substitution pharmacist "May charge" or collect the difference between the more expensive interchangeable product and what ODB will pay
- s. 4(5) provides formula for calculating the difference
- Document the patient's request



## Ontario Drug Benefit Act Amount EO to Pay: section 6

Provides the formula for calculating what the EO will pay

Drug Benefit Price (DBP) + the Mark-up (MU) + the Dispensing Fee (DF) – (the Co-payment) = what the Executive Officer pay

$(DBP + MU + DF) - (\text{co-pay}) = \text{payment}$

Drug benefit price (DBP), markup (MU) and dispensing fee are stated in the Regulations



## Ontario Drug Benefit Act "Limited Use" s. 23

- For some drugs or classes of drugs that are listed in the Formulary but only reimbursed for specified clinical criteria or indications
- Where patient does not meet clinical criteria, pharmacy may charge patient for the drug
  - Amount the same as if the drug were covered

For example:

If the patient was eligible for coverage under limited use criteria – the amount charged would be \$50

If the patient is ODB eligible & did not qualify for coverage under the LU criteria – the amount the pharmacy must charge the patient would also be \$50



## Ontario Drug Benefit Act Unlisted Drugs, Special Cases s.16 (Exceptional Access Drugs (EAP))

- For unlisted drugs (formerly s. 8 drugs, Individual Clinical Review (ICR)) and special cases
- Patient requires drug "not listed"
  - Physician can apply to EO
  - EO may make Act apply to that drug
  - Price determined by EO
- Patient requires a "listed" drug for a condition which is not an approved condition for payment for that "listed" drug e.g. Limited Use product
  - EO may make Act apply to that drug
- EO may make application apply retroactively



ODBA REGULATION 201/96  
SECTION 2

**Eligible Persons**

- Persons receiving professional service referred to in the Long Term Care Act or arranged by Community Care Access
- Resident of home licensed under sec 5 of Homes for Special Care Act
- Eligible for pension under Part I of the Old Age Security Act
- Attained 65 years of age
- Residents of charitable homes for the aged or nursing homes



ODBA, Regulation 201/96

**Seniors (65+)**

**Cannot get benefits until**

- First day of the month they receive their pension
- First day of the month following their 65<sup>th</sup> birthday and covered by OHIP

**For example: person's birthday is May 15<sup>th</sup>**

- Not eligible for benefits until June 1<sup>st</sup> (following month)



ODBA, Regulation 201/96  
section 3: Trillium Program

• **Catastrophic Drug Program**

- Persons with high drug expenditures in relation to their income
- All other forms of health insurance expended
- Insured under the Health Insurance Act, i.e. a valid Ontario Health Insurance Card
- Application to the executive officer
- Program runs from Aug. 1 of one year to July 31 of next
- Must meet annual deductible – paid in 4 installments through the year
- Once deductible met, co-pay is \$2.00 for each prescription.



ODBA, Regulation 201/96  
section 9: Extemporaneous Preparations

- **Cannot be equivalent to a manufactured product**
- **Topical or dermatological preparations restricted to specific substances that can be added**

\*detailed conditions for extemp. prep. found in Part I of Formulary



ODBA, Regulation 201/96  
Limits on Amounts paid by EO

- Administer and control costs
- Ontario Works Act, 1997 recipients – EO will only pay for a 35 day supply (may supply up to 100 day under specific conditions)
- All other eligible recipients can receive up to a 100 day supply
- Limits amounts paid where eligibility period ends – will pay to a maximum of 30 days beyond end of eligibility



ODBA, Regulation 201/96  
Limits on Amounts paid by EO

**“30 day program”**

- On all new prescriptions or prescriptions that patient has not had in previous 12 months
- Limits the initial Rx to a 30 day quantity if a larger quantity has been authorized
- Allows a person to try medication and allows for monitoring of efficacy
- Designed to reduce waste
- Allows for exceptions if patient cannot come back in 30 days (document reasons)



## Ontario Drug Benefit Act Regulation 201/96

Co payments: s.20.1/20.2

- **Introduces concept of co-payment**
  - payment of portion of the cost of prescription which is shared by patient – “co-payment”
- **Introduces concept of a “deductible”**
  - amount that must be paid initially by patient in order for an eligible person to receive benefits from a drug plan



## Ontario Drug Benefit Act Regulation 201/96

Co-payment: s. 20.1/20.2

- **s.20.1 establishes co-payment as \$2.00 or U&C whichever is less**
- **Co-payment for different groups of eligible persons subject to conditions listed in regulation**
- **s.20.2 provides for a different maximum co-payment for a specific group of eligible persons by determining criteria for this group**



## Ontario Drug Benefit Act Regulation 201/96

Co-payment: s. 20.2

- **Separates eligible persons who have attained 65 years of age into two groups based on income, s.20.2 exempts**
  - those eligible who earn less than \$16,018 as a single person
  - those eligible who cohabit with a spouse and earn less than \$24,175 as a couple
  - Co-payment for this group remains at \$2.00



## Ontario Drug Benefit Act Regulation 201/96

Higher income Seniors

- **Benefit period based on fiscal year (Aug. 1-July 31)**
  - Must pay a \$100 deductible each year
- **For new seniors (first year when turning 65) deductible based on month of birth**
  - Amount decreases from August to July (\$100 decreases through year to \$8.33 in June/July)



## ODBA, Regulation 201/96

### Amounts Charged to Person Other Than EO Section 21

- Quantity exceeds the maximum quantity the EO will pay for under sec.8
- Requires the pharmacist to inform the person why the person is being charged
  - Must give the person the choice of getting the additional quantity and paying or receiving the maximum allowable quantity
- Eligible person opts out and wants to pay (must inform the person that they could receive benefits)
- If the pharmacy does not submit online claims, they may charge the person the amount that would have been payable under sec 5(4) of the Act



## Ontario Drug Benefit Act Nutritional Products – Additional Benefits (part IX)

- **Not a Formulary benefit but an additional benefit for ODB eligible persons under defined circumstances**
  - Sole source of nutrition
  - Must meet functional impairment criteria
  - Must be supported by a Nutrition Product Form (keep for 2 years)
- **ODB does not pay the full amount on all products and pharmacist may charge patient for difference on specific products**



Ontario Drug Benefit Act  
Diabetic Testing Agents: Additional Benefit (Part IX)

- **Most testing agents (blood glucose strips covered by ODB)**
- **Requires a prescription from physician**
- **ODB only pays a maximum amount and pharmacist may collect from patient where amount exceeds maximum ODB will pay only on specified products**



ODBA, Regulation 201/96

Manual Claims

- If drug was supplied more than 7 days earlier
- Claim reversal more than 7 days after original submission
- Two or more override codes
- Claim is more than \$10,000
- Mixture which requires more than 100 minutes of preparation time

Must be made within 6 months from date of service.



Ontario Drug Benefit Act

- **Nurse Practitioners in the Extended Class - RN(EC)**
- **Limited prescribing privileges**
- **Only eligible listed drugs in the Formulary will be reimbursed by ODB**
- **RN(EC) list of drugs may change from time to time**
  - new drugs added to RN(EC) schedule automatically become eligible if they are listed in the Formulary



Ontario Drug Benefit Phone Numbers

Pharmacist Help Line

**1-800-668-6641**

Seniors Info Line

**1-888-405-0405**

Trillium Drug Program

**1-800-575-5386**  
**(416)-326-1558 (Toronto)**



Ontario Drug Benefit Program

- Remember: **this is a drug payment plan**
- **Will only pay for eligible drugs to eligible recipients**
  - Where there are questions patients should contact the help desk



**Any Questions ??**

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