

Notice from the Executive Officer

Yesterday, I wrote to you acknowledging that there are some implementation issues related to the *Transparent Drug System for Patients Act, 2006* that we have been working to resolve, as a result of such significant system and operational changes to the provincial drug system. Today, I am responding in detail with specific resolutions to these issues.

Generic pricing

We have been in discussion with generic manufacturers concerning the pricing of selected generic products. In response to concerns raised among stakeholders, I am proposing to negotiate prices for these specific single source generic drugs in limited exceptions to the 50% price rule; this would also include first-to-market generic products.

We will conclude these discussions, and include these new prices in the next update, Update 14, of the Ontario Drug Benefit Formulary/Comparative Drug Index (Formulary). As a reminder, all manufacturers must sell their listed drug products at the drug benefit price listed in the Formulary, for ODB-eligible recipients. If the manufacturer does not comply with this, the manufacturer would be violating the *Ontario Drug Benefit Act* (ODBA) and the Executive Officer may take appropriate action.

Cost-to-Operator claims

Effective as of the next update to the Formulary, pharmacies will be able to purchase drugs from generic manufacturers at the product's listed drug benefit price. In the meantime, while we conclude our discussions with generic manufacturers and recognizing that some pharmacies purchased higher-priced inventory prior to October 1, 2006, I will allow pharmacists to submit the MI intervention code up until **December 31, 2006**. Thereafter - that is, as of January 1, 2007 - cost-to-operator claims will be restricted.

Impact of DIDFA

I am providing the following clarification related to the amendments made by the *Transparent Drug System for Patients Act, 2006*. The only provisions in the *Act* that apply to the private market are the ban on rebates, the definition of professional allowances; and the Code of Conduct that governs the use of these professional allowances. This means that the Executive Officer has no role in pricing other than as stated in the ODBA, for ODB-eligible recipients.

Interchangeability designation

Currently, a drug product *cannot* be listed as interchangeable on the Formulary under the provisions of the DIDFA separately and apart from the listing of that product as a benefit under the ODBA. However, as of April 1, 2007, off-formulary interchangeability will be implemented.

For listed interchangeable products, I am providing the following clarification: if a manufacturer requests that the Executive Officer remove an interchangeable product as a listed drug product from the Formulary, the product may maintain its interchangeability designation at the discretion of the Executive Officer.

Professional allowances

Effective October 1, 2006, manufacturers are permitted to provide professional allowances up to a limit of 20% of generic sales to pharmacies for the ODB Program. The Executive Officer expects manufacturers to begin to provide these professional allowances in accordance with the definition and Code of Conduct in the amended regulations.

Reporting of the allowances will begin with payments made after January 1, 2007. The ministry is developing a reporting system for professional allowances, and will provide further communication related to the reporting requirements in the coming weeks.

Additionally, we have established a process in collaboration with the Ontario Pharmacists' Association to regularly review requests for clarification around the definition of professional allowances. Pharmacists are encouraged to channel these requests through the OPA.

Price increase criteria

I had intended to publish the criteria for price increases in October; this timing has been extended into November, 2006. Manufacturers will be notified as soon as the criteria are published on the Ministry's website.

Next update to the Formulary

I intend to publish Update 14 to Edition 39 of the Formulary in November. This Update shall include new listings of brand name products; the new negotiated prices for selected generic products; and the removal of over 400 discontinued products.

Following Update 14, a full Formulary is scheduled to be published in January 2007.

Next Steps

Some of the above changes will require regulatory changes to both the *Ontario Drug Benefit Act* and the *Drug Interchangeability and Dispensing Fee Act*. Due to the urgency of these proposed changes, and due to the need for clarifying the application of the regulations, a notice of proposed changes to the regulations will be posted in the coming days for a 7-day public consultation period.

I am also pleased to report that the Pharmacy Council will be announced within the next week, and the first meeting of the Council will take place in November. Through the Council, we will begin work immediately to implement the plan for pharmacy professional services.

In summary, I am proposing to:

1. Establish new prices for selected generic products in limited exceptions to the 50% price rule.
2. Extend the Cost-to-Operator mechanism until December 31, 2006.
3. Clarify that the only provisions in the *Transparent Drug System for Patients Act, 2006* that apply to the private market are the ban on rebates, the definition of professional allowances, and, the Code of Conduct that governs the use of these professional allowances.
4. Clarify that when a manufacturer requests that the Executive Officer remove an interchangeable product as a listed drug product from the Formulary, that the product may maintain its interchangeability designation at the discretion of the Executive Officer.
5. Confirm that up to 20% of generic sales for the ODB Program may be provided to pharmacies as professional allowances, effective October 1, 2006. Delay the requirement that pharmacies and manufacturers report on these professional allowances to January 1, 2007. The ministry is developing a reporting system for professional allowances, and will provide further communication related to the reporting requirements in the coming weeks.
6. Publish the price increase criteria for single source products at the time of the next Formulary update.
7. Publish Update 14 to Edition 39 of the Formulary in mid- to late-November.
8. As previously communicated, and as set out in the regulations, delay the reduction in mark-up from 10% to 8% until April 1, 2007, and not implement a dollar cap on the mark-up. This delay in reducing the mark-up will coincide with the implementation of payments for pharmacy professional services.

Finally, in order to assist in implementing the changes to the provincial drug system, I will establish an Implementation Working Group, including members from Rx&D, CGPA, OPA, CACDS, and CAPDM, through the Drug System Secretariat.

Again, thank you in advance for your cooperation in working through the implementation.

Ronald Sapsford
Executive Officer
Ontario Ministry of Health and Long-Term Care