From: Mai, Helen (MOH) [Helen.Mai@ontario.ca]
Sent: Thursday, May 17, 2012 12:07 PM
To: Meyer, Hendrik HLTH:EX
Subject: RE: Ontario's Generic Drug Policy - Rebates

Hi Hendrik,

The drug rebate provisions in Ontario are set out in sections 11.5 and 11.6 of the *Ontario Drug Benefit Act* (http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_90o10_e.htm#BK20) and sections 12.1 and 12.2 of the *Drug Interchangeability and Dispensing Fee Act* (http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_90p23_e.htm#BK13)

"Rebate" includes, but is not limited to, currency, discounts, refunds, free goods or travel and any benefit set out by regulation. The regulations sets out what is not a rebate (e.g., ordinary commercial terms).

In brief, the rebate section prohibits manufacturers from providing a rebate to wholesalers, operators of pharmacies or companies that own, operate or franchise pharmacies, or to their directors, officers, employees or agents for any drugs that are designated interchangeable or being considered for designation as interchangeable, and any person from accepting a rebate, directly or indirectly.

The executive officer may order manufacturers to pay the government an amount equal to the amount contrary to this section.

The calculation of the amount owing to the government because of rebates is set out as follows:

- The expected cost for a drug product or group of drug products provided by the manufacturer to the wholesaler or pharmacy is based on the drug benefit price for that drug(s) multiplied by the amount of product the wholesaler or pharmacy received from the manufacturer.
- The payment amount to government is the difference between the expected cost noted above and the actual cost to the wholesaler or pharmacy which includes the impact of any price reductions, free goods, or direct payments by the manufacturer, as examples.

The manufacturer may submit evidence to the executive officer that the amount calculated is not correct or that the manufacturer has not provided a rebate, within 14 days of being served with the order, and the executive officer is required to reconsider the order.

After reconsidering the order, the executive officer may affirm, rescind or vary the order.

Where the manufacturer has not complied with an order within 14 days of being served with it, or once the order has been affirmed or varied, and the manufacturer still has not complied with it, the executive officer may issue a further order for compliance, or the executive officer may do one or both of the following until the manufacturer pays:

- If the product is an interchangeable product, remove the drug product's designation as interchangeable
- refuse to consider the manufacturer's other drug products for future designation as interchangeable, for future designation as a listed drug product on the Formulary, or for approval under the exceptional access program of the ODBA.

The manufacturer does not have another opportunity to have a further order reconsidered.

The executive officer must give 30 days notice before the executive officer may refuse to consider the manufacturer's other drug products for designation as interchangeable, for designation as a listed drug product on the Formulary, or for approval under the exceptional access program of the ODBA.

The executive officer may publish on the Ministry's website:

- the corporate names of manufacturers who are subject to a payment order or a measure to compel compliance; and,
- any information about the enforcement action that the executive officer believes is appropriate.

There is no appeal, other than as provided in this section, from a decision or action of the executive officer to order payment or compel compliance with a payment order.

We're happy to set up a meeting to discuss if you have questions.

Thanks,
Helen

Helen Mai
Senior Program Analyst
Ministry of Health and Long-Term Care
Ontario Public Drug Programs
Tel: (416) 325-9406
Fax: (416) 325-6647
E-mail: helen.mai@ontario.ca

From: Meyer, Hendrik HLTH:EX [mailto:Hendrik.Meyer@gov.bc.ca]
Sent: May 15, 2012 7:06 PM
To: Mai, Helen (MOH)
Subject: Ontario's Generic Drug Policy - Rebates

Hello Helen,

We are looking for information on Ontario's legislation prohibiting rebates. We would appreciate if you could provide us with details of the process of how the prohibition is enforced, whether Ontario recovers rebates and how. Other information that would be useful is approximately how many people does Ontario have that are involved in enforcing this policy, does Ontario use auditors or forensic auditors, and are they inhouse or contracted out. If you have a policy manual we would appreciate if you could share it with us.

Thanks for any assistance that you can provide.

Regards,

Hendrik Meyer
Policy Analyst
Policy, Outcomes Evaluation and Research
Pharmaceutical Services Division
Ministry of Health
Telephone: 250-952-1595

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Withheld pursuant to/removed as

s.14

From: Pourmalek, Saloumeh HLTH:EX
Sent: Thursday, June 28, 2012 8:52 AM
To: Abbott, Greg W HLTH:EX; Meyer, Hendrik HLTH:EX
Subject: FW: Legislated Rebates Provisions

From: Pourmalek, Saloumeh HLTH:EX
Sent: Friday, December 2, 2011 2:17 PM
To: Pourmalek, Saloumeh HLTH:EX
Subject: RE: Legislated Rebates Provisions

s.13,s.16

From: Pourmalek, Saloumeh HLTH:EX
Sent: Tuesday, November 29, 2011 4:38 PM
To: XT:HLTH Fraser, Brent
Cc: Capelli, John HLTH:EX
Subject: Legislated Rebates Provisions

Hi Brent,

I am contacting you from Pharmaceutical Services Division of the BC Ministry of Health.

I am seeking information about your legislated provisions prohibiting manufacturer rebates. This is particularly about how some pharmacies s.13 tried to get around your detailed list of entities from which pharmacies are prohibited to receive rebates (i.e. manufacturers, wholesalers, distributors, ..., or any agents of these).

Could you please elaborate on the reasons for ensuring a comprehensive list of entities which offer rebates in legislation, the ways pharmacies tried to circumvent the receipt of rebates, and how you dealt with the situation? Perhaps you could refer me to someone who will be able to provide me with some answers?

Many thanks,
Saloumeh.

Saloumeh Pourmalek Ph.D. | Senior Policy Analyst | Policy, Outcomes Evaluation and Research | Pharmaceutical Services Division | BC Ministry of Health Services | 250.952.2240 | saloumeh.pourmalek@gov.bc.ca Please consider the environment before printing this e-mail

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From: Pourmalek, Saloumeh HLTH:EX
Sent: Thursday, June 28, 2012 8:55 AM
To: Abbott, Greg W HLTH:EX; Meyer, Hendrik HLTH:EX
Subject: FW: ON legislation - rebates

From: Mochrie, Paul HLTH:EX
Sent: Wednesday, March 9, 2011 10:54 AM
To: Campbell, Corrie L HLTH:EX
Cc: Pourmalek, Saloumeh HLTH:EX
Subject: ON legislation - rebates

Hi Corrie,

I have reviewed in detail the provisions respecting rebates as set out in the *Ontario Drug Benefit Act* and *Regulation* as well as the *Drug Interchangeability and Dispensing Fee Act* and *Regulation*.

As you know, the Ontario framework establishes a specific definition of "rebate" as well as explicit prohibitions on payment and acceptance of rebates. They also define "ordinary commercial terms" as a permissible rebating practice s.13
s.13

It would seem that the utility of Ontario's provisions for us really depends on our approach. Based on our past discussions of this issue, I understand that we are ideally looking to provide the Minister or LGIC with discretion to limit rebates without actually articulating a specific prohibition in the Act. In that context, I do not believe it would make sense to crib any of Ontario's language, with the possible exception of their definitions.

I hope the foregoing comments make sense. If you have any questions, or if it would be useful to discuss this matter further, please let me know.

Paul

Paul Mochrie
Executive Director
Business Management, Supplier Relations and Systems
Pharmaceutical Services
BC Ministry of Health Services
tel: 604.660.1303

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Withheld pursuant to/removed as

s.14

Felker, April HLTH:EX

From: Gobis Ogle, Barbara HLTH:EX
Sent: Friday, November 23, 2012 1:39 PM
To: Capelli, John HLTH:EX; Moneo, Mitch HLTH:EX
Subject: FW: November 23, 2012 Bill 35 Regulations Announced

FYI - here is what BCPhA sent to its members today.

B

-----Original Message-----
From: B Gobis Ogle s.22
Sent: Fri, November 23, 2012 1:22 PM
To: Gobis Ogle, Barbara HLTH:EX
Subject: Fwd: November 23, 2012 Bill 35 Regulations Announced

----- Forwarded Message -----
From: "BC Pharmacy Association" <info@bcpharmacy.ca>
To: "b ogle's.22
Sent: Friday, November 23, 2012 12:52:29 PM
Subject: November 23, 2012 Bill 35 Regulations Announced

If this email does not display properly, please view our online version .
To ensure receipt of our email, please add 'info@bcpharmacy.ca' to your address book.

November 23, 2012

Bill 35 Regulations Announcement Q&A

On November 23, 2012, the Minister of Health announced that the Bill 35 regulations on pricing have been approved by government. Changes to generic drug prices that are included in the regulations will come into effect on April 1, 2013.

We want to ensure that BCPhA members have a single source of information on the new regulations. We have prepared the following initial set of questions and answers on the major elements of the regulations. Where necessary, we will be seeking clarification on the intent and implications of the new measures and will update you as we have more information.

We are sure many members will have additional questions and want to provide an opportunity to collect those questions and share the information with members. As such, we are using the online member discussion forum to track your questions and provide responses to them (available by logging into the members' side of the BCPhA website and clicking on the BCPhA Community tab). This section of the website will be updated with new information as it becomes available.

Our key objective in communicating with government about the regulations was that changing any element in the supply chain could have a negative and unintended consequence on community pharmacy. We argued that, while we

understand government's need to drive down commodity drug prices, it is important that any changes that impact pharmacy be introduced with sufficient notice and provide for a transition period to ease the economic impacts. And we believe our efforts have had a positive impact.

What are the key elements of the regulations?

* Generic pricing on oral solids drops to 25 per cent on April 1, 2013
* Generic pricing on oral solids drops to 20 per cent on April 1, 2014
* Generic pricing on non-oral solids remains at 35 per cent
* Government introduced classifying some medications as eligible for "provisional" pricing outside the limits
* MALP and LCA provisions remain the same
* LCA applies to government and third-party payers
* Mark-ups remain the same
* No restrictions on incentives in any form – professional allowances, rebates, ordinary commercial terms
* Government provides itself with the opportunity to enter into pan-Canadian tendering arrangements with other provinces. No decisions to proceed included in these regulations

There is no doubt that even with the positive decision on incentives and no immediate decision on tendering, the pricing reductions found in the new regulations will have a significant negative impact on the way pharmacy operates in BC. These changes, while expected, will nonetheless require major business adjustments by all pharmacy operators in the province.

We strongly advocated against any action to eliminate or significantly reduce or regulate incentives (PAs, rebates and ordinary commercial terms). Government heard us on this and has created no regulations to deal with incentives at this time. We view this as a significant decision and one which helps buffer the impact of reduced generic drug prices.

The BCPhA will continue to advocate on behalf of community pharmacy and ensure there is clarity around any of the new requirements. Our commitment is to do our best to mitigate the negative effects that these new requirements impose.

Geraldine Vance
CEO

Click here to read the Ministry of Health's news release .

Click here to read the Drug Price Regulations .

PRICING

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Generic Drug Rebates Cross-Jurisdictional Research

Updated to July 16, 2018

Summary Table

Province	Regulations	Policy	Enforced	Comments
BC	No	No		
Alberta	No	No		Policy is to ignore rebates.
Manitoba	No	No		s.13,s.16,s.17
New Brunswick	No	No		
Nfld & Labrador	No	No		The new generic drug regulations, and agreement just negotiated with pharmacy, do not appear to address rebates.
Nova Scotia	Yes	Yes	No	As part of its current plan, government will not limit or require the reporting of rebates paid to pharmacies by drug manufacturers.
Ontario	Yes	Yes	Yes	Extensive regulations to prohibit rebates and enforce the prohibition.
Quebec	Yes	Yes	Yes	Initially banned them but now permits them to certain policy limits.s.1 s.13,s.16,s.17
Saskatchewan	No	No		

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BC

Regulations:

Pharmaceutical Services Act:

Price regulation

20 (1) Without limiting section 3 (2) (h) *[establishing and maintaining formularies]* but subject to any limit or condition prescribed under section 62 (1) (a) *[regulations respecting price regulation]*, the minister may set limits or conditions on the amount that will be paid, by the minister under this Act, for a particular drug, device, substance or related service that is a benefit.

(2) Subject to any limit or condition prescribed under section 62 (1) (b), the minister may enter into agreements with any person respecting prices of, or amounts that may be charged for, drugs, devices, substances or related services, including setting conditions that must be met for

(a) a drug, device or substance to be listed, or to continue to be listed, on a formulary, or

(b) a related service to be listed, or to continue to be listed, on a related services list.

(3) The conditions that may be set under subsection (2) include, without limitation, conditions respecting the amounts charged and the use, or prohibition of the use, of incentives.

Incentives

21 (1) A provider, a franchisor and a prescribed person, and a person who is an employee or agent of any of these, must not accept any incentive prohibited by the regulations.

(2) A supplier, a manufacturer and a prescribed person, and a person who is an employee or agent of any of these, must not provide an incentive that is prohibited by the regulations to

(a) a person described in subsection (1), or

(b) a person within a prescribed class of persons.

(3) On request of the minister, a provider, franchisor, supplier, manufacturer and prescribed person must report to the minister information respecting all of the following:

(a) amounts received or provided for

(i) drugs, devices and substances listed on a formulary,

(ii) related services listed on a related services list, and

(iii) drugs, devices, substances and related services for which payment is authorized under section 6 *[special payments]*;

(b) the nature and value of any incentive received or provided in relation to

(i) drugs, devices and substances listed on a formulary,

(ii) related services listed on a related services list, and

(iii) drugs, devices, substances and related services for which payment is authorized under section 6.

Regulations respecting price regulation

62 (1) The Lieutenant Governor in Council may make regulations for the purposes of regulating the price of drugs, devices, substances and related services as follows:

(a) setting limits and conditions on the amount that will be paid under this Act in respect of a class of drugs, devices, substances or related services;

(b) setting limits and conditions on the price of, or amount charged for, a class of drugs, devices, substances or related services, and for this purpose, the Lieutenant Governor in

Council may specify that a limit or condition applies in respect of one or more classes of beneficiaries and persons who are not beneficiaries;

(c) requiring the minister not to list, or to discontinue listing, a drug, device or substance on a formulary, or a related service on a related services list,

(i) if prescribed limits or conditions are not met, or

(ii) in prescribed circumstances.

(2) An amount for the purposes of subsection (1) may be expressed in any form, including

(a) as a formula, or

(b) in relation to other classes of drugs, devices, substances or related services,

(i) a percentage of the price of them, or

(ii) amounts that may be paid or charged for them.

(3) The Lieutenant Governor in Council may make regulations respecting incentives as follows:

(a) prescribing persons, by class, for the purposes of section 21 *[incentives]*;

(b) respecting the means of determining the value of incentives;

(c) prohibiting the receipt or offer of an incentive;

(d) providing that the prohibition set out in section 21 does not apply to specified matters that are the subject of ordinary commercial terms.

Transition — incentives

73 (1) This section applies to a person who is a party to an agreement that provides for incentives to be received or provided in relation to drugs, devices and substances listed on a formulary or in relation to related services listed on a related services list.

(2) Despite any other enactment or law to the contrary,

(a) no damages or compensation of any kind is payable by the government, and

(b) no proceedings in which damages or compensation is claimed may be commenced or maintained against the government,

arising from the contravention or termination, by a party, of an agreement referred to in subsection (1) of this section or the operation of section 21 *[incentives]*.

Policy: None

Comments/Sources:

Pharmaceutical Services Act http://www.leg.bc.ca/39th4th/1st_read/gov35-1.htm

http://www.health.gov.bc.ca/pharmacare/pdf/5-6to5-12.pdf (PharmaCare Pricing Policies)

Alberta

Regulations:

The *Drug Program Act* (awaiting Proclamation) does not appear to address the issue of rebates. This is consistent with the current Alberta Pharmaceutical Strategy which allows pharmacies to continue accepting rebates.

Policy:

As per the Alberta Pharmaceutical Strategy: "Allow pharmacies to continue accepting rebates. Generic drug manufacturers often pay rebates to community pharmacies for stocking their products. When generic drug prices are reduced, rebates are also expected to be reduced. When the new pharmacy compensation model is implemented, the Alberta government will not intervene with normal business practices for generic drug rebates."

Comments/Sources:

Drug Program Act
http://www.qp.alberta.ca/574.cfm?page=D17P5.cfm&leg_type=Acts&isbncln=9780779742158&display=html

Pharmaceutical Strategy http://www.health.alberta.ca/documents/Pharma-Strategy-2-Generic-Drugs.pdf

Manitoba

Regulations: None.

Policy: None.

New Brunswick

Regulations:

Currently none but New Brunswick has announced (March 2012) a program to address generic drug pricing and rebates:

"Address pharmacy rebates

- Require generic drug manufacturers to report the rebates paid to pharmacy and/or limit the amount of these rebates
- Consider regulating the rebates paid by generic drug manufacturers to pharmacies "

The provincial government recognizes that reducing generic drug prices will impact pharmacy revenues. In light of this, the provincial government will reinvest a portion of the savings achieved through the reduction in generic drug prices back into pharmacy services in the following ways:

- investing about $4.5 million in 2012-13 to increase dispensing fees paid to pharmacists and paying a mark-up on generic drugs to help offset the *reductions in revenues that pharmacies receive through rebates from generic drug manufacturers*;

Comments/Sources:

Program information page http://www.gnb.ca/0212/drugs/goals-e.asp

Generic Drug Pricing News Release http://www2.gnb.ca/content/gnb/en/news/news_release.2012.03.0226.html

Newfoundland and Labrador

Regulations:

None. The *Pharmaceutical Services Act* and Interchangeable Drug Products Formulary Regulations establish new generic drug pricing requirements but do not address generic drug rebates.

Policy:

On April 15, 2012, the government entered into a tentative four-year agreement with the Pharmacists' Association of Newfoundland and Labrador, the essential elements of which include:

- a new generic drug pricing policy,
- payment for professional services such as reviews of a patient's medication profile; and
- reinvestment in pharmacies operating in underserviced areas of the province.

The agreement does not appear to address rebates.

Comments/Sources:

Pharmaceutical Services Act http://www.assembly.nl.ca/Legislation/sr/statutes/p12-01.htm

Interchangeable Drug Products Formulary Regulations http://assembly.nl.ca/Legislation/sr/regulations/rc120023.htm

Pharmacist's Association Agreement News Release http://www.releases.gov.nl.ca/releases/2012/health/0415n01.htm

Nova Scotia

Regulations:

The *Fair Drug Pricing Act* Section 14(1)(b) allows for the Minister to enter into agreements with any person or government respecting rebates related to the provision, sale, distribution, purchase or pricing of drugs, devices or services.

Section 17(2)(e) allows the Governor in Council to make regulations imposing rules, terms, restrictions or conditions respecting rebates and professional allowances paid to providers in relation to benefits.

14 (1) The Minister may enter into agreements with any person or government respecting

(b) rebates related to the provision, sale, distribution, purchase or pricing of drugs, devices or services;

17 (2) The Governor in Council may make regulations respecting the activities of providers in relation to any matters under this Act, including but not limited to regulations

(e) imposing rules, terms, restrictions or conditions respecting rebates and professional allowances paid to providers in relation to benefits;

The *Fair Drug Pricing Regulations* Section 2 provides a definition for "rebate". Section 3(1)(b) provides that for an interchangeable product to be designated, or continue to be designated, as a benefit the manufacturer must report any rebates and professional allowances in relation to the benefit.

Section 5(1) and 5(2) allows the Minister to require providers and manufacturers to report any rebates and professional allowances received in relation to an interchangeable product that is designated as a benefit.

Maximum price for interchangeable products

3 (1) Except as provided in subsection (2), all of the following criteria must be met for an interchangeable product to be designated, or continue to be designated, as a benefit:

(a) the cost to the provider for the product from a manufacturer or a wholesaler must not exceed the maximum as set out in the following table on and after the applicable start date:

(b) the manufacturer reports any rebates and professional allowances in relation to the benefit in accordance with Section 5.

Requirement to report rebates

5 (1) The Minister may require a provider to report any rebates and professional allowances received in relation to an interchangeable product designated as a benefit.

(2) The Minister may require a manufacturer to report any rebates and professional allowances provided in relation to an interchangeable product that is designated as a benefit.

Policy:

As per the published Fair Drug Pricing Plan, Nova Scotia will not currently require reporting of rebates pursuant to the *Fair Drug Pricing Act.*

"Tendering for drugs and limiting rebates

As part of its current plan, government will not tender for drugs or limit or require the reporting of rebates paid to pharmacies by drug manufacturers. However, the Fair Drug Pricing Act allows government to use these measures in the future if necessary."

Comments/Sources:

Fair Drug Pricing Act http://nslegislature.ca/legc/bills/61st_3rd/3rd_read/b017.htm

Fair Drug Pricing Regulations http://www.gov.ns.ca/just/regulations/regs/fdpricing.htm

Fair Drug Pricing Plan Summary http://www.gov.ns.ca/health/fairdrugprices/prices-plan.asp

Ontario

Regulations:

The *Ontario Drug Benefit Act:*

Section 11.5(1) prohibits a manufacturer from providing rebates to certain entities for the drugs as set out in this section. Section 11.5(2) provides the extended definition of "manufacturer". Section 11.5(3) prohibits certain entities from accepting a rebate. Section 11.5(4) allows the executive officer to order a manufacturer that does not comply with subsection (1) to pay an amount to the Minister of Finance. Section 11.5(5) sets out the rules for calculating the amount that is to be paid under subsection(4). Section 11.5(6) explains the drug benefit price. Section 11.5(7) allows the manufacturer to submit evidence and request the executive officer to reconsider an order to pay. Section 11.5(8) sets out the actions of the executive officer after reconsideration of an order to pay. Section 11.5(9) sets out what action the executive officer may take where a manufacturer has not complied with an the order, or if the order has been affirmed or varied, the affirmed or varied order. Section 11.5(10) sets a limit on reconsideration. Section 11.5(11) requires the executive officer to serve the manufacturer with notice before acting under paragraph 2 of subsection (9). Section 11.5(12) allows the executive officer to order a person who has accepted a rebate contrary to subsection (3) to pay an amount to the Minister of Finance. Section 11.5(13) Allows a person to request the executive officer to reconsider an order made under subsection (12). Section 11.5(14) allows the executive officer to require the manufacturer or other person to pay an amount less than the calculated amount. Section 11.5(15) provides the definition for "rebate".

Rebates, etc.

11.5 (1) A manufacturer shall not provide a rebate to wholesalers, operators of pharmacies, or companies that own, operate or franchise pharmacies, or to their directors, officers, employees or agents,

(a) for any listed drug product or listed substance; or

(b) for any drug in respect of which the manufacturer has made an application to the executive officer for designation as a listed drug product, while that application is being considered. 2006, c. 14, s. 19.

Extended definition of "manufacturer"

(2) For the purposes of this section and in section 11.6, unless the context requires otherwise, and in section 13.1 and subsection 14 (3),

"manufacturer" includes a supplier, distributor, broker or agent of a manufacturer, except in,

(a) clause (1) (b) of this section,

(b) subsection (6) of this section,

(c) paragraph 2 of subsection (9) of this section, and

(d) subsection (11) of this section. 2006, c. 14, s. 19.

May not accept rebate

(3) No wholesaler, operator, company, director, officer, employee or agent mentioned in subsection (1) shall accept a rebate that is mentioned in subsection (1), either directly or indirectly. 2006, c. 14, s. 19.

Executive officer may make order

(4) If the executive officer believes, on reasonable grounds, that a manufacturer is not complying with subsection (1), the executive officer may make an order requiring the manufacturer to pay to the Minister of Finance the amount calculated under subsection (5). 2006, c. 14, s. 19.

Calculation

(5) For the purposes of this section, the following rules apply to calculating the amount that is to be paid under subsection (4):

1. The amount shall be calculated by determining the difference between the expected value of all units of drug products and listed substances purchased and the actual cost of acquiring those units by the wholesaler, operator of a pharmacy, or company that owns, operates or franchises pharmacies.

2. The expected value mentioned in paragraph 1 shall be determined by multiplying the drug benefit price by the volume of units provided by the manufacturer or wholesaler for all the listed drug products and listed substances.

3. The actual cost of acquiring those products and substances mentioned in paragraph 1 shall be determined by subtracting the monetary value of the rebate from the amount paid for the drug products and listed substances by the wholesaler, operator of a pharmacy, or company that owns, operates or franchises pharmacies. 2006, c. 14, s. 19.

Deemed drug benefit price

(6) For the purposes of subsection (5), the drug benefit price of a drug in respect of which clause (1) (b) applies shall be deemed to be the price submitted by the manufacturer. 2006, c. 14, s. 19.

Reconsideration

(7) Within 14 days of being served with the order, the manufacturer may submit evidence to the executive officer as to its compliance with subsection (1), or that the amount calculated under subsection (5) is not correct, and the executive officer shall reconsider the order based on that evidence. 2006, c. 14, s. 19.

Actions of executive officer after reconsideration

(8) After reconsidering the order, the executive officer may do one of the following, and shall promptly serve the manufacturer with notice of his or her decision.

1. Affirm the order.
2. Rescind the order.
3. Vary the order. 2006, c. 14, s. 19.

Executive officer may act

(9) Where a manufacturer has not complied with an order under subsection (4) within 14 days of being served with it, or has submitted evidence within 14 days under subsection (7) and the order has been affirmed or varied under subsection (8) and the manufacturer has not complied with the affirmed or varied order within 14 days of being served with it, the executive officer may either issue a further order under subsection (4) or do either or both of the following:

1. If the drug that is the subject of the order is a listed drug product, remove its designation.
2. Not make further designations of any of the manufacturer's drug products as listed drug products under section 1.3, nor consider any of its drug products for approval under section 16, nor designate any of its products as interchangeable under the *Drug Interchangeability and Dispensing Fee Act* until such time as the executive officer is of the opinion that the manufacturer is no longer offering the rebate. 2006, c. 14, s. 19.

Limit on reconsideration

(10) Subsections (7) and (8) do not apply to a further order mentioned in subsection (9). 2006, c. 14, s. 19.

Required notice

(11) Where the executive officer proposes to act under paragraph 2 of subsection (9), the executive officer shall serve the manufacturer with at least 30 days notice. 2006, c. 14, s. 19.

Executive officer order where rebate accepted

(12) Where the executive officer believes, on reasonable grounds, that a person has accepted a rebate contrary to subsection (3), the executive officer may make an order requiring the person to pay to the Minister of Finance the amount calculated under subsection (5). 2006, c. 14, s. 19.

Reconsideration

(13) Subsections (7) and (8), subsection (9), other than paragraphs 1 and 2, and subsection (10) apply with any necessary modifications where an order has been made under subsection (12). 2006, c. 14, s. 19.

Lesser amount

(14) Despite any other provision of this section, the executive officer may, in an order under subsection (4) or (12), require the manufacturer or other person to pay an amount less than the amount calculated under subsection (5) and, where the executive officer does so, the following apply:

1. The executive officer shall set out in the order both the lesser amount and how it was calculated.
2. Any right of reconsideration that applies with respect to a calculation under subsection (5) applies with respect to the calculation under paragraph 1. 2006, c. 14, s. 19.

Definition

(15) In this section,

"rebate", subject to the regulations, includes, without being limited to, currency, a discount, refund, trip, free goods or any other prescribed benefit, but does not include something provided in accordance with ordinary commercial terms. 2010, c. 1, Sched. 21, s. 1.

(16)-(18) Repealed: 2010, c. 1, Sched. 21, s. 1.

Section 11.6(1) sets out the rules with regard to an order made or notice given by the executive officer under section 11.4 or 11.5.

Section 11.6(2) allows the executive officer to publish certain information regarding enforcement of action.

Section 11.6(3) confirms there is no appeal from a decision or action of the executive officer under section 11.4 or 11.5, except as provided for in those sections.

Rules re ss. 11.4 and 11.5

11.6 (1) The following rules apply with regard to an order made or a notice given by the executive officer under section 11.4 or 11.5:

1. The order or notice must be in writing, and set out in brief the reason for which it is made.
2. An order must set out how any amount required to be paid under the order was calculated, and specify any right of reconsideration that is available and the time within which the reconsideration is available.
3. In the case of an order or notice under section 11.4 or an order or notice under section 11.5 that applies to a manufacturer, the order or notice may be served by leaving a copy of the document with an officer, director or agent of the manufacturer, or with an individual at any place of business of the manufacturer who appears to be in control or management of the place of business.
4. In the case of an order or notice under section 11.5 that applies to a person mentioned in subsection 11.5 (3), the order or notice may be served by leaving a copy of the document with the person if the person is an individual, or with an officer, director or agent of the person, or with an individual at any place of business of the person mentioned in subsection 11.5 (3) who appears to be in control or management of the place of business.
5. An order must specify the time period with respect to which the order is made, which may include a time period with respect to which a previous order was made, if the previous order has not been complied with.
6. An order must set out the time period in which the manufacturer or person mentioned in subsection 11.5 (3) is required to comply with the order.
7. An order must specify the consequences for failing to comply with the order. 2006, c. 14, s. 19.

Same, publication of enforcement action

(2) The executive officer may publish on the Ministry's website the corporate names of manufacturers or any other persons against whom the executive officer has taken action under section 11.4 or 11.5 and may also publish any information he or she considers appropriate about the action that has been taken. 2006, c. 14, s. 19.

No appeal

(3) There is no appeal from a decision or action of the executive officer under section 11.4 or 11.5, except as provided for in those sections. 2006, c. 14, s. 19.

Section 18.(1)(k.5.1) allows the Lieutenant Governor in Council to make regulations clarifying the definition of "rebate" in section 11.5.

Regulations

18. (1) The Lieutenant Governor in Council may make regulations,

(k.5.1) clarifying the definition of "rebate" in section 11.5, including providing that certain benefits are not rebates, prescribing benefits for the purpose of that definition, clarifying how the calculations are to be made in that section and defining "ordinary commercial terms" for the purposes of that definition, including setting limits on ordinary commercial terms;

Ontario Drug Benefit Act Regulation 201/96 General:

Section 1.(11) establishes that a "rebate" does not include the value of a benefit that is provided in accordance with ordinary commercial terms that meet all of the conditions set out in this subsection. Section 1.(12) establishes that a "rebate" does not include the value of a benefit provided in accordance with ordinary commercial terms with respect to a listed drug product that is not interchangeable where the ordinary commercial terms are a discount for prompt payment.

(11) For the purposes of section 11.5 of the Act, a "rebate" does not include the value of a benefit that is provided in accordance with ordinary commercial terms that meet all of the following conditions:

1. The benefit is provided in the ordinary course of business in the supply chain system of listed drug products that are designated as interchangeable under the *Drug Interchangeability and Dispensing Fee Act* between any of a manufacturer, a wholesaler, an operator of a pharmacy or a company that owns, operates or franchises pharmacies.
2. The value of the benefit is set out in a written agreement between any of a manufacturer, a wholesaler, an operator of a pharmacy and a company that owns, operates or franchises pharmacies.
3. The benefit relates to an ordinary commercial relationship that is any of the following:
   i. A prompt payment discount.
   ii. A volume discount.
   iii. A distribution service fee.

4. The total value of any benefits does not exceed 10 per cent of the value of the listed drug products based on the drug benefit price in the Formulary and the number of units dispensed by a pharmacy and reimbursed under the Act.

5. A person who receives the benefit reports to the executive officer, if required by the executive officer to do so, the net selling price of the drug products representing the drug benefit price less the value of the benefits received. O. Reg. 220/10, s. 1 (4).

(12) For the purposes of section 11.5 of the Act, a "rebate" does not include the value of a benefit provided in accordance with ordinary commercial terms with respect to a listed drug product that is not interchangeable where the ordinary commercial terms are a discount for prompt payment. O. Reg. 220/10, s. 1 (4).

The *Drug Interchangeability and Dispensing Fee Act:*

Section 12.1(1) prohibits a manufacturer from providing rebates to certain entities for the drugs as set out in this section. Section 12.1(2) provides the extended definition of "manufacturer". Section 12.1(3) prohibits certain entities from accepting a rebate. Section 12.1(4) allows the executive officer to order a manufacturer that does not comply with subsection (1) to pay an amount to the Minister of Finance. Section 12.1(5) sets out the rules for calculating the amount that is to be paid under subsection(4). Section 12.1(6) allows the manufacturer to submit evidence and request the executive officer to reconsider an order to pay. Section 12.1(7) sets out the actions of the executive officer after reconsideration of an order to pay. Section 12.1(8) sets out what action the executive officer may take where a manufacturer has not complied with an order, or if the order has been affirmed or varied, the affirmed or varied order. Section 12.1(9) sets a limit on reconsideration. Section 12.1(10) requires the executive officer to serve the manufacturer with notice before acting under paragraph 2 of subsection (8). Section 12.1(11) allows the executive officer to order a person who has accepted a rebate contrary to subsection (3) to pay an amount to the Minister of Finance. Section 12.1(12) Allows a person to request the executive officer to reconsider an order made under subsection (11). Section 12.1(13) allows the executive officer to require the manufacturer or other person to pay an amount less than the calculated amount. Section 12.1(14) provides the definition for "drug benefit price" and "rebate" (Amendments to the definition of "rebate" in this section made by 2010,c. 1, Sched. 5 will come into force on April 1, 2013). Section 12.1(15) allows the Lieutenant Governor in Council to make regulations clarifying the definition of "rebate" in this section (Amendments to this section made by 2010,c. 1, Sched. 5 will come into force on April 1, 2013).

Rebate, etc.

12.1 (1) A manufacturer shall not provide a rebate to wholesalers, operators of pharmacies, or companies that own, operate or franchise pharmacies, or to their directors, officers, employees or agents,

(a) for any interchangeable product; or

(b) for any product in respect of which the manufacturer has made an application to the executive officer for designation as an interchangeable product, while that application is being considered. 2006, c. 14, s. 3.

Extended definition of "manufacturer"

(2) For the purposes of this section and in section 12.2, unless the context requires otherwise,

"manufacturer" includes a supplier, distributor, broker or agent of a manufacturer, except in,

(a) clause (1) (b) of this section,

(b) paragraph 2 of subsection (8) of this section,

(c) subsection (10) of this section, and

(d) clauses (b) and (c) of the definition of "drug benefit price" in subsection (14) of this section. 2006, c. 14, s. 3.

May not accept rebate

(3) No wholesaler, operator, company, director, officer, employee or agent mentioned in subsection (1) shall accept a rebate that is mentioned in subsection (1), either directly or indirectly. 2006, c. 14, s. 3.

Executive officer may make order

(4) If the executive officer believes, on reasonable grounds, that a manufacturer is not complying with subsection (1), the executive officer may make an order requiring the manufacturer to pay to the Minister of Finance the amount calculated under subsection (5). 2006, c. 14, s. 3.

Calculation

(5) For the purposes of this section, the following rules apply to calculating the amount that is to be paid under subsection (4):

1. The amount shall be calculated by determining the difference between the expected value of all units of the drug products purchased and the actual cost of acquiring those units by the wholesaler, operator of a pharmacy, or company that owns, operates or franchises pharmacies.

2. The expected value mentioned in paragraph 1 shall be determined by multiplying the drug benefit price by the volume of units provided by the manufacturer or wholesaler for all the products.

3. The actual cost of acquiring those products mentioned in paragraph 1 shall be determined by subtracting the monetary value of the rebate from the amount paid for all the products by the wholesaler, operator of a pharmacy, or company that owns, operates or franchises pharmacies. 2006, c. 14, s. 3.

Reconsideration

(6) Within 14 days of being served with the order, the manufacturer may submit evidence to the executive officer as to its compliance with subsection (1), or that the amount calculated under subsection (5) is not correct, and the executive officer shall reconsider the order based on that evidence. 2006, c. 14, s. 3.

Actions of executive officer after reconsideration

(7) After reconsidering the order, the executive officer may do one of the following, and shall promptly serve the manufacturer with notice of his or her decision:

1. Affirm the order.

2. Rescind the order.

3. Vary the order. 2006, c. 14, s. 3.

Executive officer may act

(8) Where a manufacturer has not complied with an order under subsection (4) within 14 days of being served with it, or has submitted evidence within 14 days under subsection (6) and the order has been affirmed or varied under subsection (7) and the manufacturer has not complied with the affirmed or varied order within 14 days of being served with it, the executive officer may either issue a further order under subsection (4) requiring the manufacturer to pay a revised amount calculated under subsection (5), or do either or both of the following:

1. If the drug that is the subject of the order is an interchangeable product, remove its designation.

2. Not make further designations of any of the manufacturer's products as interchangeable under this Act, or as listed drug products under section 1.3 of the *Ontario Drug Benefit Act*, nor consider any of its products for approval under section 16 of that Act, until such time as the executive officer is of the opinion that the manufacturer is no longer offering the rebate. 2006, c. 14, s. 3.

Limit on reconsideration

(9) Subsections (6) and (7) do not apply to a further order mentioned in subsection (8). 2006, c. 14, s. 3.

Required notice

(10) Where the executive officer proposes to act under paragraph 2 of subsection (8), the executive officer shall serve the manufacturer with at least 30 days notice. 2006, c. 14, s. 3.

Executive officer order where rebate accepted

(11) Where the executive officer believes, on reasonable grounds, that a person has accepted a rebate contrary to subsection (3), the executive officer may make an order requiring the person to pay to the Minister of Finance the amount calculated under subsection (5). 2006, c. 14, s. 3.

Reconsideration

(12) Subsections (6) and (7), subsection (8), other than paragraphs 1 and 2, and subsection (9) apply with any necessary modifications where an order has been made under subsection (11). 2006, c. 14, s. 3.

Lesser amount

(13) Despite any other provision of this section, the executive officer may, in an order under subsection (4) or (11), require the manufacturer or other person to pay an amount less than the amount calculated under subsection (5) and, where the executive officer does so, the following apply:

1. The executive officer shall set out in the order both the lesser amount and how it was calculated.
2. Any right of reconsideration that applies with respect to a calculation under subsection (5) applies with respect to the calculation under paragraph 1. 2006, c. 14, s. 3.

Definitions

(14) In this section,

"drug benefit price" means, with respect to a product,

(a) its drug benefit price under the *Ontario Drug Benefit Act*,

(b) in the case of a product that is not a benefit under the *Ontario Drug Benefit Act*, a price submitted by the manufacturer under the regulations that has been posted by the executive officer in the Formulary, or

(c) in the case of a product mentioned in clause (1) (b), the price submitted by the manufacturer; ("prix au titre du régime de médicaments")

"rebate", subject to the regulations, includes, without being limited to, currency, a discount, refund, trip, free goods or any other prescribed benefit, but does not include,

(a) a discount for prompt payment offered in the ordinary course of business, or

(b) a professional allowance. ("rabais") 2006, c. 14, s. 3.

Note: On a day to be named by proclamation of the Lieutenant Governor, the definition of "rebate" is repealed and the following substituted:

"rebate", subject to the regulations, includes, without being limited to, currency, a discount, refund, trip, free goods or any other prescribed benefit, but does not include something provided in accordance with ordinary commercial terms. ("rabais")

See: 2010, c. 1, Sched. 5, ss. 1 (1), 2.

Regulations

(15) The Lieutenant Governor in Council may make regulations clarifying the definition of "rebate" in this section, including providing that certain benefits are not rebates, prescribing benefits for the purpose of that definition, clarifying how the calculations are to be made in this section and defining "professional allowance" for the purposes of that definition, including governing how professional allowances are to be calculated, setting limits on professional allowances and incorporating the content of the Code of Conduct referred to in subsection 11.5 (15) of the *Ontario Drug Benefit Act* as amended from time to time. 2006, c. 14, s. 3.

Note: On a day to be named by proclamation of the Lieutenant Governor, subsection (15) is repealed and the following substituted:

Regulations

(15) The Lieutenant Governor in Council may make regulations clarifying the definition of "rebate" in this section, including providing that certain benefits are not rebates, prescribing benefits for the purpose of that definition, clarifying how the calculations are to be made in this section and defining "ordinary commercial terms" for the purposes of that definition, including setting limits on ordinary commercial terms. 2010, c. 1, Sched. 5, s. 1 (2).

See: 2010, c. 1, Sched. 5, ss. 1 (2), 2.

Section 12.2(1) sets out the rules with regard to an order made or notice given by the executive officer under section 12.1 . Section 12.2(2) allows the executive officer to publish certain information regarding enforcement of action. Section 12.2(3)

confirms there is no appeal from a decison or action of the executive officer under section 12.1, except as provided for in that section.

Rules re s. 12.1

12.2 (1) The following rules apply with regard to an order made or a notice given by the executive officer under section 12.1:

1. The order or notice must be in writing, and set out in brief the reason for which it is made.
2. An order must set out how any amount required to be paid under the order was calculated, specify any right of reconsideration that is available, and the time within which reconsideration is available.
3. In the case of an order or notice under section 12.1 that applies to a manufacturer, the order or notice may be served by leaving a copy of the document with an officer, director or agent of the manufacturer, or with an individual at any place of business of the manufacturer who appears to be in control or management of the place of business.
4. In the case of an order or notice under section 12.1 that applies to a person mentioned in subsection 12.1 (3), the order or notice may be served by leaving a copy of the document with the person if the person is an individual, or with an officer, director or agent of the person, or with an individual at any place of business of the person mentioned in subsection 12.1 (3) who appears to be in control or management of the place of business.
5. An order must specify the time period with respect to which the order is made, which may include a time period with respect to which a previous order was made, if the previous order has not been complied with.
6. An order must set out the time period in which the manufacturer or person mentioned in subsection 12.1 (3) is required to comply with the order.
7. An order must specify the consequences for failing to comply with the order. 2006, c. 14, s. 3.

Same, publication of enforcement action

(2) The executive officer may publish on the Ministry's website the corporate names of manufacturers or any other persons against whom the executive officer has taken action under section 12.1 and may also publish any information he or she considers appropriate about the action that has been taken. 2006, c. 14, s. 3.

No appeal

(3) There is no appeal from a decision or action of the executive officer under section 12.1, except as provided for in that section. 2006, c. 14, s. 3.

The Drug Interchangeability and Dispensing Fee Act, R.R.O. Regulations 935 General:

Section 2.(1) sets out the meaning of "professional allowance" in the definition of "rebate" for the purposes of section 12.1 of the Act. Section 2.(1.1) sets out a formula that determines whether benefits provided under subsection (1) are a rebate or a professional allowance (On April 1, 2013, subsection 1.1 is revoked, O. Reg. 221/10, ss. 2 (6), 7 (5). Section 2.(2) provides that a benefit is not a professional allowance if the contents of the Code of Conduct set out in Schedule 1 are not complied with (On April 1, 2013, subsection (2) is revoked, O. Reg. 221/10, ss. 2 (6), 7 (5). Section 2.(3) establishes that for the purposes of section 12.1 of the Act, a "rebate" does not include the value of a benefit that is provided in accordance with ordinary commercial terms that meet all of the conditions set out in this subsection.

2. (1) For the purposes of section 12.1 of the Act,

"professional allowance", in the definition of "rebate", means, subject to subsection (2), a benefit, in the form of currency, services or educational materials that are provided by a manufacturer to persons listed in subsection 12.1 (1) of the Act for the purposes of direct patient care as set out in paragraphs 1 to 8 of this subsection:

1. Continuing education programs that enhance the scientific knowledge or professional skills of pharmacists, if held in Ontario.
2. Continuing education programs for specialized pharmacy services or specialized certifications, if held in North America.
3. Clinic days provided by pharmacists to disseminate disease or drug-related information targeted to the general public including flu shot clinics, asthma clinics, diabetes management clinics, and similar clinics. For this purpose, a "clinic day" includes any additional staff to support the clinic day or the regular pharmacy business while the pharmacist is hosting a clinic day, during that day.
4. Education days provided by pharmacists that are targeted to the general public for health protection and promotion activities. Such education days must be held in the pharmacy, or a school, long-term care home, community centre, place of worship, shopping mall, or a place that is generally similar to any of these. For this purpose, an "education day" includes any additional staff to support the education day or the regular pharmacy business while the pharmacist is hosting an education day, during that day.
5. Compliance packaging that assists their patients with complicated medication regimes.

6. Disease management and prevention initiatives such as patient information material and services, blood pressure monitoring, blood glucose meter training, asthma management and smoking cessation, used in their pharmacy. For this purpose, "disease management and prevention initiatives" includes any additional staff required to support these initiatives or the regular pharmacy business while the pharmacist is hosting a disease management and prevention initiative, during the time it is being held.

7. Private counselling areas within their pharmacy.

8. Hospital in-patient or long-term care home resident clinical pharmacy services, such as medication reconciliation initiatives or other hospital or long-term care home-identified clinical pharmacy priorities. For this purpose, "clinical pharmacy services" includes the costs of any additional staff required to support these services or the regular pharmacy business while the pharmacist is hosting a clinical pharmacy service, during the time it is being held. O. Reg. 458/06, s. 2.

Note: On April 1, 2013, subsection (1) is revoked. See: O. Reg. 221/10, ss. 2 (6), 7 (5).

(1.1) Where the value of all of the benefits provided under subsection (1) exceeds the value of X in the formula below, in respect of all of a manufacturer's interchangeable products that are dispensed by a pharmacy and that are not reimbursed under the *Ontario Drug Benefit Act*, then the benefits that are in excess of X are a rebate and not a professional allowance,

$$X = 25\% \text{ of } P$$

where,

"X" is the total dollar amount of professional allowances that may be provided by a manufacturer to persons listed in subsection 12.1 (1) of the Act, and

"P" is the total dollar amount of a manufacturer's interchangeable products, whether or not the products are listed drug products under the *Ontario Drug Benefit Act*, that are not reimbursed under the *Ontario Drug Benefit Act*, based on the number of units dispensed by the pharmacy, at each product's price, which shall not exceed the price the product may be sold at under subsection 8 (1) where that subsection applies to the product.

O. Reg. 221/10, s. 2 (1-3).

Note: On April 1, 2013, subsection (1.1) is revoked. See: O. Reg. 221/10, ss. 2 (6), 7 (5).

(2) A benefit is not a professional allowance if the contents of the Code of Conduct set out in Schedule 1 are not complied with. O. Reg. 221/10, s. 2 (4).

Note: On April 1, 2013, subsection (2) is revoked. See: O. Reg. 221/10, ss. 2 (6), 7 (5).

(3) For the purposes of section 12.1 of the Act, a "rebate" does not include the value of a benefit that is provided in accordance with ordinary commercial terms that meet all of the following conditions:

1. The benefit is provided in the ordinary course of business in the supply chain system of interchangeable products between any of a manufacturer, a wholesaler, an operator of a pharmacy or a company that owns, operates or franchises pharmacies.
2. The value of the benefit is set out in a written agreement between any of a manufacturer, a wholesaler, an operator of a pharmacy and a company that owns, operates or franchises pharmacies.
3. The benefit relates to an ordinary commercial relationship that is any of the following:
   i. A prompt payment discount.
   ii. A volume discount.
   iii. A distribution service fee.
4. In the case of product that is not supplied to an eligible person under the *Ontario Drug Benefit Act*, the total value of any benefits does not exceed 10 per cent of the value of the interchangeable products based on the number of units dispensed by a pharmacy at each product's price, which shall not exceed the price the product may be sold at under subsection 8 (1) where that subsection applies to the product.
5. A person who receives the benefit reports to the executive officer, if required by the executive officer to do so, the net selling price of the drug products representing the price of the product less the value of the benefits received. O. Reg. 221/10, s. 2 (5).

3. Revoked: O. Reg. 458/06, s. 2.

4. Revoked: O. Reg. 204/96, s. 1.

Public Sector:

For ODBA-reimbursed drugs, professional allowance limits have been eliminated effective July 1, 2010. Under the previous ODBA regulations pharmacies were permitted to receive professional allowances in an amount equal to 20% of the value of drugs reimbursed under the ODBA. Section 1.(6). To compensate for this loss of revenue, the government paid $1.00 for each claim submitted by a pharmacy from July 1, 2010 to March 31, 2011. This amount was reduced to $0.65 from April 1, 2011 to March 31, 2012 and to $0.35 from April 1, 2012 to March 31, 2013, after which these transition payments will cease. Section 1.(8) Benefits received in the form of a professional allowance prior to July 1, 2010, will be treated as such, if the person receiving it reports them as a professional allowance in accordance with the provisions of the prior regulations.

Private sector:

DIDFA R.R.O. 1990, Regulation 935 General. The changes to the DIDFA regulations also phase out professional allowance payments that pharmacies may receive for private sales of "interchangeable drugs". These amounts, which were previously unregulated, are now limited in the first year to 50% of interchangeable product private sales (July 1, 2010), 35% in the second year (April 1, 2011), and 25% in the third year (April 1, 2012). As of April 1, 2013, no professional allowance payments will be permitted.

Policy:

The drug rebate provisions in Ontario are set out in sections 11.5 and 11.6 of the *Ontario Drug Benefit Act* (http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_90o10_e.htm#BK20) and sections 12.1 and 12.2 of the *Drug Interchangeability and Dispensing Fee Act* (http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_90p23_e.htm#BK13).

"Rebate" includes, but is not limited to, currency, discounts, refunds, free goods or travel and any benefit set out by regulation. The regulations sets out what is not a rebate (e.g., ordinary commercial terms).

In brief, the rebate section prohibits manufacturers from providing a rebate to wholesalers, operators of pharmacies or companies that own, operate or franchise pharmacies, or to their directors, officers, employees or agents for any drugs that

are designated interchangeable or being considered for designation as interchangeable, and any person from accepting a rebate, directly or indirectly.

The executive officer may order manufacturers to pay the government an amount equal to the amount contrary to this section.

The calculation of the amount owing to the government because of rebates is set out as follows:

- The expected cost for a drug product or group of drug products provided by the manufacturer to the wholesaler or pharmacy is based on the drug benefit price for that drug(s) multiplied by the amount of product the wholesaler or pharmacy received from the manufacturer.
- The payment amount to government is the difference between the expected cost noted above and the actual cost to the wholesaler or pharmacy which includes the impact of any price reductions, free goods, or direct payments by the manufacturer, as examples.

The manufacturer may submit evidence to the executive officer that the amount calculated is not correct or that the manufacturer has not provided a rebate, within 14 days of being served with the order, and the executive officer is required to reconsider the order.

After reconsidering the order, the executive officer may affirm, rescind or vary the order.

Where the manufacturer has not complied with an order within 14 days of being served with it, or once the order has been affirmed or varied, and the manufacturer still has not complied with it, the executive officer may issue a further order for compliance, or the executive officer may do one or both of the following until the manufacturer pays:

- if the product is an interchangeable product, remove the drug product's designation as interchangeable
- refuse to consider the manufacturer's other drug products for future designation as interchangeable, for future designation as a listed drug product on the Formulary, or for approval under the exceptional access program of the ODBA.

The manufacturer does not have another opportunity to have a further order reconsidered.

The executive officer must give 30 days notice before the executive officer may refuse to consider the manufacturer's other drug products for designation as interchangeable, for designation as a listed drug product on the Formulary, or for approval under the exceptional access program of the ODBA.

The executive officer may publish on the Ministry's website:

- the corporate names of manufacturers who are subject to a payment order or a measure to compel compliance; and,
- any information about the enforcement action that the executive officer believes is appropriate.

There is no appeal, other than as provided in this section, from a decision or action of the executive officer to order payment or compel compliance with a payment order.

Comments/Sources:

Ontario Drug Benefit Act http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_90o10_e.htm

Ontario Drug Benefit Act Regulation http://www.e-laws.gov.on.ca/html/regs/english/elaws_regs_960201_e.htm

Drug Interchangeability and Dispensing Fee Act
http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_90p23_e.htm

Drug Interchangeability and Dispensing Fee Act Regulation
http://www.e-laws.gov.on.ca/html/regs/english/elaws_regs_900935_e.htm

Quebec

Regulations:

Prescription Drug Insurance Act

2. — *Coverage*

22. The Board shall pay the cost of the pharmaceutical services determined by government regulation according to the tariff established by an agreement under section 19 of the Health Insurance Act (chapter A-29), in addition to the cost of the services rendered to fill or renew a prescription.

It shall also pay the cost of medications according to the price indicated in the list of medications drawn up by the Minister pursuant to section 60 and, with respect to medications provided by an institution, according to the price established in that list.

If, after an investigation, the Board believes that a pharmacist has received rebates, gratuities or other benefits not authorized by regulation for pharmaceutical services or medications and the pharmacist is claiming payment for those services or medications or has received payment for them in the preceding 36 months, the Board may deduct an amount corresponding to the value of the rebates, gratuities or other benefits from the payment for those pharmaceutical services or medications or obtain the reimbursement of that amount by way of compensation or otherwise, as the case may be.

Sections 22.2 to 22.4 of the Health Insurance Act govern the procedure applicable to a decision made by the Board under the third paragraph as if the decision had been made under the second paragraph of section 22.2 of that Act.

Health Insurance Act

22.2. Where the Board believes that services for which payment is claimed by a professional in the field of health or for which he has obtained payment in the preceding 36 months were services furnished in non-conformity with the agreement, the Board may refuse payment for such services or have them reimbursed by compensation or otherwise, as the case may be. Disputes resulting from this paragraph are settled by the council of arbitration instituted by section 54.

Where, after an investigation, the Board believes that services for which payment is claimed by a professional in the field of health or for which he has obtained payment in the 36 preceding months were services that have not been furnished, that he has not furnished in person or that he has falsely described, or services that were non-insured services, services not considered insured by regulation or services not

established as insured services by regulation, the Board may refuse payment for such services or have them reimbursed by compensation or otherwise, as the case may be.

Where the Board decides to refuse payment for services or to make compensation, it must inform the professional in the field of health of the reasons for its decision.

In the cases provided for in this section, the burden of proof that the decision of the Board is ill-founded, is on the professional in the field of health.

A professional in the field of health who wishes to appeal a decision of the Board before the Superior Court or the Court of Québec according to their respective jurisdictions, must do so within six months of receiving such decision.

For the purposes of this Act and within the scope of the basic prescription drug insurance plan, the second, third, fourth and fifth paragraphs, adapted as required, apply to an institution.

22.4. Every amount owed under this Act by a health professional shall give rise to a recovery charge of 10% of the outstanding amount owed on the date on which the Board, in order to collect the amount, either resorts to a recovery measure under section 22.2 or section 50 or exercises a recourse before the Superior Court or the Court of Québec according to their respective jurisdictions. The charge shall not be less than $50 nor more than $10,000.

Where several recourses or measures are exercised by the Board to recover an amount owing, the charge provided for in the first paragraph shall be applied only once.

The Board may cancel or reduce the charge where it considers that it would not be payable had it not been for an error or omission attributable to the Board or where the amount of the debt that gave rise to the charge is reduced or cancelled.

Regulation respecting benefits authorized for pharmacists

1. The only benefits authorized within the meaning of the third paragraph of section 22 of the Act respecting prescription drug insurance (R.S.Q., c. A-29.01) are the professional allowances and other authorized benefits provided for in this Regulation.

2. A professional allowance is a reduction as a discount, rebate or premium, good, service, gratuity or any other benefit granted, paid or provided, directly or indirectly, by a generic drug manufacturer to an owner pharmacist, other than the discount referred to in paragraph 2

of section 2 of Schedule I to the Regulation respecting the conditions governing the accreditation of manufacturers and wholesalers of medications shall be recognized (c. A-29.01, r. 2), that is used only for the purposes and before the expiry date and limit set in this section.

The purposes contemplated by this section are

(1) the funding of training and continuing education programs and activities in Québec intended to upgrade the scientific knowledge or professional skills of pharmacists and pharmacy technical assistants. The cost of the programs or activities and their frequency must be reasonable in relation to the nature of the activities offered;

(2) the funding of activities intended for the general public that take place in the pharmacy concerning the promotion or protection of health, disease prevention and the communication of information on diseases or medications, and that are based on scientific grounds. The cost of the activities, their frequency and the number of patients involved per pharmacy must be reasonable in relation to the nature of the activities offered;

(3) the acquisition of educational equipment and material used in the pharmacy and intended to improve the management of chronic diseases and services to train in the reading of devices required for that purpose, in particular devices to measure arterial pressure, glycemia or used for asthma management or anticoagulant therapy, including the relevant software but excluding the purchase or rental of computers. Professional allowances may not be used by an owner pharmacist to purchase an inventory of devices or materials intended for sale at retail;

(4) the acquisition or maintenance of equipment intended to achieve greater quality and safety in the distribution of medications in the pharmacy, in particular devices used for the automated processing of medications. To calculate the professional allowances received by an owner pharmacist, the cost to acquire equipment referred to in this subparagraph may be spread over a reasonable number of years subsequent to the acquisition, taking into account the service life of the equipment; and

(5) the remuneration of pharmacists and pharmacy technical assistants assigned to maintaining or improving the delivery of professional services to promote the optimal use of medications, in particular the preparation and implementation of pharmaceutical care plans.

The limit set in this section is a maximum amount per generic drug manufacturer for a given pharmacy and a given year, corresponding to 15% of the total value of the sales by the manufacturer of generic drugs on the List of medications to an owner pharmacist or, as the case may be, to all the owner pharmacists, for that same year, under the basic prescription drug insurance plan.

The expiry date set in this section is the last day of the sixth month following the end of the year in which the reduction, rebate, discount, premium, good, service, gratuity or other benefit was granted, paid or provided to the owner pharmacist.

For the purposes of the third and fourth paragraphs, "year" means a fiscal year of the pharmacy.

3. For the purposes of this Regulation, the following good or service provided by a manufacturer of innovative drugs to an owner pharmacist or paid by such a manufacturer for the benefit of an owner pharmacist is an authorized benefit other than a professional allowance for the following purposes and under the following conditions:

(1) the carrying out of training and continuing education programs and activities in Québec intended to upgrade the scientific knowledge or professional skills of pharmacists and pharmacy technical assistants. The cost of the programs or activities and their frequency must be reasonable in relation to the nature of the activities offered;

(2) the carrying out of activities intended for the general public that take place in the pharmacy concerning the promotion or protection of health, disease prevention and the communication of information on diseases or medications, and that are based on scientific grounds. The cost of the activities, their frequency and the number of patients involved per pharmacy must be reasonable in relation to the nature of the activities offered;

(3) the educational equipment or material used in the pharmacy and intended to improve the management of chronic diseases and services to train in the reading of devices required for that purpose, in particular devices to measure arterial pressure, glycemia or used for asthma management or anticoagulant therapy, including the relevant software but excluding the purchase or rental of computers. The goods supplied may not constitute an inventory of devices or materials intended for sale at retail;

(4) the device to measure glycemia or the insulin pen given without consideration to a patient by the pharmacist.

4. An owner pharmacist must keep a record of all the professional allowances and other benefits authorized under this Regulation, including any other benefit received by the pharmacist, directly or indirectly, from a manufacturer.

Regulation respecting the conditions governing the accreditation of manufacturers and wholesalers of medications

SCHEDULE I

MANUFACTURER'S COMMITMENT

1. The manufacturer undertakes to submit a guaranteed selling price per package size for any drug that he wishes to have entered on the List of medications drawn up under section 60 of the Act respecting prescription drug insurance (R.S.Q., c. A-29.01).

The guaranteed selling price shall be established as follows:

(1) it must be submitted for each package size of the drug, the number of package sizes being limited to 2, and the price must take into account any price granted for multiples of the package size;

(2) it may differ for sales to pharmacists or to wholesalers, but such difference may not exceed 6.25%. As of 1 April 2012, the difference may not exceed 6.50%;

(3) it must remain in force throughout the period of validity of the List of medications;

(4) it must not be higher than any selling price granted by the manufacturer for the same drug under other provincial drug insurance programs.

The guaranteed selling price is the price that a buyer must pay for a drug. It is reduced by the value of any reduction granted by the manufacturer as a rebate, discount or premium and by the value of any good or service provided without consideration to a buyer by the manufacturer, other than a benefit authorized under the Regulation respecting the benefits authorized for pharmacists (c. A-29.01, r. 1).

The guaranteed selling price must include, in addition to the sum demanded as the price, any amount received for marketing, service, guarantee, commission, transport or delivery and any amount received in any other respect, excluding fees payable to the seller by reason of the buyer's failure to comply with the conditions of payment provided for in the sales contract.

2. The manufacturer undertakes to respect, in his transactions with wholesalers and pharmacists, the guaranteed selling price that he submitted, and consequently he agrees to comply with the following requirements:

(1) every sale of a drug must be recorded in writing in an invoice indicating the net price paid by the buyer for each drug;

(2) the manufacturer may grant a discount for a payment made within 30 days following the purchase, provided that the discount does not exceed 2% of the net price;

(3) no reduction in the price of the drug may be applied to other merchandise;

(4) no reduction in the price of a drug may be granted to a buyer or an intermediary, including a wholesaler, a commercial name or a chain of pharmacies for the attainment of a fixed purchase volume for a given period, and no good or service may be provided without consideration or reduction as a rebate, discount or premium, other than a benefit authorized within the meaning of the Regulation

respecting the benefits authorized for pharmacists (c. A-29.01, r. 1), or a professional allowance for an owner pharmacist who deals through a wholesaler, a commercial name or a chain of pharmacies that is paid in whole to the owner pharmacist, and other than a discount referred to in paragraph 2;

(5) *(paragraph revoked);*

(6) upon the sale of a drug, no term of payment greater than 90 days may be granted to a pharmacist, even in the case of a consignment; notwithstanding the foregoing, in the case of a sale of drugs to a wholesaler, the manufacturer may grant a term of payment of up to 120 days.

2.1. The manufacturer undertakes to reimburse to the Board an amount corresponding to the value of any reduction as a rebate, discount or premium, of any good, service or gratuity or of any other benefit granted to an owner pharmacist that is not a benefit authorized within the meaning of the Regulation respecting the benefits authorized for pharmacists (c. A-29.01, r. 1) or a discount referred to in paragraph 2 of section 2. The manufacturer also undertakes to pay to the Board a sum corresponding to 20% of that amount as administrative expenses.

2.2. The generic drug manufacturer undertakes to send the Board an annual report on or before 1 March for the preceding calendar year giving the detail of the reductions as rebates, discounts or premiums, the gratuities, goods, services or any other benefit, other than the discount referred to in paragraph 2 of section 2, granted by the manufacturer to each owner pharmacist in Québec. The report must also state the value of all the sales of generic drugs on the List of medications that are sold directly to owner pharmacists or indirectly through wholesalers, a commercial name or a chain of pharmacies, under the basic prescription drug insurance plan. If a pharmacist owns more than one establishment, the data must be detailed by establishment. If a pharmacy is owned by a partnership of pharmacists or a joint-stock company, the data must be detailed by partnership or company and, where applicable, by establishment.

The manufacturer agrees to the Board sending the report to the Ministère de la Santé et des Services sociaux, the Institut national d'excellence en santé et en services sociaux and the Agence du revenu du Québec. The manufacturer also undertakes to provide that department, that body and that agence, on request, and the Board with all additional information they may require in relation to the content of the report.

Policy:

Pursuant to the regulation, Quebec policy permits professional allowances up to 15% (20% up to April 1, 2012) provided that this money is used for the purposes defined in the regulation.

Comments/Sources:

Prescription Drug Insurance Act
http://www2.publicationsduquebec.gouv.qc.ca/dynamicSearch/telecharge.php?type=2&file=%2F%2FA_29_01%2FA29_01_A.htm

Health Insurance Act
http://www2.publicationsduquebec.gouv.qc.ca/dynamicSearch/telecharge.php?type=2&file=%2F%2FA_29%2FA29_A.htm

Regulation Respecting Benefits Authorized For Pharmacists
http://www2.publicationsduquebec.gouv.qc.ca/dynamicSearch/telecharge.php?type=2&file=/A_29_01/A29_01R1_A.htm

Regulation respecting the conditions governing the accreditation of manufacturers and wholesalers of medications
http://www2.publicationsduquebec.gouv.qc.ca/dynamicSearch/telecharge.php?type=3&file=/A_29_01/A29_01R2_A.HTM

Article http://www.secorgroup.com/files//pdf/ARTICLES/generics_June182010_rpt.pdf

Article http://www.cpjournal.ca/doi/pdf/10.3821/1913-701X-144.1.12b

Saskatchewan

Regulations: The *Prescription Drugs Act* does not mention rebates.

Policy: None found. The Generic Drug Pricing Plan News Release does not mention rebates.

Comments/Sources:

Prescription Drugs Act http://www.qp.gov.sk.ca/documents/English/Statutes/Statutes/P23.pdf

Generic Drug Pricing Plan News Release http://www.gov.sk.ca/news?newsId=e5dc0530-5d2a-4ec9-898e-59297eb16678

K:\3 POLICY OUTCOMES, EVALUATION & RESEARCH\Project - PharmaCare\Ongoing Projects\Pharmaceutical Services Act - 2011\2012\Regulations\Rebates Cross Jurisdictional Research.docx

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s.13;s.17

Page 58 to/à Page 60

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PHARMACEUTICAL SERVICES DIVISION
ISSUES NOTE

TITLE: Rebates

ISSUE

s.13 However, the terms of the newly negotiated Pharmaceutical Services Agreement suggest that s.13
s.13
s.13 and towards controlling prices by setting maximum list price for generic drugs. The agreement allows for individual negotiations between the Province and any pharmacy, wholesaler, distributor, manufacturer or other party conducting business in British Columbia.

s.13
s.13
s.13 Appendix A). Rebate has to be defined, its true value calculated, and exceptions, offences or penalties determined where appropriate.

Although the federal *Competition Act* does not apply to provinces that have enabling legislation to control the business relationships of different entities within their borders, s.13
s.13
s.13 In addition, the minister will still have the authority to restrict rebates as a condition for enrolment in the PharmaCare program.

RESOLUTION

s.13

APPENDIX A - Ontario *Drug Benefit Act* (provisions around rebate)

Rebates, etc.

11.5 (1) A manufacturer shall not provide a rebate to wholesalers, operators of pharmacies, or companies that own, operate or franchise pharmacies, or to their directors, officers, employees or agents,

(a) for any listed drug product or listed substance; or

(b) for any drug in respect of which the manufacturer has made an application to the executive officer for designation as a listed drug product, while that application is being considered. 2006, c. 14, s. 19.

Extended definition of "manufacturer"

(2) For the purposes of this section and in section 11.6, unless the context requires otherwise, and in section 13.1 and subsection 14 (3),

"manufacturer" includes a supplier, distributor, broker or agent of a manufacturer, except in,

(a) clause (1) (b) of this section,

(b) subsection (6) of this section,

(c) paragraph 2 of subsection (9) of this section, and

(d) subsection (11) of this section. 2006, c. 14, s. 19.

May not accept rebate

(3) No wholesaler, operator, company, director, officer, employee or agent mentioned in subsection (1) shall accept a rebate that is mentioned in subsection (1), either directly or indirectly. 2006, c. 14, s. 19.

Executive officer may make order

(4) If the executive officer believes, on reasonable grounds, that a manufacturer is not complying with subsection (1), the executive officer may make an order requiring the manufacturer to pay to the Minister of Finance the amount calculated under subsection (5). 2006, c. 14, s. 19.

Calculation

(5) For the purposes of this section, the following rules apply to calculating the amount that is to be paid under subsection (4):

1. The amount shall be calculated by determining the difference between the expected value of all units of drug products and listed substances purchased and the actual cost of acquiring those units by the wholesaler, operator of a pharmacy, or company that owns, operates or franchises pharmacies.
2. The expected value mentioned in paragraph 1 shall be determined by multiplying the drug benefit price by the volume of units provided by the manufacturer or wholesaler for all the listed drug products and listed substances.
3. The actual cost of acquiring those products and substances mentioned in paragraph 1 shall be determined by subtracting the monetary value of the rebate from the amount paid for the drug products and listed substances by the wholesaler, operator of a pharmacy, or company that owns, operates or franchises pharmacies. 2006, c. 14, s. 19.

Deemed drug benefit price

(6) For the purposes of subsection (5), the drug benefit price of a drug in respect of which clause (1) (b) applies shall be deemed to be the price submitted by the manufacturer. 2006, c. 14, s. 19.

Reconsideration

(7) Within 14 days of being served with the order, the manufacturer may submit evidence to the executive officer as to its compliance with subsection (1), or that the amount calculated under subsection (5) is not correct, and the executive officer shall reconsider the order based on that evidence. 2006, c. 14, s. 19.

Actions of executive officer after reconsideration

(8) After reconsidering the order, the executive officer may do one of the following, and shall promptly serve the manufacturer with notice of his or her decision.

1. Affirm the order.
2. Rescind the order.

3. Vary the order. 2006, c. 14, s. 19.

Executive officer may act

(9) Where a manufacturer has not complied with an order under subsection (4) within 14 days of being served with it, or has submitted evidence within 14 days under subsection (7) and the order has been affirmed or varied under subsection (8) and the manufacturer has not complied with the affirmed or varied order within 14 days of being served with it, the executive officer may either issue a further order under subsection (4) or do either or both of the following:

1. If the drug that is the subject of the order is a listed drug product, remove its designation.
2. Not make further designations of any of the manufacturer's drug products as listed drug products under section 1.3, nor consider any of its drug products for approval under section 16, nor designate any of its products as interchangeable under the *Drug Interchangeability and Dispensing Fee Act* until such time as the executive officer is of the opinion that the manufacturer is no longer offering the rebate. 2006, c. 14, s. 19.

Limit on reconsideration

(10) Subsections (7) and (8) do not apply to a further order mentioned in subsection (9). 2006, c. 14, s. 19.

Required notice

(11) Where the executive officer proposes to act under paragraph 2 of subsection (9), the executive officer shall serve the manufacturer with at least 30 days notice. 2006, c. 14, s. 19.

Executive officer order where rebate accepted

(12) Where the executive officer believes, on reasonable grounds, that a person has accepted a rebate contrary to subsection (3), the executive officer may make an order requiring the person to pay to the Minister of Finance the amount calculated under subsection (5). 2006, c. 14, s. 19.

Reconsideration

(13) Subsections (7) and (8), subsection (9), other than paragraphs 1 and 2, and subsection (10) apply with any necessary modifications where an order has been made under subsection (12). 2006, c. 14, s. 19.

Lesser amount

(14) Despite any other provision of this section, the executive officer may, in an order under subsection (4) or (12), require the manufacturer or other person to pay an amount less than the amount calculated under subsection (5) and, where the executive officer does so, the following apply:

1. The executive officer shall set out in the order both the lesser amount and how it was calculated.
2. Any right of reconsideration that applies with respect to a calculation under subsection (5) applies with respect to the calculation under paragraph 1. 2006, c. 14, s. 19.

Code of conduct

(15) The executive officer shall establish a Code of Conduct respecting professional allowances under this Act and the *Drug Interchangeability and Dispensing Fee Act* in consultation with the pharmacy and drug manufacturing industries, and shall update the Code of Conduct from time to time in consultation with those industries. 2006, c. 14, s. 19.

Publication

(16) The executive officer shall publish the Code of Conduct on the website of the Ministry and may publish it in any other format that the executive officer considers advisable. 2006, c. 14, s. 19.

Where conflict

(17) In the event of conflict between what is published on the Ministry's website under subsection (15) and what is published in another format, the Ministry's website prevails. 2006, c. 14, s. 19.

Definition

(18) In this section,

"rebate", subject to the regulations, includes, without being limited to, currency, a discount, refund, trip, free goods or any other prescribed benefit, but does not include,

(a) a discount for prompt payment offered in the ordinary course of business, or

(b) a professional allowance. 2006, c. 14, s. 19.

Rules re ss. 11.4 and 11.5

11.6 (1) The following rules apply with regard to an order made or a notice given by the executive officer under section 11.4 or 11.5:

1. The order or notice must be in writing, and set out in brief the reason for which it is made.
2. An order must set out how any amount required to be paid under the order was calculated, and specify any right of reconsideration that is available and the time within which the reconsideration is available.
3. In the case of an order or notice under section 11.4 or an order or notice under section 11.5 that applies to a manufacturer, the order or notice may be served by leaving a copy of the document with an officer, director or agent of the manufacturer, or with an individual at any place of business of the manufacturer who appears to be in control or management of the place of business.
4. In the case of an order or notice under section 11.5 that applies to a person mentioned in subsection 11.5 (3), the order or notice may be served by leaving a copy of the document with the person if the person is an individual, or with an officer, director or agent of the person, or with an individual at any place of business of the person mentioned in subsection 11.5 (3) who appears to be in control or management of the place of business.
5. An order must specify the time period with respect to which the order is made, which may include a time period with respect to which a previous order was made, if the previous order has not been complied with.
6. An order must set out the time period in which the manufacturer or person mentioned in subsection 11.5 (3) is required to comply with the order.
7. An order must specify the consequences for failing to comply with the order. 2006, c. 14, s. 19.

Same, publication of enforcement action

(2) The executive officer may publish on the Ministry's website the corporate names of manufacturers or any other persons against whom the executive officer has taken action under section 11.4 or 11.5 and may also publish any information he or she considers appropriate about the action that has been taken. 2006, c. 14, s. 19.

No appeal

(3) There is no appeal from a decision or action of the executive officer under section 11.4 or 11.5, except as provided for in those sections. 2006, c. 14, s. 19.

Regulation

18. (1) The Lieutenant Governor in Council may make regulations,

(k.5.1) clarifying the definition of "rebate" in section 11.5, including providing that certain benefits are not rebates, prescribing benefits for the purpose of that definition, clarifying how the calculations are to be made in that section and defining "professional allowance" for the purposes of that definition, including governing how professional allowances are to be calculated, setting limits on professional allowances and incorporating the content of the Code of Conduct referred to in subsection 11.5 (15) as amended from time to time;