




Provincial Legislation Ontario Drug Benefit Act and Regulations


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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, listed substance, designated...



Ontario Drug Benefit Act Powers of the Executive Officer

- 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
- Keep, maintain and publish the Formulary
- Apply the Act for unlisted or restricted criteria drugs
- Manage the listing or removal of designated products

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Ontario Drug Benefit Act Powers of the Executive Officer

- Designate products as interchangeable with other products under DIDFA or their removal
- Negotiate agreements with manufacturers, agree to pricing with manufacturers
- Define template requirements for information provided to EO
- Make payments under the programs
- Establish clinical criteria for drugs under s.23
- Pay for professional services and determine amounts based on prescribed conditions.




Ontario Drug Benefit Act Pharmacy Council

- Creation of the Pharmacy Council to advise 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 The Formulary

- ODB Formulary/Comparative Drug Index commonly referred to as the Formulary serves a dual purpose and identifies:
 - all “listed drug products” and “listed substances” eligible for reimbursement by the ODB program
 - all products that are interchangeable for the purposes of DIDFA
 - drug benefit prices
- Products and prices effective the date published in the Formulary (or ceases when removed)
- Any other information necessary for administering the ODB program




Ontario Drug Benefit Act The Formulary

12 “Parts” or sections

- Part I – Introduction
 - Background, How to Use, Dispensary Reimbursement/Procedures, Information/Contacts
- Part II – Preamble
- Part III – Formulary/Comparative Drug Index (CDI)


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Ontario Drug Benefit Act The Formulary


- Part IV – Alphabetical Index for Part III
- Part V – Pharmaco-Therapeutic Classification Index
- Part VI – Facilitated Access Program and eligible drugs e.g. HIV/AIDS and Palliative care drugs,
- Part VII – Trillium Program

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Ontario Drug Benefit Act The Formulary

- Part VIII – 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)



Ontario Drug Benefit Act Eligible Persons


- member of a “prescribed class”
 - insured under the Health Insurance Act (OHIP)
 - 65 years of age or older
 - eligible for pension under Part I of the Old Age Security Act or
 - Receiving services or residing in a home identified in the Regulations (O.R. 201/96)
- persons entitled to receive drug benefits under
 - Family Benefits Act, Ontario Works Act, Ontario Disability Support Program Act



Ontario Drug Benefit Act Application of the Act


- Only applies to
 - supplying of “listed drug products”
 - persons eligible to receive benefits
- Does not apply to the cash or private sector*

* Health care sector divided into groups – 1) public sector, publicly funded by government or 2) private sector, cash paying or people covered by private insurance




Ontario Drug Benefit Act Billing Restrictions: Section 4

- No operator of a pharmacy or a physician can charge or accept payments from anyone except the EO for the purposes of this Act
- Allows for collection of the co-payment from the patient
- Can collect from the patient only what the Act allows
- Collection of co-payment is not mandatory – “pharmacist may charge...”




Ontario Drug Benefit Act “No Substitution” by “patient”

- Patient choice protected in the ODB Program, same principle as DIDFA
- Brand or more expensive listed interchangeable drug product is **requested by patient**, i.e. no substitution
- “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




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 i.e. drug benefit cost, markup and fee less the co-pay.
- EO may pay a different amount subject to prescribed requirements
- Allows for agreements to pay different amounts where agreements are in place e.g. capitation on Methadone



Ontario Drug Benefit Act Amount executive officer to Pay Section 6

- Provides the formula for calculating what the EO will pay,
(Drug Benefit Price + Markup + Dispensing Fee – co-payment) = what the Minister pays
- Above components determined by Regulations



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 (currently \$7.00) 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 Executive Officer to pay

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

$(DBP + MU + DF) - (\text{co-pay}) = \text{payment}$
 $(10.00 + 0.80 + 7.00 - 6.11) = 11.69$
 (phm't collects \$6.11 copay)

- Pharmacist responsible for collecting co-pay




Ontario Drug Benefit Act
Amount Executive Officer to pay

Where dispensing fee is less than the co-payment prescribed, the lower dispensing fee also becomes the co-payment

$(DBP + MU + DF) - (\text{co-pay}) = \text{payment}$
 $(10.00 + 0.80 + 4.99 - 4.99) = 10.80$
 (phm't collects \$4.99 copay)


- Pharmacist responsible for collecting co-payment



Ontario Drug Benefit Act
Amount Executive Officer to pay

High Acquisition Cost


- Acquisition cost higher than drug benefit cost
- Mechanism to recover the difference from the EO provided in the Act
(must maintain documentation for proof, i.e. invoice)



Ontario Drug Benefit Act
Amount Executive Officer to pay

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
Amount Executive Officer to pay


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 an adverse drug reaction form for the pharmacist
 - Oral Rx – pharmacist must ensure that an adverse drug reaction form is provided by the physician



Ontario Drug Benefit Act
Refusal to Dispense Prohibited: s. 10

- Cannot refuse to supply a listed drug product to an eligible person to avoid meeting requirements of the Act
- Exception – the use of professional judgement, e.g. harm may come to patient



Ontario Drug Benefit Act
Administration: s.11-s.11.3

- Opting out by pharmacies
- Suspending pharmacy operators right to payments
- Suspending physicians right to payments
- Claims from eligible persons



Ontario Drug Benefit Act Administration: s.11.4 - s.11.6

- Process for pricing listed drug products by manufacturers
- Rebates by manufacturers
- Enforcement and penalties by EO
- Defines “rebates” (s. 11.5 (18))
- EO establishes “Code of Conduct” (s 11.5 (15)) for provision of “professional allowances/rebates”



Ontario Drug Benefit Act Administration: s.12 – s.15

- Agreements, confidentiality, collection of personal health information, inspections, etc.
- Requirement for manufacturers and pharmacies to provide information other than personal health information
- Inspections and powers of inspectors
 - broad powers to examine any records relating to the business practices relating to the Act
- Offences and penalties




Ontario Drug Benefit Act Unlisted Drugs, Special Cases s.16

- For unlisted drugs (formerly s. 8 drugs) 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



Ontario Drug Benefit Act “Limited Use” s. 23

- For some drugs or classes of drugs where specified clinical criteria must be met in order to be reimbursed
 - Specific conditions
 - Use of drugs by particular patients or group of patients from a particular physician or class of physicians
 - Requirement a specific person or an expert panel recommend or approve use a particular drug or class of drugs
- Where patient does not meet clinical criteria, pharmacy may charge patient for the drug
 - Amount the same as if the drug were covered



Ontario Drug Benefit Act Regulation 201/96

- Introduction of new concepts and definitions, some examples:
 - Deductibles and co-pays
 - Therapeutic substitution
 - Professional allowance
 - Catastrophic drug coverage
- Clarifies the role and powers of the Executive Officer
- Concepts and definitions are made for purposes of the Act and the Drug Benefit Program




Ontario Drug Benefit Act Regulation 201/96

Clarifies the difference between a “rebate” and “professional allowance”

Professional Allowances in the definition of “rebate” means

- **a benefit**, in the form of currency, services or educational materials that are provided by a manufacturer to a wholesaler, operators of pharmacies or companies that own, operate or franchise pharmacies or their directors officers, employees or agents, **for the purposes of direct patient care as identified in paragraphs 1-8**

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**Ontario Drug Benefit Act
Regulation 201/96**

Professional Allowances s. 1(10):

1. Continuing education programs that enhance scientific knowledge or professional skills if held in Ontario
2. Continuing education programs for specialized services or specialized certifications if held in N. America
3. Clinic days provided by pharmacists to disseminate disease or drug related information to the general public

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**Ontario Drug Benefit Act
Regulation 201/96**

Professional Allowances:

4. Education days provided by pharmacists for health protection and promotion days, targeted to general public
5. Compliance packaging assisting patients with complicated medication regimes
6. Disease management and prevention initiatives


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**Ontario Drug Benefit Act
Regulation 201/96**

Professional Allowances:

7. Private counselling areas in pharmacies
8. Hospital in-patient or long term care home resident clinical pharmacy services



**Ontario Drug Benefit Act
Regulation 201/96**

Professional Allowances

- Benefits not to be confused with professional services
- Formula for calculating professional allowances in regulations
 - any amount in excess of the calculations considered a rebate and subject to recovery
- Benefit not a professional allowance if not in compliance with Code of Conduct



ODBA, Regulation 201/96

Eligible Persons: Designated Class


- Receiving home care services under the Health Insurance Act
- Residing in homes licenced under s.5 of the Homes for Special Care Act
- Eligible for a pension under Part I of the Old Age Security Act (Canada)
- Persons who have attained 65 years of age (some conditions apply)
- Residing in an approved charitable home for the aged under the Charitable Institutions Act
- Residing in homes under the Homes for Aged and Rest Homes Act
- Residents of homes under the Nursing Homes Act



**Ontario Drug Benefit Act
Regulation 201/96**

Trillium Program

- Catastrophic Drug Program
 - 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.



Ontario Drug Benefit Act Regulation 201/96

Trillium Program: Requirements

- Insured under the Health Insurance Act, i.e. a valid Ontario Health Insurance Card
- Total household unit have collectively spent amount determined by the regulations
- Application to the executive officer
- All forms of health insurance expended




Ontario Drug Benefit Act Regulation 201/96

Extemporaneous Preparations/Compounds*

- Cannot be equivalent to a manufactured product
- For internal consumption and contains a solid dosage form of a listed product and no other active ingredient
- For topical or dermatological use and contains a listed drug product and no other active ingredient other than those listed in the regulations e.g. menthol, camphor etc.
- For injection and prepared under direct supervision of a pharmacist registered in Ont. (some restrictions)
- For specific ophthalmic preparations
- Maximum of 5 minutes compounding time paid

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




Ontario Drug Benefit Act Amounts paid by Executive Officer

Total cost of extemporaneous preparations is the sum of (DBP of ingredient + Acquisition cost of any unlisted ingredient + time*)

Total the minister will pay ((Ext.DBP + MU) + time) + fee – copay)


* time is included as part of cost



Ontario Drug Benefit Act Regulation 201/96

Amounts Paid by Minister: s.13-17

- Legislative authority to determine DBP, markup and dispensing fee
- The Drug Benefit Price - as listed in the Formulary
- Mark Up currently 8%
- Dispensing Fee for pharmacies is currently \$7.00 (or Usual and Customary Fee if lower than ODB fee)



Ontario Drug Benefit Act Regulation 201/96

Amounts paid by executive officer

Dispensing Physicians

- Dispensing fee for physicians whose office is within 20 km. of an accredited pharmacy is \$4.28
- All other cases dispensing fee is \$5.10




Ontario Drug Benefit Act Regulation 201/96

Limits on Amounts paid by executive officer

- Authority to administer and control costs
- Ontario Works Act, 1997 recipients limited quantities
 - Sufficient for a 35 day supply
- 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 e.g. Trillium

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Ontario Drug Benefit Act Regulation 201/96

Limits on Amounts paid by executive officer

"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 regardless of quantity authorized
- Allows a person to try medication and allows physician to monitor for efficacy
- Designed to reduce waste
- Provides for exceptions if patient cannot come back in 30 days (document reasons)
- Administered through adjudication system



Ontario Drug Benefit Act Regulation 201/96

Co payments: s.20.1/20.2

- Introduces co-payments and new definitions such as:
 - Deductible amount, allowable drug costs, Fiscal period (Aug 1 – July 31)
- Introduces concept of a "deductible"
 - amount that must be paid initially in order for an eligible person to receive benefits from a drug plan
 - Different from co-pay – cost sharing on each prescription



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 subject to conditions listed in regulation
- s.20.2 provides for different co-payments for the specific group of eligible persons that have attained 65 years of age and determines criteria for these groups



Ontario Drug Benefit Act Regulation 201/96

Co-payment: s. 20.2

- Separates eligible persons based on income, by exempting those that have attained 65 years of age
 - who earn less than \$16,018 as a single person or cohabit with a spouse and earn less than \$24,175 as a couple
 - Co-payment for this group remains at \$2.00
- Establishes a different criteria and higher co-payment for those that earn more than \$16,018 as a single or \$24,175 as a couple




Ontario Drug Benefit Act Regulation 201/96

Co payment and criteria for higher income eligible seniors: s.20.2

- \$100 deductible (pay the first \$100)
- Establishes higher co-pay once the deductible is satisfied as:
 - \$2.83 for accredited pharmacies operating in hospitals
 - \$4.05 or \$4.83 for dispensing physicians depending on distance to a pharmacy
 - \$6.11 for community pharmacies or lower if U&C is less than \$6.11

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Ontario Drug Benefit Act Regulation 201/96

Higher income Seniors


- Benefit period based on fiscal year (Aug. 1-July 31)
 - Must pay the \$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)



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




Ontario Drug Benefit Act

Limited Use Part III (ODBA s. 23)

- For specified drug products or classes of drug products
- Reimbursement tied to criteria/conditions for use of drug
- Physician indicates LU code
 - Written, verbal, faxed
- Expiration of LU Rx dependent on specified drug


Continued...



Ontario Drug Benefit Act

Limited Use Part III (ODBA s. 23)

- Physician responsible for criteria
- Criteria not met, EO not responsible for payment, pharmacist may charge patient
 - should explain to patient reasons
 - charge the patient the same as if it were an ODB product




Ontario Drug Benefit Act

Regulation 201/96


Amount charged to eligible persons: s.21

- May charge eligible persons for a listed drug under certain conditions:
 - Quantity exceeds maximum quantity defined by the Act (e.g. greater than 100 days supply)
 - Explain to patient the reason why
 - Offer patient the choice to pay or receive only quantity allowed
- May charge amount payable by EO, if eligible person elects to pay and is advised before dispensing that drug is available free of charge
- Document



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



**ODBA, Regulation 201/96
Code of Conduct: Schedule 3**

- Guidance document governing use of professional allowances
- Principles
 - Payments from manufacturers to pharmacies in the form of professional allowances must only be used for defined activities
 - All persons involved in the drug distribution system must act transparently
 - All suppliers and operators of pharmacies must commit to abide by the Code of Conduct



**ODBA, Regulation 201/96
Code of Conduct: Schedule 3**

- Prohibition of Professional Allowances:
 - Advertising or promotional flyers (exception: clinic days as defined)
 - Entertainment, social or sporting events
 - Meals and travels not directly associated with defined programs
 - Convention displays

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**ODBA, Regulation 201/96
Code of Conduct: Schedule 3**


- Personal gifts to operators
- Staff wages or benefits except as defined
- Packaging costs or delivery services in respect of prescription and dispensing fees
- Taxes
- Inventory costs

continued




**ODBA, Regulation 201/96
Code of Conduct: Schedule 3**

- Fees or penalties for inventory adjustments
- Purchases of sales and prescription related items
- Fees for listing products in inventory
- Renovations, leasehold improvements and similar matters
- Store fixtures
- Real estate purchases or sales, encumbrances, leases or rents.



**ODBA, Regulation 201/96
Code of Conduct: Schedule 3**

- Pharmacy representatives shall conduct business ethically and in a manner that is in the best interest of the patient
- Procurement and purchasing decisions cannot be solely based on the provision of professional allowances
- Detailed reporting to EO



Ontario Drug Benefit Act

- Remember this is a drug plan and rules apply
- Will only pay for eligible drugs for eligible recipients
- Questions about the program should be directed to the ODB help desk




**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 Act

Questions?