

Torys on Food and Drug Regulatory

F&DR 2010-3

April 12, 2010

Ontario Drug System Reform

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The Ontario government has published proposed regulatory changes under the *Ontario Drug Benefit Act* and the *Drug Interchangeability and Dispensing Fee Act* (DIDFA) that will affect the prices paid for generic drugs in both the public and the private sectors. These proposals come in the wake of the announcement of major drug system reform by the government last week.

Under the proposed regulations, the drug benefit price for interchangeable drugs (the price that the government will pay to pharmacies for supplying generic drugs to beneficiaries under Ontario drug programs) will generally be set at 25% of the cost of the brand name product (the 25% Pricing Rule).¹ The 25% Pricing Rule is scheduled to come into effect on May 15, 2010. Generic drug prices will also be capped in the private sector, initially at 50% of the drug benefit price (effective May 15, 2010), and then capped at 35% (effective April 1, 2011) and 25% (effective April 1, 2012). The prices of drugs that are not listed in the Ontario Drug Benefit Formulary as interchangeable will not be capped by the regulations.²

Under the proposed regulations, the provision of professional allowances (amounts paid by manufacturers to pharmacies to be used for patient benefit initiatives) will be curtailed, with permissible amounts being reduced to 5%, from 20%, of the cost of the products reimbursed in the public sector, effective May 15, 2010. Professional allowances will also be reduced in the private sector, initially to 50%, then 35%, and finally 25% of the cost of the products reimbursed in the private sector, coincident with the reduction of generic drug prices in the private sector. Professional allowance-reporting obligations will be eliminated for pharmacies, but not manufacturers.

“Rebates” continue to be prohibited, but benefits provided in accordance with “ordinary commercial terms” are now excluded from the prohibition, effective May 15, 2010. Regarding generic drugs, for a benefit to be considered in accordance with ordinary commercial terms, (i) the benefit must be provided in the ordinary course of business; (ii) the value of the benefit must be set out in a written agreement; and (iii) the benefit must relate to an ordinary commercial relationship that is any of the following: a prompt payment discount, a volume discount or a distribution service

¹ There will be exceptions to the 25% Pricing Rule if the brand name product is listed as a benefit, and one or more interchangeable products have existed for more than 10 years, or if the brand name product was, but is no longer, listed as a benefit and has not been listed for more than 5 years. There are also exceptions in cases where there is only a single generic source or if a manufacturer can establish an increase in raw material costs.

² This means that no caps will apply in the private sector for drugs that are not otherwise eligible for coverage under Ontario drug programs.

To discuss these issues, please contact the author.

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fee. Regarding brand name products, it appears that only prompt payment discounts provided in accordance with ordinary commercial terms will be permitted.³

The proposed regulations will also prohibit reimbursement for “private label products” under Ontario drug programs and prohibit the designation of private label products as interchangeable under DIDFA. Private label products include a drug product in respect of which (i) the manufacturer applying for interchangeability does not directly fabricate the product and is not controlled by or does not control the person fabricating; (ii) the manufacturer does not have an arm’s-length relationship with pharmacy operators or companies that own, operate or franchise pharmacies; and (iii) the product is to be supplied under a marketing arrangement associating the product with one or more pharmacy operators or companies that own, operate or franchise pharmacies. This amendment will come into effect on May 15, 2010.

Finally, the proposed regulations contemplate the creation of four categories of pharmacies, depending upon their location (rural versus urban), the number of pharmacies already serving the area, the distance between pharmacies in an area, and the volume of claims submitted. The markups and dispensing fees that the government will pay for under Ontario drug programs will be determined according to a pharmacy’s categorization, with pharmacies in rural and underserved areas qualifying for payment of higher markups⁴ and dispensing fees. Pharmacy systems that self-distribute (i.e., distribute through their own wholesalers) will be entitled to a lower (5%) markup.

The government will consider written comments on the proposed regulations received before May 8, 2010. 

³ 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.

⁴ In no instance, however, can the markup be greater than \$125.