F&DR 2010-7
June 17, 2010

Ontario Drug System Reform Now Finalized

By Ingrid VanderElst

The Ontario government has published the final version of the amended regulations (final regulations) under the *Ontario Drug Benefit Act* (ODBA) and the *Drug Interchangeability and Dispensing Fee Act* (DIDFA). As we reported when the draft regulations were first published for comment (Torys' bulletin), the amendments will reduce the prices paid for generic drugs in both the public and the private sectors, and will affect commercial arrangements between entities in the drug supply chain. Many key amendments will come into force on July 1, 2010 and some on later dates.

The final regulations have been revised since they were first published for comment and the key provisions are outlined below.

Generic Drug Prices

As in the proposed regulations, the drug benefit price for listed interchangeable drugs (the price that the government will pay to pharmacies for supplying generic drugs to beneficiaries under Ontario drug programs) will still generally be capped at 25% of the cost of the original product, effective July 1, 2010 (the 25% Pricing Rule),[1] but there are new exceptions to the rule.

- One new exception is triggered if the drug benefit price of the original product has been reduced by more than 20% in the two-year period preceding the date on which the interchangeability designation is sought; in this case, the price will generally be capped at 25% of the price of the original product ***before*** its first price reduction.
- Another new exception applies to interchangeable drugs that are not solid dosage forms, for which the price will generally be capped at 35% of the price of the original product.
- Finally, a new exception applies to products proposed for reimbursement under the ODBA on or after April 1, 2012 if the proponent submits evidence that the patent of the original product was successfully challenged and the proponent has not entered into any arrangement with the original manufacturer other than a cross-licensing agreement. In this case, the price will be capped at 50% of the drug

[1] The amendments have created an immediate exception to the current 50% cap on generic drug prices for drugs containing atorvastatin; the price for any such drugs proposed for interchangeability are immediately capped at 25%. This exception will be revoked on July 1, 2010, when prices of all generic drugs will generally be capped at 25%. Presumably, the Ministry of Health is expecting applications for interchangeability designations in anticipation of patent expiry for the original product.

To discuss these issues, please contact the author.

benefit price of the original product for the three-month period following the decision to reimburse.[2]

The treatment of generic drug prices in the private sector is unchanged in the final regulations: prices will still be capped in the private sector, initially at 50% of the drug benefit price (effective July 1, 2010), and then capped at 35% (effective April 1, 2011) and finally capped at the drug benefit price (effective April 1, 2012). The prices of drugs that are not listed in the Ontario Drug Benefit Formulary as interchangeable are not capped by the regulations.[3]

Rebates

Under the final regulations, professional allowances (amounts paid by manufacturers to pharmacies to be used for patient benefit initiatives) will be completely eliminated in the public sector effective July 1, 2010. Professional allowances will be phased out and eventually eliminated in the private sector as well, when amendments to DIDFA come into force on April 1, 2013. During the phase out, caps on professional allowances will be reduced in the private sector, initially to 50%, then 35%, and then 25% of the cost of the products reimbursed in the private sector, coincident with the reduction of generic drug prices in that sector.

Under the final regulations, benefits provided in accordance with "ordinary commercial terms" continue to be excluded from the prohibition against rebates, but further limitations have been placed on these benefits. Regarding generic drugs, in addition to the requirements set out in the earlier proposed regulations (i.e., benefits must be provided in the ordinary course of business, be set out in a written agreement and relate to a prompt payment discount, a volume discount or a distribution service fee), the final regulations stipulate that the total value of any benefits must not exceed 10% 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 ODBA. (In the case of drugs supplied in the private sector, the limit is set at 10% of the value of the interchangeable drug products, based on the number of units dispensed by a pharmacy at each product's price.) If requested, the manufacturer and the person who receives the benefit must report the net selling price of the drug products to the Executive Officer of the Ontario Drug Programs. For brand name products, the final regulations, like the proposed regulations, appear to permit only prompt payment discounts granted according to ordinary commercial terms.[4] The provisions relating to ordinary commercial terms come into force on July 1, 2010.

Private Label Products

The final regulations still prohibit reimbursement for "private label products" under Ontario drug programs and prohibit the designation of private label products as interchangeable under DIDFA. The definition of private label products, which has been expanded to capture more arrangements, now

---

[2] The regulations also contain an exception to the pricing rule for applications to list single-source generic drugs (with a ceiling that is the drug benefit cost of the original product) and for continued listing of generic drugs that have been single source for two years or for situations in which a manufacturer can establish an increase in raw material costs, with an absolute limit, which is the price of the original drug (these exceptions existed in the regulations prior to amendment). According to the final amendments, the exceptions relating to continued listing have been expanded to permit an exception to the pricing rules if a manufacturer can establish that direct manufacturing costs have increased and the absolute price ceiling has been abolished if the manufacturer can justify a higher price.

[3] This means that no caps will apply in the private sector for drugs that are not otherwise eligible for coverage under Ontario drug programs.

[4] There is also seemingly no requirement for the prompt payment discount to be provided in the ordinary course of business or to be set out in a written agreement.

includes a drug product whose manufacturer (who applies for listing or interchangeability) neither directly fabricates the product nor controls or is controlled by the person fabricating, and *either* (i) the manufacturer has no arm's-length relationship with a wholesaler, a pharmacy operator or a company that owns, operates or franchises pharmacies; *or* (ii) the product is to be supplied under a marketing arrangement associating the product with a wholesaler or one or more pharmacy operators or companies that own, operate or franchise pharmacies. This amendment will come into effect on July 1, 2010.

Pharmacy Compensation

The final regulations no longer contain the concept of different markups payable in respect of drugs sourced from comprehensive wholesalers versus self-distributors or different markups depending on pharmacy location. The markup will remain at 8% for all supplies under the ODBA. As under the proposed regulations, four categories of pharmacies are created, depending upon their location (rural versus urban) and the distance between pharmacies in an area, with rural and underserviced areas qualifying for higher dispensing fees.

Finally, the final regulations create a compensation scheme whereby the Executive Officer will pay pharmacy operators a fixed fee for every claim submitted over a three-year period beginning on July 1, 201o. The fee is set to decline annually and will be eliminated on March 31, 2013.