

Ontario Generic Drug Price Reforms Finalized

The **Ontario Ministry of Health and Long-Term Care** (Ministry) has finalized the significant reforms relating to **generic drug pricing** first announced on April 7, 2010. The changes have been implemented through amendments to the **Drug Interchangeability and Dispensing Fee Act (DIDFA)** and the **Ontario Drug Benefit Act (ODBA)** and their respective regulations. They will affect the pricing of generic drugs for the government funded Ontario Drug Benefit Plan (ODB Plan), employer sponsored drug plans and the general public.

The final regulations have some differences from the initial draft regulations. However, there are only a few changes to the draft DIDFA regulation that will affect private drug plans sponsors. There are more changes with respect to the ODBA regulations that will affect the ODB Plan.

Based on the final regulations, this Communiqué updates and replaces our earlier Communiqués and will be of particular interest to group benefit sponsors in Ontario. Sponsors in other jurisdictions should also be interested as these reforms may influence change in other provinces.

Highlights of the Proposed Reforms

Decrease in Generic Drug Prices

Generic drug prices for both the ODB Plan and for private plans will be decreased to 25 per cent of the brand drug price, though it will take several years for private plans to reach this price as shown in the following table. These prices will apply to generic drug products whether or not the products are listed drug products under the ODBA.

Legislated generic drug price as a per cent of equivalent brand drug price

Date	ODB Plan	Private Plans
Current	50%	Unregulated
July 1, 2010	25%	50%
April 1, 2011	25%	25%
April 1, 2012	25%	25%

Elimination of Pharmacy Professional Allowances (Rebates)

The reduction and eventual elimination of professional allowances is shown in the following table.

Legislated maximum professional allowance as a per cent of the generic drug price

Date	ODB Plan	Private Plans
Prior to April 7, 2010	20%	Unregulated
Current	0%	Unregulated
July 1, 2010	0%	50%
April 1, 2011	0%	35%
April 1, 2012	0%	25%
April 1, 2013	0%	0%

Generic Substitute for Lipitor® (atorvastatin)

Temporary amendments to the regulations to both the DIDFA and ODBA decrease the price of generic substitutes for Lipitor® (atorvastatin) to, respectively, 50 percent and 25 per cent of the brand name drug price as of the date that the generic drug is first proposed for designation. The Ontario Drug Formulary has been changed, effective June 18, 2010, to list atorvastatin at 50 per cent of the cost of Lipitor®.

Patent Challenges

With respect to the ODB Plan, a generic drug can be sold for up to 50 per cent, not 25 per cent, of the brand name drug price for a three month period after the generic drug becomes a listed drug product if the following conditions are met:

- the generic drug is first proposed for designation as a listed drug product on or after April 1, 2012;
- the manufacturer of the generic drug has shown that it, or the manufacturer of a generic drug that is interchangeable with a brand name drug, has successfully challenged the patent of the brand name drug so that the interchangeable generic drug can be sold in Canada earlier than it otherwise could have been;
- the manufacturer has not entered into any arrangement, other than cross-licensing, with the brand name drug manufacturer; and
- the manufacturer agrees to the three month time limit.

Dispensing Fees and Mark-up

Pharmacy dispensing fees for the ODB Plan will change depending on a pharmacy's category. The maximum dispensing fee has increased from the original proposal for the third and fourth categories. Since there is no maximum dispensing fee for private plans, these changes will not apply to them.

The four categories of pharmacies are based on whether they are rural or urban and how isolated they are from other pharmacies:

1. Pharmacies not described in any of the following categories (that is, pharmacies in cities or in areas that are not underserved).
2. Pharmacies located in a postal code with the second figure of "0" (which signifies a rural location) or with a score of more than 40 on the Ministry's Rurality Index for Ontario and one of the following conditions is met:
 - no other pharmacy within five kilometres;
 - the nearest pharmacy is no more than five kilometres away and is the only other pharmacy within a five kilometre radius; or
 - the nearest other pharmacy is at least five kilometres away but no more than 10 kilometres.
3. Pharmacies located in a postal code with the second figure of "0" or with a score of more than 40 on the Ministry's Rurality Index for Ontario and the nearest other pharmacy is at least 10 kilometres away but no more than 25 kilometres.
4. Pharmacies located in a postal code with the second figure of "0" or with a score of more than 40 on the Ministry's Rurality Index for Ontario and the nearest other pharmacy is at least 25 kilometres away.

Date	Category	Dispensing Fee
Current	All	\$7
July 1, 2010	1	\$8
	2	\$9
	3	\$10
	4	\$11
April 1, 2011	1	\$8.20
	2	\$9.22
	3	\$11.28
	4	\$12.30
April 1, 2012	1	\$8.40
	2	\$9.45
	3	\$11.55
	4	\$12.61
April 1, 2013	1	\$8.62
	2	\$9.69
	3	\$11.84
	4	\$12.92
April 1, 2014	1	\$8.83
	2	\$9.93
	3	\$12.14
	4	\$13.25

The changes with respect to mark-up under the ODB plan set out in the earlier proposed amendment to the ODBA regulation have been removed in the final version. Therefore, all pharmacies can continue to mark-up drug prices by 8 per cent of the drug price and do not have to cap their mark-up at \$125 per prescription.

Other Changes

Although the payment of professional allowances to pharmacies will no longer be an exception to the ban on rebates under both the ODBA and the DIDFA, a new exception, “ordinary commercial terms” (that is, prompt payment discounts, volume discounts and distribution service fees) has been added under both regulations. The value of any benefit provided to a pharmacy under “ordinary commercial terms” will be capped at 10 per cent of the drug price.

Pharmacies and drug wholesalers will be prohibited from selling private label prescription drugs.

An additional \$100 million will be added to the fund that compensates pharmacists for clinical pharmacy services provided to Ontarians. Part of this amount will be used to pay for transition fees to pharmacies on the following basis:

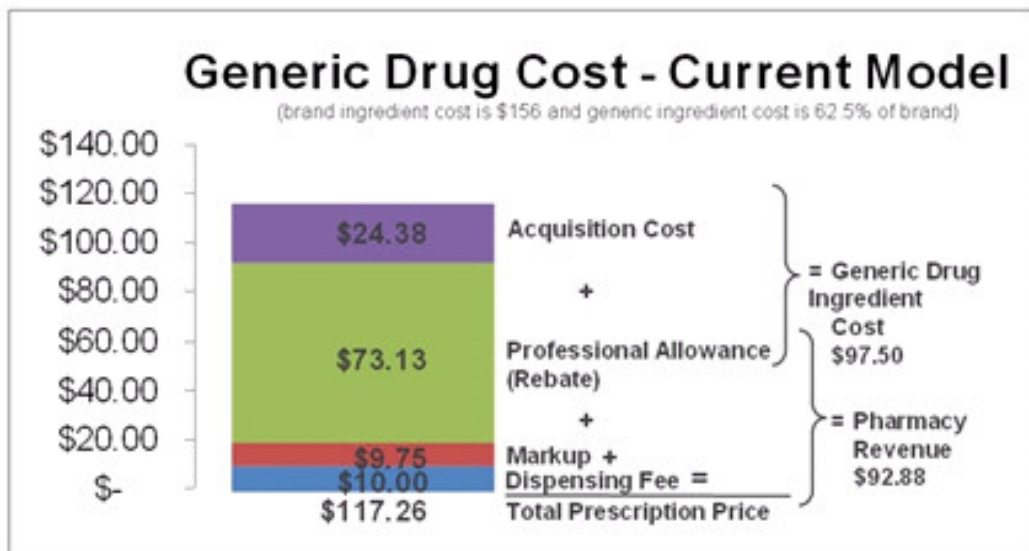
- \$1 per prescription from July 1, 2010 to March 31, 2011;
- \$0.65 per prescription from April 1, 2011 to March 31, 2012; and
- \$0.35 per prescription from April 1, 2012 to March 31, 2013.

The transition fee applies to ODB Plan prescriptions only and not private drug plan prescriptions.

Effect of Changes

The following are illustrations of the current pricing model and the pricing models for an employer sponsored drug plan at the time each of the generic drug pricing decreases is implemented. Please note that the illustrations are based on a particular brand name drug price. A different brand name drug price will result in different numbers. As well, the actual price change could differ depending on how much a pharmacy changes its mark-up and dispensing fee.

Generic Drug Price for Private Plans Under the Current Model

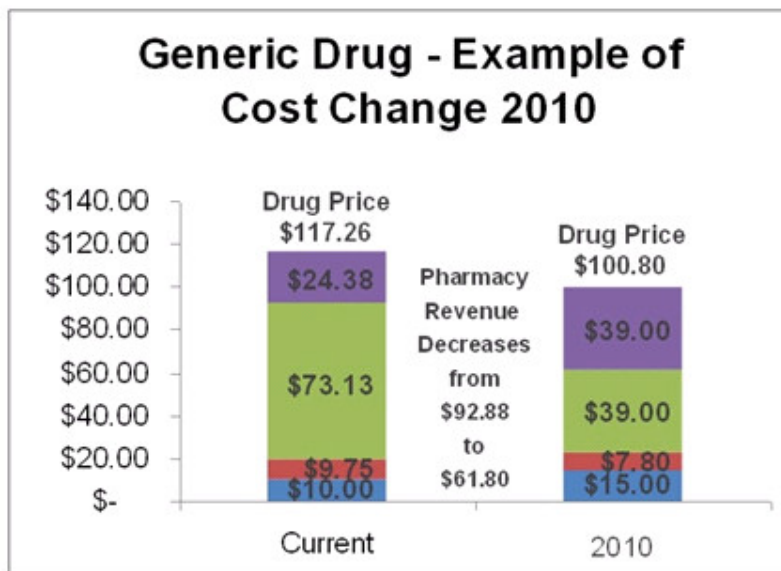


In the above illustration, the following methodology has been used:

- the brand name drug cost is \$156;
- the equivalent generic drug ingredient cost is 62.5 per cent of the brand price: \$97.50;
- the professional allowance paid by the manufacturer to the pharmacist is 75 per cent of the ingredient cost: \$73.13;
- the mark-up up is 10 per cent of the ingredient cost: \$9.75;
- the dispensing fee is \$10;
- the total prescription price is \$117.26;
- the acquisition cost for the pharmacy is \$24.37 (the ingredient cost minus the professional allowance); and
- the revenue earned by the pharmacist is \$92.88 (the professional allowance plus the mark-up plus the dispensing fee).

Generic Drug Price Under Legislated Changes in 2010

On July 1, 2010, the comparison between the total generic drug price under the current rules and the price change immediately after the new rules are implemented is as follows.

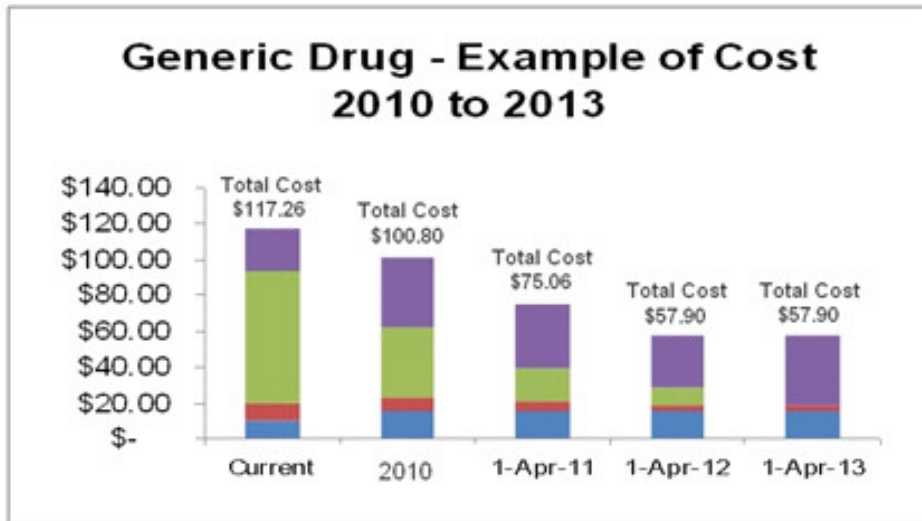


This illustration shows:

- the equivalent generic drug ingredient cost is reduced from 62.5 per cent to 50 per cent of the \$156 brand name drug price: \$78;
- the professional allowance is reduced from 75 per cent to 50 per cent of the ingredient cost: \$39;
- the pharmacist acquisition cost is now \$39 (the ingredient cost minus the professional allowance of \$39);
- the mark-up up remains 10 per cent of the ingredient cost: \$7.80;
- because the pharmacist can increase the dispensing fee, assume that it has been increased to \$15; and
- the revenue earned by the pharmacist is \$61.80 (the professional allowance plus the mark-up plus the dispensing fee).

Generic Drug Prices Under Legislated Changes from 2011 to 2013

Under the amended legislation, further generic drug price decreases will occur on April 1, 2011, April 1, 2012 and April 1, 2013. These changes are set out below.



Assuming that the dispensing fee is \$15 and the mark-up 10 per cent, a generic drug prescription that currently costs \$117.26 will cost \$57.90 by April 1, 2013, a decrease of 50 per cent. Out of that \$57.90 prescription price, the pharmacist's revenue will be \$18.90. This will be 32.6 per cent of the total price, down from 79.2 per cent.

Implications for Plan Sponsors

While the price of many generic drugs will decrease over the next three years, this does not mean that drug benefit plan costs will decrease.

The current price of generic drugs in Ontario ranges between 30 per cent and 80 per cent of the brand name drug price with generic drugs released after 2006 making up most of the high end of this range. For most drug plans in Ontario, the current weighted average generic drug price is likely closer to 55 per cent to 65 per cent of the brand name drug price though this varies by plan.

Therefore, drug plans that have a weighted average generic price around 55 per cent will not see a measurable decrease in their overall generic drug prices until generic drug prices are decreased to 35 per cent of brand prices in 2011. The net impact for Ontario plan sponsors will depend on the current mix of generic drugs under the plan and the reaction of the pharmacy industry in the marketplace. It is too soon to be able to conduct meaningful analysis that will determine the over-all cost impact for plan sponsors.

There are several factors that could increase over-all drug plan costs:

- dispensing fees for all prescriptions, whether for generic or brand name drugs, may rise. It has been reported that some Ontario pharmacies have raised their dispensing fees to \$15;
- pharmacies might increase the mark-up included in the ingredient cost from the current levels – typically 10 per cent of the drug cost. Mark-up is determined through an agreement between a pharmacy and the pharmacy benefit manager and any change would have to be renegotiated. However, pharmacies might refuse to accept the provider drug card unless the mark-up is significantly increased;
- in order to make up for lost revenue in Ontario, pharmacy chains might significantly increase generic drug prices, mark-up or dispensing fees in its pharmacies outside of Ontario; and
- market forces may affect drug prices and plan costs in unexpected ways.

Comment

In drafting the final version of the amendments to the DIDFA and ODBA regulations, the Ontario government did not make any significant concessions to the pharmacy sector and maintained all of the changes that support reduced drug prices for private payers.

The drug system reforms will still significantly affect pharmacists and pharmacies although there have been some improvements with respect to dispensing fees and mark-up under the ODB Plan from what was originally proposed.

Overall, the final amendments are good news for private drug plans. However, the impact on private drug plan costs is not completely known since not only do generics account for only part of the overall cost of a drug plan, but pharmacies might attempt to recoup some of their lost revenue by increasing other prescription costs or increasing prescription costs in other provinces.

More information on the Ontario reforms is available from the [Ministry of Health](#)

- *Mercer Communique June 2010*