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Highlights

Amendments to Regulations under Ontario's Drug Benefit Act and Drug Interchangeability and Dispensing Fee Act were passed this Fall following passage of the Transparent Drug System for Patients Act, 2006 (Bill 102) last April. This Advisory discusses the potential impact of those changes on employer sponsored drug programs.

Hewitt

The Hewitt Research Advisory is a regular Hewitt newsletter designed to provide a detailed overview of specific legislative and regulatory developments in Canada relating to human resources.

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Ontario's Attempt at Drug Transparency Still Murky

Last spring, the Ontario government introduced a package of proposed reforms aimed at changing the province's publicly-funded drug program. These changes were largely implemented through Bill 102, the *Transparent Drug System for Patients Act, 2006* and were documented in a Hewitt Research Advisory dated April 27, 2006. Reform highlights included making the Ontario Drug Benefit Program (ODB) the second in-line payer for prescription drugs for working seniors, containing escalating drug costs, providing patients better access to medications, and promoting the appropriate use of drugs.

Bill 102 received royal assent on June 20, 2006 and regulations were drafted to amend existing regulations under two other statutes, the *Ontario Drug Benefit Act* and the *Drug Interchangeability and Dispensing Fee Act*. A 30-day period of public consultation expired in late August and, on September 28, 2006, the government announced that the regulations were coming into effect. Some, but not all provisions of the regulations took effect on October 1, 2006.

Hewitt Comment: *The changes implemented by the government relate to the ODB only - a program through which the Ontario Ministry of Health and Long Term Care covers most of the cost of the approximately 3,000 prescription drug products and some limited-use drug products listed in the Ontario Drug Benefit Formulary for people 65 years of age and older. While some elements have a direct impact on plan sponsors, several of the key components of Bill 102 are still awaiting clarification. The direct impact of many of the changes on employer sponsored drug programs is uncertain at this point.*

Working Seniors

One significant omission from the drug system reforms as enacted relates to the issue of working seniors. Although the package of reforms was in part designed to ensure that the ODB became the second payer for "working seniors with private insurance plans", no implementation date for this proposed

change was provided, and no definition of working senior is contained in either the Act or the Regulations.

Hewitt Comment: *It remains uncertain how and when the government will implement this change originally slated for October 1, 2006. Preliminary discussions with the government indicate that the criteria to be used to determine what constitutes a "working senior" will be an individual over age 65, who is working; and has access to private drug coverage. At this point they have not finalized how these definitions will be interpreted.*

What is unclear is whether the private drug coverage must be from the current employer. If the "coverage" does not have to come from the same source as where the senior is working, a number of possible scenarios arise. Consider the following:

- *Example 1: Individuals who continue employment past age 65 and have drug coverage through their employer. The employer-sponsored plan will be first payor for the senior's drugs as opposed to the ODB. At this point it is clear that in this situation the government intends that the private plan will be the first payor.*
- *Example 2: Retirees with post-retirement medical coverage who take a part-time job with an employer who does not offer benefits. Depending on the interpretation of the government's definition of "working senior", the retiree benefit plan from the former employer may now become first payor for drug coverage because of their new part-time job.*
- *Example 3: Individuals over age 65 who work part-time and have coverage available through their spouse's plan (either a working spouse or a retired spouse with post-retirement benefits). Again, due to the lack of clarity in the definition of working senior, the spouse's benefit plan could become first payor in this situation.*

These examples illustrate the potentially broad impact and significant additional cost to employers. It is clear that companies who have active employees with benefits over age 65 will see their drug costs increase as a result of this legislation. However, the potential impact on employers with post-retirement benefit plans where their retirees supplement their income with part-time employment is much greater. Therefore, employers should watch with interest for indications from the Ontario government of how this definition will be interpreted.

Generic Drug Pricing

A major cost reducing goal announced by the government when it tabled Bill 102 was reforming the government-funded system of generic drug pricing in Ontario. Effective October 1, 2006, by fixing the percentage of the reimbursement price of brand-name equivalents at 50 per cent of the brand name product (instead of the current 70 per cent or 63 per cent), the Regulations have realized this goal.

Hewitt Comment: *These generic pricing changes relate specifically to generic drugs on the ODB formulary. Given that currently generics are priced at either 70 per cent or 63 per cent of the brand name equivalent, this change will result in savings to both the government as well as employer plans. The amount of savings accruing to employer plans will depend on the portion of their current drug claims that are for ODB listed generic products. Plans that encourage generic use through either a*

mandatory generic provision or through a managed formulary will likely see the biggest savings. Although the official effective date of this change is October 1, 2006, the changes will actually come into effect on November 1, 2006. Pharmacies have until that date to use up existing supplies of generic drugs purchased at the higher prices prior to October 1.

Markup

Other changes originally announced were also implemented by the Regulations. Effective April 1, 2007, the 10 per cent mark-up (with a \$25 cap) that the ODB will pay pharmacies on the price of a listed drug will be reduced to 8 per cent.

***Hewitt Comment:** The change in the mark-up relates only to products paid for under the ODB plan. Therefore, unless changes are made within the private claims adjudication system, the current mark-up rules will continue to apply. While many private insurers may attempt to duplicate the new pricing structures, pharmacists may resist passing on any additional savings. At this time, we do not anticipate any savings for employers due to this change.*

Generic Interchangeability

One major change to the announced reforms introduced through the public consultation process dealt with the expansion of drug interchangeability; – i.e., the ability to render generic drugs interchangeable with brand name drugs. This interchangeability will be permitted when two drugs have “similar active ingredients and/or similar dosage forms”.

The Bill however has a specific provision disallowing therapeutic substitution, which is defined as “chemically different active ingredients that are considered to be therapeutically equivalent”.

This change will take effect April 1, 2007.

***Hewitt Comment:** Although this legislation is aimed at the ODB, employer plans will derive indirect benefits through their implementation. To the extent that private plans require or encourage generic substitution consistent with the new rules, the plan will see cost savings. Employers will want to confirm that the new definition of generic interchangeability will be applied to their plan.*

Breakthrough Drugs

In the Regulations, the government provided a faster review process for breakthrough drugs. Previously, manufacturers had to await receipt of Health Canada approval before a new drug could be added to the ODB Formulary; all that is required now is that a New Drug Submission be filed with the federal department and that the product be a new chemical entity. If it can then be shown, either that the new product provides effective treatment for an immediately life-threatening or serious disease with significant advantages over available drug therapies or for which no treatment or other effective drug therapy currently exists, or that significant cost savings can otherwise be achieved, early designation on the ODB Formulary can be secured.

***Hewitt Comment:** More rapid listing of breakthrough drugs has the potential to reduce cost for employers. Today, these breakthrough drugs are often covered by postretirement benefit plans that supplement ODB coverage. Going forward, if payment of these drugs moves more quickly from employer plans to the government, a cost savings will accrue to employers. However, if these breakthrough drugs are added as Conditional Listings, seniors will only receive reimbursement if the*

proper paperwork is completed. Employers will want to ensure that their plan maximizes the reimbursement available from the ODB before paying the cost of these Conditional Listing products.

Drug Pricing and Rebates

An area of particular concern that emerged from the public consultation process was the practice whereby manufacturers would provide "rebates" to wholesalers or pharmacy owners and operators for stocking their products. Although the Ministry of Health knew of the practice, it was unaware that the rebates offered were up to 60 per cent of the value of the drugs sold. As a result, the Regulations now stipulate what "professional allowances" can be provided to pharmacies by manufacturers. The amount of the allowance is now limited to 20 per cent, and a Code of Conduct has been incorporated into the Regulations to govern the practice going forward.

***Hewitt Comment:** Similar to the reduction in mark-up, these changes only impact rebates on drugs sold to ODB claimants. The government does not regulate rebates on non-ODB plans and drugs. The question becomes whether the reduction of costs in one area (ODB) will result in a compensating increase in costs elsewhere (private plans).*

The Executive Officer

A newly-created position, the Executive Officer, now has the direct ability to designate or remove products from the ODB. Previously, such updating required the filing of regulations. The intent is that the Executive Officer's ability to update the Formulary without resort to the passage of new regulations will streamline the process and hasten the addition of generic products onto the provincial Formulary. To date, no one has yet been named to fill the post of Executive Officer, whose functions will be performed by the Deputy Minister until such time as an appointment is made.

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