

**SUBMISSION TO
THE ONTARIO MINISTRY OF HEALTH
AND LONG-TERM CARE**

on

**THE PROPOSED REGULATIONS TO AMEND ONTARIO REGULATION
935 UNDER THE *DRUG INTERCHANGEABILITY AND DISPENSING FEE
ACT* AND ONTARIO REGULATION 201/96 UNDER
*THE ONTARIO DRUG BENEFIT ACT***

Ontario Pharmacists' Association

And the

Canadian Association of Chain Drug Stores

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Introduction

The Ontario Pharmacists' Association (the "OPA") and the Canadian Association of Chain Drug Stores (the "CACDS") as well as its members in Ontario as represented by the Ontario Chain Drug Association, are jointly submitting these comments regarding the proposed regulations (the "Current Proposed Regulations") to amend Ontario Regulation 935 ("Reg. 935") under the *Drug Interchangeability and Dispensing Fee Act* (the "DIDFA") and Ontario Regulation 201/96 ("Reg. 201/96") under the *Ontario Drug Benefit Act* (the "ODBA") to the Minister of Health and Long-Term Care (the "Minister") and the Executive Lead, Drug System Secretariat of the Ministry of Health and Long-Term Care (the "Ministry").

Discussion

On October 1, 2006, the *Transparent Drug System for Patients Act* (TDSPA) and O. Reg. 458/06 (the "TDSPA Regulations") amended the ODBA and Reg. 201/96 and the DIDFA and Reg. 935 to become the law in Ontario. The final form of the TDSPA Regulations, in particular the flat 50% price rule that was included in the final form of the TDSPA Regulations, imposed substantial and unanticipated financial impacts on pharmacy and our members. In reviewing this submission on the Current Proposed Regulations, the Ministry needs to be cognizant of the fact that, as the flat 50% price rule was not included in the draft of the TDSPA Regulations that was published for public comment on the Ministry website on July 24, 2006 (the "July 24 Proposed Regulations"), there was no opportunity for our members to consider or make any submissions on the flat 50% price rule and the impact of the rule on pharmacy and pharmacy systems.

After operating under the new regime for just one month, many of our members are indicating that the economics imposed by the TDSPA and the TDSPA Regulations will mean their existing patient care services will need be reduced or eliminated to remain financially viable.

Cost to Operator Claims and the Use of the MI Code

As the 70/90 pricing system was unchanged in the July 24 Proposed Regulations, we assumed and our members assumed that, at least with respect to the reimbursement mechanism, the status quo would continue and the Ministry would reimburse pharmacy under the 70/90 pricing system and the permitted mark-up would be calculated based on this system. However, the final form of the TDSPA Regulations implemented a flat 50% price rule which meant inventory purchased under the previous regime would now be reimbursed under the flat 50% price rule.

In addition, the Current Proposed Regulations propose amending section 14 of O. Reg. 201/96, the provision of the regulations that deals with calculating the acquisition cost of a listed drug product, to prohibit cost to operator claims for interchangeable listed drug products after January 1, 2007. This January 1, 2007 deadline and the flat 50% price rule will detrimentally increase the financial impact on pharmacy operators.

The system should be fair to all participants and if the January 1, 2007 deadline is imposed as suggested, the system will be inherently unfair to pharmacy as pharmacy has no remedy under the ODBA where a manufacturer chooses to sell a listed drug product for the purposes of supplying a drug to eligible persons under the ODBA at a price higher than the drug benefit price.

Subsection 11.4(1) of the ODBA provides that a manufacturer is obligated to sell a listed drug product at the drug benefit price for the purposes of supplying a drug to eligible persons under the ODBA. If the manufacturer does not comply with this requirement, the executive officer may make an order under subsection 11.4(3) of the ODBA requiring the manufacturer to pay to the Minister of Finance the amount of the difference between the higher selling price charged by the manufacturer and the drug benefit price determined on the units of the listed drug product sold to eligible persons. However, there is no remedy for pharmacy in the ODBA. If subsection 6(3) of the ODBA does not apply to interchangeable listed drug products, then the operator of the pharmacy will be financially compromised if a manufacturer does not comply with its obligations under subsection 11.4(1) and sells a listed drug product at a selling price higher than the drug benefit price. If the cost to operator claims on interchangeable listed drug products are prohibited after January 1, 2007 and the manufacturers continue to sell at prices greater than the drug benefit price, what the government had calculated to be a \$65,000,000 unfair cost to pharmacy as a result of “cost to operator claims”, which was a central issue that government vowed would be remedied as part of the amendments to the ODBA, will increase to well over \$180,000,000 (minimum) (annualized).

The best way to illustrate is by example. Consider a scenario where a generic manufacturer chooses to sell at the price of the original product (which we will assume is \$100 per unit in the public drug system). The drug benefit price per unit will be \$50 per unit. To purchase a unit of the interchangeable listed drug product, the pharmacy pays the manufacturer \$100. Upon being sold to an eligible person, the pharmacy is reimbursed by the executive officer \$50, the amount of the drug benefit price, plus \$5, the permitted 10% mark-up. The executive officer pursues the manufacturer for selling above the drug benefit price in violation of subsection 11.4(1) and, as permitted by 11.4(3) makes an order for repayment to the Minister of Finance of an amount of up to \$50 (the difference between the selling price and the drug benefit price) on each unit sold to eligible persons (the scope of the ODBA is limited in the statute to sales to eligible persons). The manufacturer complies with the order and pays the \$50 to the Minister of Finance for each unit sold to eligible persons. The net result of the foregoing scenario is that the manufacturer has sold the interchangeable drug product at the drug benefit price as required under the ODBA, the government of Ontario has made a net payment of \$0 (the government has paid the drug benefit price to the pharmacy and has been reimbursed the difference between the drug benefit price and the selling price by the manufacturer) and the pharmacy has incurred a net loss of \$50. If the manufacturer pays the amount prescribed in the executive officer’s order, arguably there is no further order that the executive officer can make to prohibit the manufacturer from continuing to breach its obligations under subsection 11.4(1) as it is only in the event of non-payment that a manufacturer may suffer further sanction such as loss of listing under subsection 11.4(7). Accordingly, there is effectively no penalty imposed on a manufacturer for breaching its obligations under subsection 11.4(1) and selling at a price higher than the drug benefit price, the manufacturer simply has to pay back the money in excess of the drug benefit price to the government of Ontario.

The intent of the ODBA must be twofold: (a) to provide mechanisms to ensure that participants comply with their obligations under the ODBA; and (b) to be fair to participants. Subsection 6(3) and subsection 11.4(4) of the ODBA work in concert so that, as a net effect, the manufacturer charges no more than the drug benefit price, the executive officer pays no more than the drug benefit price and the pharmacist is reimbursed for his or her acquisition cost. This is fair to participants. The imposition of a deadline by which cost to operator claims for

interchangeable listed drug products will be prohibited is unfair to pharmacy and should be deleted.

Recommendations

1. **Cost to operator claims must be permitted for pharmacy for all listed drug products, both interchangeable listed drug products and original products, as pharmacy has no remedy under the ODBA where a manufacturer chooses to sell a listed drug product for the purposes of supplying a drug to eligible persons under the ODBA at a price higher than the drug benefit price.**

Section 3 of the Current Proposed Regulations amending O Reg. 201/96 should be deleted.

~~**3(1) Section 14 of the Regulation is amended by adding the following subsection:**~~

~~**(3) The operator of a pharmacy may submit a claim for payment in accordance with section 6(3) of the Act where the executive officer is satisfied that,**~~

~~**(a) the operator of a pharmacy has been unable to purchase inventory at the drug benefit price of the drug product published in the Formulary on October 23, 2006; or**~~

~~**(b) the operator of a pharmacy is unable to acquire an interchangeable drug product and must dispense the original product.**~~

~~**(2) Clause 14(3)(a) of the Regulation, as made by subsection (1), is revoked.**~~

Payment of the Mark-Up on Cost to Operator Claims

A second major issue that arises is that subsection 6(3) only reimburses pharmacy for the acquisition cost. Currently there are no provisions in either the ODBA or O. Reg. 201/96 that permit a mark-up on these cost to operator claims. Pharmacy is now left in a position where the costs and expenses that are incurred in stocking the interchangeable listed drug products that are normally compensated by the mark-up will be required to be absorbed by pharmacy operators on interchangeable listed drug products that cannot be purchased by pharmacy at the 50% drug benefit price, including for inventory purchased prior to October 1, 2006 and where the manufacturer does not honour its obligations under 11.4(1) of the ODBA. As a conservative estimate, as a result of the implementation of the flat 50% price rule and the manufacturers' non-compliance with the obligations concerning the drug benefit price, pharmacy will absorb at a minimum \$88,000,000 (annualized) in costs and expenses that would normally be compensated by the mark-up.

The mark-up is provided to operators of pharmacies to ensure that certain costs and expenses incurred in stocking inventory of interchangeable listed drug products is compensated. Pharmacists should be entitled to the mark-up for claims made under subsection 6(3) of the ODBA. A mechanism to permit a mark-up to the cost to operator claims is permitted by subsection 5(2) of the ODBA which provides that the executive officer may pay the operator of a pharmacy an amount different from the amount provided for under section 6 of the ODBA for prescribed classes of eligible persons, subject to any prescribed requirements.

The Ministry must use this opportunity to revise the Current Proposed Regulations to ensure that pharmacy is fairly reimbursed under the ODBA by permitting a mark-up on cost to operator claims.

Recommendation

A mark-up will be permitted on cost to operator claims effective as of October 23, 2006. Our suggested language is set forth below:

Section 14 of the Regulation is amended by adding the following subsection:

(3) Subject to subsection (4), the executive officer shall pay the prescribed mark-up on claims for payment submitted in accordance with section 6(3) of the Act.

(4) For inventory purchased prior to October 1, 2006, the permitted mark-up will only be paid until January 1, 2007.

Return to 70/90 Pricing System

Another fundamental issue that arises from the flat 50% price rule imposed by the TDSPA Regulations is the impact on other elements of the revenue stream and the additional operational burden that is imposed. Multiple prices for the same drug product are now necessary. Members are experiencing great difficulty in accounting for the drug benefit pricing for interchangeable listed drug products because of the difference in the third party payor's price, the private payor's price and the drug benefit price that may be charged for the same product. Implementation of an

inventory management system that would permit the manufacturer, wholesaler, distributor or retailer to track and manage multiple prices for the same drug product is complexly difficult and prohibitively expensive to achieve. This issue, as well the issues set forth in the provision of this submission discussing Cost to Operator Claims and the Use of the MI Code and, in part, the issues set forth in the Payment of the Mark-Up on Cost to Operator Claims, and in addition, the prohibitive costs that would be incurred in carrying duplicate inventories for the public and private system, is resolved if we return to the 70/90 pricing system outlined in the July 24 Proposed Regulations with the Ministry able to extract price concessions from the manufacturer through volume discounts. However, to accomplish the Ministry's goal of cost certainty, we are proposing that, as a condition of listing, the volume discount provided to the Ministry must not be less than an amount which would reduce the effective rate paid for the interchangeable listed drug product under the ODBA by the Ministry to an amount equal to 50% of the original product price or less. The amendments to Reg. 935 in section 2 and 3 of the Current Proposed Regulations and those proposed to O. Reg. 201/96 in section 1 and 2 of the Current Proposed Regulations would also be included. This proposal will retain a manageable system for our members and will provide the Ministry with the minimum price certainty objectives that it is seeking. Further, as indicated our concerns outlined in Cost to Operator Claims and the Use of the MI Code and, in part, the Payment of the Mark-Up on Cost to Operator Claims previously set forth in this submission, can be addressed by a return to the 70/90 pricing system for listing of interchangeable listed drug products.

Recommendation

We recommend a return to the 70/90 pricing system with volume discounts to be negotiated by the Ministry and the manufacturer. As a condition of listing under the 70/90 pricing system, the volume discount provided to the Ministry must not be less than an amount which would reduce the effective rate paid for the interchangeable listed drug product by the executive officer for eligible persons under the ODBA to an amount equal to 50% of the original product price or less.

Directions Regarding Rebates and Professional Allowances

It was our understanding from conversations with the Ministry during the process to amend the ODBA and the DIDFA that clarity to ambiguous provisions in the legislation would be resolved through policy decisions and directions by the executive officer. However, there is currently no formal process whereby clarity can be sought from the executive officer. This is extremely problematic as some generic manufacturers are requiring certainty in determining whether non-enumerated items properly fall within the scope of professional allowance funding. Accordingly, not all of the eligible professional allowance funding is currently flowing to pharmacy.

As illustrative examples, although there are many others, it is currently unclear whether certain equipment and technology is intended to be included within the definition of professional allowances. The TDSPA Regulations removed the term "equipment and education materials" from the lead in to the "Disease management and prevention initiatives" in the definition of professional allowances in the July 24 Proposed Regulations, which could be interpreted as indicating that the Ministry intended to expand items eligible for professional allowance funding beyond just equipment and education materials. However, by deleting the term "equipment" from the lead in description and not including the term "equipment" in the enumerated examples provided in the paragraph when published in the TDSPA Regulations, there has been some

suggestion that equipment would not be included. Therefore, while blood pressure monitoring is an included service and eligible for professional allowance funding, it is unclear whether equipment such as blood pressure monitoring devices to provide such service is within the scope of professional allowance funding. In addition, it is still not clear where “technology” is intended to be covered within the scope of professional allowances. For example, if software is available to help educate a patient on a specific disease state, and allows the pharmacist to track parameters such as blood pressure, while it would be logical that this technology be captured within the scope of disease management and prevention initiatives, as it is not enumerated it is not clearly permitted and professional allowance funding will not be provided. Some generic manufacturers are referring to these ambiguities to delay provision of professional allowance funding and are requiring almost absolute certainty that items properly fall within the scope of professional allowance funding as a condition to fund professional allowances for pharmacy. As a result, professional allowance funding is being limited and is only being provided retrospectively in many cases.

Under the ODBA and the DIDFA, if the executive officer believes, on reasonable grounds, that a person is providing or receiving a rebate, the executive officer may make an order requiring repayment of the amount of the rebate. Accordingly, the ability to determine if a rebate has been provided or received is granted to the executive officer. Further, the ODBA and DIDFA also restrict court review of these decisions by the executive officer. Therefore, it is the executive officer’s interpretation that is crucial in interpreting the legislation.

We recognize the constraints on the executive officer’s time and that the executive officer will be overwhelmed if a preclearance is required on every proposal. We need a process. We propose that clarification requests regarding rebates and professional allowances submitted by industry would be first vetted through an industry review committee to determine if submission to the executive officer is warranted. We are proposing that the regulations be amended to provide that the executive officer would establish an industry review committee with representation from the Ontario Pharmacists’ Association, CACDS, the generic industry and the government (the “IRC”) to review and vet clarification requests from pharmacy and the generic industry regarding professional allowances and rebates and to specify that where a significant issue of interpretation regarding whether a certain specified activity would be a rebate or a professional allowance is identified by the IRC, it could be submitted to the executive officer (along with all relevant background materials deemed necessary by the IRC) and the executive officer would be required to issue a decision on his interpretation of the legislation within a prescribed period of time of being presented with the issue. We accept that the opinion of the executive officer could be qualified or could be non-binding, but without some direction from the executive officer the current situation is untenable and is leading to a situation where limited professional allowances are being provided by the generic manufacturers out of a concern that the executive officer could later determine them to be rebates.

Recommendation

O. Reg. 201/96 and Reg. 935 should be amended to provide for the following: The executive officer would establish an industry review committee with representation from the Ontario Pharmacists’ Association, CACDS, the generic industry and the government (the “IRC”) to review and vet clarification requests from pharmacy and the generic industry regarding professional allowances and rebates. Where a significant issue of interpretation regarding whether a certain specified activity would be a rebate or a professional allowance is

identified by the IRC, it could be submitted to the executive officer (along with all relevant background materials deemed necessary by the IRC) and the executive officer would be required to issue within a prescribed period of time of being presented with the information by the IRC a non-binding decision on his or her interpretation.

Scope of Professional Allowances

The scope of professional allowances in the TDSPA Regulations and subsequently Reg. 935 and O. Reg. 201/96 is still too narrow and must be broadened in line with the intent of supporting patient care, by allowing pharmacies to apply allowances as necessary to support their practice. This would ensure the sustainability of community pharmacy and continued access to community pharmacy, ensure that current services can continue to be provided and provide for new and innovative patient services.

Recommendation

We propose the following definition:

“professional allowance”, in the definition of rebate, means benefits, in the form of currency, services or educational materials that are provided by a manufacturer to operators of pharmacies or companies that own, operate or franchise pharmacies for the purposes of supporting pharmacy practice to benefit patient care.

Calculation of the 20% Cap for Professional Allowances

The calculation of the 20% cap on the net price to the government under subsection 1(9) of O. Reg. 201/96 (the “20% Cap”) is proving to be unworkable in commercial practice and will restrict professional allowances from being available. The calculation for the 20% Cap should be based on the drug benefit price (the gross price to pharmacy). In addition, subsection 1(9) of Ont. Reg. 201/96 should be amended so that it is clear that benefits determined to be a rebate under that subsection will only be a rebate in respect of the manufacturer as the manufacturer is the only party that is able to calculate the 20% Cap so that pharmacy operators are not caught by the actions of the manufacturer. This is especially true given that the discount amounts that may be granted by manufacturers to the Ministry may not be published.

Recommendation

The calculation for the 20% Cap should be based on the drug benefit price (the gross price to pharmacy).

Changes to the Code of Conduct

The issues with the Code of Conduct as set out in our respective submissions on the July 24 Proposed Regulations still need to be addressed.

Recommendation

As indicated in our respective submissions on the July 24 Proposed Regulations:

1. **The reasonableness tests should be removed from the Code of Conduct. The reasonableness tests for the calculation of professional allowances are impractical because of the subjective nature of the interpretation of the term, and therefore require individual and ongoing interpretation from the executive officer.**
2. **The references to stakeholders should be deleted from the Code of Conduct.**
3. **Confidential business information should be protected from access by parties other than the Ministry.**
4. **The obligation in the Code of Conduct to make the executive officer aware of the flow of funds should be deleted. The restrictions under the *Transparent Drug Systems for Patients Act, 2006* relates to rebates and the executive officer and the Ministry have adequate investigative and enforcement rights under the legislation to ensure that these restrictions are complied with.**

Increase to Dispensing Fee

Unless the professional allowance provisions in the Current Proposed Regulations, including the restrictions in the Code of Conduct, are amended, the dispensing fee will need to be increased.

Other Proposed Changes in the Current Proposed Regulations

We agree with the proposed changes to sections 1, 7 and 8 of Reg. 935, sections 11 and 12.1 of O. Reg. 201/96 and paragraph 1 under the heading *fundamental principles* in schedule 1, paragraph 1, 6 and 13 under the heading *professional allowances may never be used for* of the Code of Conduct.