



**Canadian Association of Chain Drug Stores**  
**Association Canadienne des chaînes de pharmacies**

The Voice of Community Pharmacy in Canada

La voix de la pharmacie communautaire au Canada

## ***Canadian Association of Chain Drug Stores***

### **Submission to the Ontario Standing Committee on Social Policy**

### **Regarding Bill 102**

June 5, 2006

## Submission to the Standing Committee on Social Policy Regarding Bill 102

### Executive Summary

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The introduction of Bill 102 was eagerly anticipated by CACDS members. Canada's community pharmacy chains were hoping that the legislation's provisions would address the much-needed reforms to Ontario's drug system in the context of current reality and represent a significant step forward for the pharmacy profession in Canada, and for patient care.

Generally, CACDS supports the government's intent to move toward a more transparent, accessible drug system in Ontario. Two of the government's announced policies are extremely praiseworthy. The move to compensate pharmacists for cognitive services is excellent. It will, for the first time, recognize the expertise pharmacists bring to services that extend well beyond dispensing. And the policy to establish a Pharmacy Council is similarly well-considered. The Council will ensure that the knowledge and skills of pharmacists are involved in the development of future pharmaceutical and health policy. In fact, it is such a good idea, that it must be included in the legislation, and enshrined in law. These are forward-looking and long-sought initiatives, and properly recognize the unique front-line role of pharmacists in the health care system.

However, CACDS is concerned that the overall effect of Bill 102 and the associated drug system policy announcements will be harmful both to the practice and business of pharmacy and to patient care in Ontario. In addition, we are concerned that the emphasis on reducing pharmacy funding could be emulated by other public and private drug plans elsewhere in Canada, thereby resulting in a negative impact on pharmacy and patients in other jurisdictions.

We agree with the estimate of the Ontario Chain Drug Association (OCDA), that the Ontario government's current plans to reform the province's drug system, unless amended, would reduce overall pharmacy funding, rendering current levels of pharmacy service and care in Ontario unsustainable. Among the expected results would be pharmacy closures, staff layoffs, reduced hours of service, increased patient wait times in pharmacies, reduced investment in patient education programs and reduced access to newer, more expensive therapies at many stores.

Two things are particularly striking about the new plan unveiled by the government:

1. **The attempts to extract cost savings from pharmacy, which is not a leading cost driver:** According to the government's figures, in the last 10 years, prescription drug costs have increased by nearly 150%. By comparison, since 1993, pharmacist dispensing fees have increased by only 2%. And inventory allowances have remained at a static percentage of the cost of acquiring and stocking drugs.

2. **There is more opportunity to further enhance the system:** While the new plan contains some welcome features, overall, the current proposals highlight a missed opportunity for Ontario to take a leadership role in leveraging pharmacists' ability to enhance pharmaceutical care and manage costs.

Pharmacists are uniquely qualified to drive innovation, improve health outcomes and help better manage health costs. Drug use is increasing, as a result of the aging population. Given this fact, it is imperative that pharmacists – health professionals expert in pharmaceuticals – play a larger, more central role. Specifically, pharmacists play a leading role in:

- Ensuring that prescription medicines are used properly and safely, avoiding adverse events, and enhancing patient adherence to treatment protocols.
- Managing rising drug costs resulting from increased utilization, multiple-medication regimens and the more frequent use of newer, more expensive therapies.

Additionally, the government could consider partnering with CACDS on initiatives to improve the drug system. We have been open, eager and enthusiastic about the prospect of needed system reform. We presented an extensive briefing document to the Drug System Secretariat, replete with positive, practical, effective ideas. Very little of what we offered is reflected in the new bill and policies.

Finally, there are many successful examples from other jurisdictions that the government can learn from. Provinces across Canada and countries around the world have worked in collaboration with pharmacy to create novel programs that improve patient health and cost-management. The government has paid scant attention to these success stories.

## **Recommendation**

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The CACDS specifically endorses the analysis, concerns and recommended amendments put forward by the Ontario Pharmacists Association and Ontario Chain Drug Association. We also support the advocacy initiatives and the negotiating role of the Ontario Pharmacists Association.

The CACDS submission includes several specific recommended amendments to Bill 102, as well as recommended pharmacy policies designed to improve patient care and control health costs.

We believe that, in order to avert serious negative consequences to the profession and business of pharmacy, as well as to Ontario patients, the government must amend Bill

102 and reconsider certain announced policies associated with its drug system reform plan.

Furthermore, many of the policy recommendations may not be able to be implemented by chain pharmacies and software vendors, given the government's aggressive timeframes. The Ministry must consult with OPA, OCDA and CACDS to understand the implementation considerations in the sophisticated and complex infrastructure of chain pharmacies. Timeframes may need to be extended to accommodate changes.

## **CACDS Submission**

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This submission focuses on three key elements:

1. Analysis of Bill 102 and related policy statements, with recommended amendments and policy revisions. Endorsement and support for the positions of the Ontario Chain Drug Association regarding the bill.
2. Concerns with respect to unanticipated effects Bill 102 could have on the practice and business of pharmacy in other Canadian jurisdictions.
3. Insights from other jurisdictions, regarding alternative policy approaches that could have been taken by the Ontario government.

## **Background**

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The Government of Ontario has announced a plan to reform the drug system in Ontario, with the stated intent to increase stakeholder consultation, transparency and access for patients. The elements of this plan include the introduction of Bill 102, the *Transparent Drug System for Patients Act, 2006*, as well as a number of separate policy announcements made by the Minister of Health.

The Canadian Association of Chain Drug Stores (CACDS) is generally supportive of the stated intent of the government's plan. In addition, we recognize the need to manage the cost of the drug system, within the context of overall health care costs.

However, the CACDS has a number of specific concerns regarding the impact Bill 102 and its associated policy announcements will have on the practice and business of pharmacy, and on patient access and care in Ontario. Moreover, because Ontario's public drug system is the single largest in Canada, policies applied in Ontario often act as a template adopted by other provinces and private drug plans. Therefore, CACDS also has concern with respect to the effect Ontario's plans could have on these other jurisdictions.

This submission will offer analysis of a number of the Ontario government's proposed provisions, both within and outside Bill 102. In addition, we will recommend amendments to the legislation. Finally, this document will cover alternative approaches to pharmacy policy development - approaches that we would recommend to the government, in its undertaking to introduce comprehensive reforms to Ontario's drug system.

## Key Government Provisions

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This submission addresses provisions contained within Bill 102 itself, as well as policy proposals announced as part of the government's drug system reform plans, but that are not found in the legislation.

### Bill 102:

This submission includes recommended amendments to the Bill so that certain provisions are actually incorporated into the legislation. The proposed amendments appear in Appendix II. They can be summarized as follows:

- The Establishment in law of the Pharmacy Council and the Citizens' Council
- Clarity on the interchangeability of prescription drug products
- Reimbursement for professional services
- Inspection powers of the Executive Officer

Another area of concern among elements in the legislation is the outright **prohibition of manufacturer allowances**, or what the bill calls "rebates". The government has implied that professional allowances to pharmacies are a ready source of cost savings to the health system, and that their elimination will have little impact on pharmacy and patient care.

This is incorrect. In fact, professional allowances represent a key source of overall funding used by pharmacies to maintain store operations, pay and train staff members, continuously upgrade technology, and provide patient education and disease management programs.

From a straightforward economic perspective, funding received from government through dispensing fees and inventory allowances is not sufficient to cover the costs of providing pharmacy care. This leaves a "**fiscal gap**" that pharmacies must fill through other means. Because pharmacy is both a health profession and a business, pharmacies are able to negotiate these allowances with suppliers, thereby ensuring their continued economic viability. The prohibition of professional allowances, without replacing this funding through other means, would have the effect of cutting hundreds of millions of dollars per year from pharmacy funding. This would put many Ontario chain pharmacies, particularly those in rural areas, in immediate economic peril.

This submission outlines several recommended amendments to the Bill in order to clarify the definition of, and specifically permit, appropriate professional allowances. (Appendix II.), while supporting the government's direction to eliminate inappropriate use of allowances, such as gifts, trips, and personal incentives.

## Policy Announcements:

Some of the government's announced proposals are positive and progressive.

The initiative to begin **compensating pharmacists for cognitive services** (i.e. services that go beyond dispensing medicines and providing associated counseling) would, for the first time, acknowledge the broad range of care provided by pharmacists, and to fairly reimburse them under the Ontario Health Insurance Program. The government deserves praise for its leadership in establishing this pioneering program. We will look forward to working closely with the government and the OPA in defining the details as to which kinds of care will be included in the schedule of reimbursed services, and in ensuring that all Ontario pharmacists have fair and streamlined access to the dedicated funds.

Another welcome announcement is the promise to create a new **Pharmacy Council**. The involvement of pharmacists on this consultative body would help ensure a strong pharmacy voice in the future development of pharmaceutical and health policy for the province, and help create more opportunities for pharmacists to work in primary care practices, including Family Health Teams.

The CACDS has recommended that Bill 102 be amended to include the Pharmacy Council (as well as the promised Citizens' Council) in the text of the legislation. We have also added a clause that we be represented on the Pharmacy Council.

Additional policy announcements provide cause for grave concern to pharmacy.

The proposal to **reduce mark-ups, or what CACDS terms an "inventory allowance" from 10% to 8%, and to cap claims at \$25** would be extremely harmful to community pharmacies. These steps together would cut pharmacy funding by some \$169 million per year, according to OPA figures. It is also important to note that, after wholesaler upcharges, which average 5.6%, the proposed new pharmacy inventory allowance would leave only a 2.4% margin for pharmacies. Moreover, the \$25 cap would make it uneconomical for pharmacies to maintain inventories of drugs costing more than \$312.50 per claim. Pharmacies would actually lose money in acquiring and stocking many newer, more expensive medicines, such as those used to treat cancer, HIV/AIDS, multiple sclerosis and rheumatoid arthritis.

The CACDS recommends that the government maintain the current 10% rate for inventory allowance, and review and revise the proposed \$25 cap.

The government has announced plans to **increase dispensing fees from \$6.54 to \$7.00**. This is a very small increase, especially given that dispensing fees have risen

only 2% since 1993. During the same period, the Consumer Price Index has increased by 27%. Coupled with the other financial proposals in the Bill, the fee increase will not compensate for what pharmacy is losing in funding.

The population has also aged. More patients are seniors with chronic health conditions, and this has required pharmacists to spend more time, on average, on counseling for each prescription. Prescription processing, filling, and patient counseling has also become much more complex. Complicated adjudication/payment systems, increased professional requirements through standards of practice, are just two examples.

A \$7.00 fee does not cover the actual cost of dispensing and counseling. By comparison, the current average fee for patients covered by private plans is up to and in some cases over \$12.00. This fee is much more reflective of the value of services. The agreement between the Canadian Auto Workers and the Big Three Automakers recognized this value by ensuring an \$11.00 professional fee was provided to pharmacists.

The CACDS recommends that the government review and revise the proposed \$7.00 dispensing fee.

### **Summary – Bill 102 and Associated Policy Announcements:**

Taken together, the sum of the provisions in the government's drug system reform plan would have the effect of cutting approximately \$500 million annually from overall pharmacy funding. Needless to say, this would have a significant negative impact on the business of pharmacy.

However, these proposals would also have significant **human costs**, both to those working in pharmacy, and to patients who rely on pharmacy care. Chain pharmacies are heavily invested in providing innovative patient care programs, information technology systems, expanded hours of service and sophisticated technical support to enable access to pharmacist services. Patients across the province would be affected, but particularly hard hit would be rural areas and small communities in which the pharmacist is the only local health professional.

In addition, many other stores would have no other choice but to **reduce levels of service**, through staff layoffs, reduced opening hours, longer waits at the dispensary, and reduced investment in patient and community health education programs. Finally, many pharmacies will be unable to stock newer, more expensive drugs, which are in increasingly common use in treating a range of conditions.

CACDS is also concerned that the current reform plan, by emphasizing the reduction of pharmacy funding, has **missed valuable opportunities to reduce overall health system costs**, while significantly improving patient care and outcomes. For example, a

report commissioned by CACDS in 2004 found that Ontario could realize between \$576 million and \$703 million in annual savings through policies that support pharmacy interventions. Through averting adverse events, hospitalization, long-term care and death, and by enhancing pharmacy disease management of conditions such as asthma and diabetes the Ontario government could significantly reduce the human and economic burden of disease.

## **Effects on Other Jurisdictions**

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It is well established that many initiatives undertaken in Ontario, with respect to the Ontario Drug Benefit program and the drug system, are emulated both among other provincial formularies and among private sector drug plans. While this may, strictly speaking, not be the responsibility of the Ontario government, it is incumbent upon the province to understand that, as the administrator of the largest single drug plan in Canada, its actions do have “ripple effects”.

CACDS is concerned that what the Ontario government has proposed will also result in significant cuts to pharmacy capacity and service, as well as to patient care, for patients covered by public and private plans across Canada.

In particular, we believe that the Ontario government is **sending a wrong signal by concluding that pharmacy represents an appropriate target from which to extract cost savings**, rather than an under-employed resource in enhancing patient health and managing health costs.

It is frustrating that the Ontario government has chosen not to take advantage of the **experience and expertise the CACDS has developed working in collaboration with other provinces**. We are working in close partnership with other provincial governments, with the specific objective of improving care, improving outcomes and managing health care costs. Given the opportunity to share our knowledge and ideas, **the CACDS has been solution-oriented**, and successful in helping devise effective, cooperative strategies. It is disappointing that the government accepted very few of the recommendations that CACDS and others, including OPA, put forth in the DSS consultation.

As a national association, it will be the CACDS’ responsibility to share its concerns and analysis regarding the negative aspects of Ontario’s proposed reform plan with governments, pharmacy associations, patients and other health stakeholders.

## Alternative Policy Development Approaches

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A great deal of concern has been expressed, not only by pharmacists, but also by other health stakeholders, regarding the process employed by the Ontario government in developing, unveiling and proceeding with its drug system reform plans.

Among the issues that have raised objections are:

1. **The Drug System Secretariat (DSS) Consultation Meetings:** The government states that the DSS consulted experts from around the world, met with more than 100 stakeholder groups, received submissions, held public meetings and conducted stakeholder research.

However, the government has never released a report on the DSS consultations to the public, so stakeholders have no idea what was said and what recommendations were made to government. Moreover, the government did not provide true transparency, by consulting stakeholder with regard to the specific provisions they intended to introduce. This may be a key reason for the lack of understanding of the economics of pharmacy inherent in Bill 102 and its associated policy announcements.

2. **The lack of impact analyses:** It is not clear whether the Ontario government undertook independent impact analyses of the elements of its proposed reform plan. If such analyses were in fact conducted, they have not been publicly released. These steps would seem to be logical and prudent, to say the least, when contemplating wide-ranging reforms to a vital \$3.4 billion drug system.
3. **The rushed legislative process:** Once again, when proposing such extensive changes to Ontario's drug legislation and policy, the public and stakeholders could reasonably expect that sufficient time would be devoted to the legislative process. This would help ensure that those affected could offer comprehensive, accurate input and evaluation of the government's proposals. The impression left by the government's chosen process and timeline is that of avoidance of proper consultation.
4. **Implementation Challenges:** The timeframe for implementation for many of the recommendations does not respect the complex and centralized systems of chain pharmacies.

Different approaches undertaken in other jurisdictions have suggested alternative processes that are more collaborative, consultative and transparent.

## **Quebec - Bill 130:**

Quebec, facing many of the same drug system issues as Ontario, undertook its own process to develop a new law and new policies. Their approach was different, however.

- In May, 2004, the Quebec government invited health stakeholders to a conference on optimal drug use.
- The consensus from that conference was used as a basis for the development of a “draft pharmaceutical policy”.
- The draft policy was published in December, 2004, to present Quebecers with “a global and coherent set of directions and strategies on access, price and optimal use of medication”.
- The draft policy specifically included 34 “Ministerial Proposals”, so that stakeholders could comment on the precise government plans.
- The tabling of the draft policy was followed by a series of parliamentary committee hearings to which all stakeholders were invited.
- Finally, nearly a year later, in November, 2005, Bill 130 was introduced in the National Assembly.

This extensive process was launched because of the importance of the issue, to “ensure that everyone contributes to the success of this policy”, and to “permit all concerned to tell us their reactions and suggest improvements”.

**Quebec’s approach to the same issues, opportunities and challenges as those in Ontario was a model of consultation and transparency.** This ensured that there would be no unpleasant surprises once Bill 130 was tabled. And it ensured that the Quebec government had a solid, educated understanding of the impact their proposals would have on stakeholders such as pharmacy.

## **British Columbia - PharmaCare Supply Chain Review Process:**

In 2005, BC commissioned a preliminary supply chain review, with the objective of determining value for money of the pharmacy products and services purchased on behalf of BC PharmaCare beneficiaries. This review was to help shape future BC health policies regarding pharmacy, including cost-management considerations.

- Pharmacists strongly objected to the preliminary review, because it was based on a number of faulty assumptions and lack of data.

- The BC government did not proceed with developing new policy based on the preliminary review.
- Instead, the BC government met with the BC Pharmacy Association and the CACDS, to discuss methods of improving the assessment of the value of pharmacy products and services, and of ensuring accurate assumptions and data.
- The three parties agreed to support a new approach and a new study, using the methodology of Activity-Based Assessment.

**The BC government demonstrated flexibility, openness and transparency**, which is anticipated to result in better knowledge and information on which to base policy affecting pharmacy.

#### **Nova Scotia – Various Policies:**

The province of Nova Scotia maintains a close, collaborative working relationship with pharmacy. This has led to the introduction of a number of policies to encourage greater participation by pharmacists in health care delivery. Among these policies are:

- Appropriately-set dispensing fees. Pharmacists receive \$10.42 per prescription, up to an actual acquisition (AAC) cost of \$140. If AAC exceeds \$140, the fee is \$15.63.
- Mandated 3% per year increases in the dispensing fee, for the three year period 2004-2007.
- Pharmacists can “prescribe” diabetes testing equipment for patients, and bill directly for this service, at the same rate as a physician.
- The continued care prescription policy allows pharmacists, where there is an established relationship with the patient, and the patient is on a long-term therapy, to renew an expired prescription and provide up to 30 days supply.

These policies, developed in partnership with pharmacists, contribute to a health pharmacy profession, as well as to lower overall costs through reduced physician and emergency room visits.

#### **Australia – Fourth Community Pharmacy Agreement:**

The Government of Australia and the Pharmacy Guild of Australia have entered into an agreement that provides a model to define the elements of pharmacy reimbursement.

In addition, the agreement establishes rules for ongoing adjustments to the reimbursement formula, based on factors such as inflation, pharmacy wage costs, and changes in prescription volume.

This model provides for predictability and an appropriate level of risk-sharing by both government and pharmacy. The establishment of the agreement also addressed and redressed outstanding challenges that existed under the previous system.

## **Conclusion**

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The CACDS believes that Bill 102 must be amended, and that a number of the associated policy announcements must be reviewed and revised, in order to prevent serious, lasting harm to pharmacy and to patient care.

In addition, we believe that the harmful nature of the legislation and new policies is based on a lack of true understanding of the real world economics of pharmacy, and based on faulty assumptions regarding pharmacy reimbursement. These conditions, together with a less than transparent and comprehensive consultation process, have led to the current circumstances, in which Ontario may face the closure of up to 10% of pharmacies, if the government proceeds without amendments and policy changes.

However, the good news is that the negative impact on pharmacy and patients can be averted. To do so, the government should:

- Agree to the recommended amendments to Bill 102
- Establish the Pharmacy Council in law
- Agree to revisit several of the announced policies, with an open and comprehensive consultation with pharmacy, about specific proposed provisions, through the Pharmacy Council

In addition, the **CACDS would be willing to prepare a report for the government on innovative pharmacy policy measures employed in different jurisdictions.** The featured measures would be those that ensure continued viability and health for the pharmacy profession and business, and that enhance patient care, while helping to manage rising health costs. We look forward to working cooperatively with the government, to help achieve the original intent of Bill 102: a more transparent, accessible, effective and cost-effective drug system.

## **Appendix I**

### **Background – The Canadian Association of Chain Drug Stores**

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The CACDS is the national voice of community chain pharmacy in Canada. The 21 members of CACDS are traditional chain drug stores, grocery chains and mass merchandisers with pharmacies.

Together, CACDS members operate 5,602 pharmacies that dispense 78% of the nation's prescriptions each year. CACDS members employ more than 97,000 Canadians, including 70% of the pharmacists in Canada. The 180 Associate Members of CACDS represent all supply categories and services in the retail pharmacy industry, including pharmaceuticals, health and wellness products, self-care medications and other consumer products. CACDS was founded in 1995.

#### **CACDS Mission:**

Our mission is to ensure a strong chain drug store sector which provides Canadian consumers with access to high quality products and health care services.

We will achieve this by:

- Contributing to the development of innovative health care solutions;
- Promoting and enhancing the role and value of our chain pharmacy members and their pharmacists in the health care system;
- Ensuring that governments and regulators whose decisions affect the economic viability of chain drug stores understand our issues and make better use of the infrastructure available in member locations;
- Working with our supplier community to increase consumer satisfaction through greater efficiency and effectiveness of our supply chain; and
- Monitoring and informing our members on industry-wide issues.

## **Economic Contribution:**

Community chain pharmacy makes a significant contribution to the economic well-being of Canada, and of the province. In Ontario, CACDS members operate 2,285 or 80 per cent of the pharmacies and employ almost 40,000 people. Every day 1.6 million people visit a pharmacy in Ontario. It is estimated that each pharmacy services an average population of 4,383 individuals. In addition:

- Pharmacy contributes \$1.2 billion per year to Ontario's economy in income, GST and provincial sales taxes as well as spin-off business to other sectors such as advertising, manufacturing, technology and insurance
- Pharmacies (and personal care stores) represent 6.4% of the Ontario retail trade revenue.
- Pharmacies (and personal care stores) contributed \$392 million in provincial sales tax in 2001
- Pharmacies contribute an estimated \$20 million annually in community involvement
- Ontarians spend \$11.9 billion on personal health and wellness products at community pharmacies

**Appendix II**  
**Proposed Amendments to Bill 102**

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**Bill 102 2006**

**An Act to amend the  
Drug Interchangeability and  
Dispensing Fee Act and the  
Ontario Drug Benefit Act**

Her Majesty, by and with the advice and consent of the Legislative Assembly of the Province of Ontario, enacts as follows:

**PART I**  
**AMENDMENTS TO THE  
DRUG INTERCHANGEABILITY AND  
DISPENSING FEE ACT**

**1. (1) The definition of "designated" in section 1 of the *Drug Interchangeability and Dispensing Fee Act* is repealed and the following substituted:**

**"designated"** means designated by the executive officer in the Formulary;  
(**"désigné"**)

**(2) Section 1 of the Act is amended by adding the following definitions:**

**"executive officer"** means the executive officer of the Ontario public drug programs appointed under the *Ontario Drug Benefit Act*; (**"administrateur"**)

**"Formulary"** means the Formulary that the executive officer is required to keep, maintain and publish under the *Ontario Drug Benefit Act*; (**"Formulaire des médicaments"**)

**2. The Act is amended by adding the following section:**

**Executive officer and interchangeability**

**1.1 (1)** The executive officer may designate a product as being interchangeable with another product by designating it as such in the Formulary.

**Formulary and interchangeability**

**(2)** A product becomes interchangeable with another product on the effective date of its being designated as interchangeable with that product, and ceases to be interchangeable with that product on the effective date of the removal of its interchangeability designation by the executive officer.

**Requirements for interchangeability**

(3) The executive officer may designate a product as being interchangeable with another product if it is in the public interest to do so, but shall not do so if,

(a) it does not contain a drug or drugs in the same amounts of the same or similar active ingredients in the same or similar dosage form as the other product; or

(b) the prescribed conditions under clause 14 (1) (a) have not been met.

### **Ceasing to be interchangeable**

(4) The executive officer may remove a product's interchangeability designation,

(a) where authorized to do so under subsection 12.1 (7);

(b) if one of the conditions prescribed under clause 14 (1) (b) has been breached; or

(c) in any case, if he or she considers it advisable in the public interest to do so.

### **Modification**

(5) Any modification of a designation takes place on the effective date of its being designated in the Formulary as a modification.

### **Transitional**

(6) A product that was interchangeable with another product immediately before October 1, 2006 continues to be interchangeable with that product until its interchangeability designation is removed by the executive officer.

### **3. Subsection 4 (5) of the Act is repealed and the following substituted:**

#### **~~Selection of interchangeable product~~**

~~(5) If a prescription directs the dispensing of a product that is not an interchangeable product and there is an interchangeable product that contains a drug or drugs in the same amounts of the same or similar active ingredients in the same or similar dosage form as the product prescribed, the dispenser may dispense the interchangeable product.~~

### **4. The Act is amended by adding the following sections:**

#### **~~Rebate, etc.~~**

#### **Rebates**

**12.1 (1)** A manufacturer shall not provide a rebate to wholesalers, operators of pharmacies, or companies that own, operate or franchise pharmacies, or to their directors, officers, employees or agents,

(a) for any interchangeable product; or

(b) for any product in respect of which the manufacturer has made an application to the executive officer for designation as an interchangeable product, while that application is being considered.

### **May not accept rebate**

(2) No person shall accept a rebate that is mentioned in subsection (1), either directly or indirectly.

### **Professional allowance**

(2.1) Subject to subsection (2.2), a manufacturer may provide a professional allowance to wholesalers, operators of pharmacies, or companies that own, operate or franchise pharmacies.

### **Disclosure of professional allowance**

(2.2) A manufacturer that provides a professional allowance to wholesalers, operators of pharmacies, or companies that own, operate or franchise pharmacies shall inform the executive officer of the details of the professional allowance.

### **Executive officer may make order**

(3) If the executive officer believes, on reasonable grounds, that a manufacturer is not complying with subsection (1), the executive officer may make an order requiring the manufacturer to pay to the Minister of Finance the amount calculated under subsection (4).

### **Calculation**

(4) For the purposes of this section, the following rules apply to calculating the amount that is to be paid under subsection (3):

1. The amount shall be calculated by determining the difference between the expected value of all units of the drug products purchased and the actual cost of acquiring those units by the wholesaler, operator of a pharmacy, or company that owns, operates or franchises pharmacies.
2. The expected value mentioned in paragraph 1 shall be determined by multiplying the drug benefit price by the volume of units provided by the manufacturer or wholesaler for all the products.
3. The actual cost of acquiring those products mentioned in paragraph 1 shall be determined by subtracting the monetary value of the rebate from the amount paid for all the products by the wholesaler, operator of a pharmacy, or company that owns, operates or franchises pharmacies.

## **Reconsideration**

(5) Within 14 days of being served with the order, the manufacturer may submit evidence to the executive officer as to its compliance with subsection (1), or that the amount calculated under subsection (4) is not correct, and the executive officer shall reconsider the order based on that evidence.

## **Actions of executive officer after reconsideration**

(6) After reconsidering the order, the executive officer may do one of the following, and shall promptly serve the manufacturer with notice of his or her decision:

1. Affirm the order.
2. Rescind the order.
3. Vary the order.

## **Executive officer may act**

(7) Where a manufacturer has not complied with an order under subsection (3) within 14 days of being served with it, or has submitted evidence within 14 days under subsection (5) and the order has been affirmed or varied under subsection (6) and the manufacturer has not complied with the affirmed or varied order within 14 days of being served with it, the executive officer may either issue a further order under subsection (3) requiring the manufacturer to pay a revised amount calculated under subsection (4), or do either or both of the following:

1. If the drug that is the subject of the order is an interchangeable product, remove its designation.
2. Not make further designations of any of the manufacturer's products as interchangeable under this Act, or as listed drug products under section 1.3 of the *Ontario Drug Benefit Act*, nor consider any of its products for approval under section 16 of that Act, until such time as the executive officer is of the opinion that the manufacturer is no longer offering the rebate.

## **Limit on reconsideration**

(8) Subsections (5) and (6) do not apply to a further order mentioned in subsection (7).

## **Required notice**

(9) Where the executive officer proposes to act under paragraph 2 of subsection (7), the executive officer shall serve the manufacturer with at least 30 days notice.

## **Definitions**

(10) In this section,

~~“drug benefit price” means, with respect to a product,~~

(a) its drug benefit price under the *Ontario Drug Benefit Act*,

(b) in the case of a product that is not a benefit under the *Ontario Drug Benefit Act*, a price submitted by the manufacturer under the regulations that has been posted by the executive officer in the Formulary, or

(c) in the case of a product mentioned in clause (1) (b), the price submitted by the manufacturer; (~~“prix au titre du régime de médicaments”~~)

“professional allowance” means a benefit in the form of money that is provided by a manufacturer in the ordinary course of business to wholesalers, operators of pharmacies or companies that own, operate or franchise pharmacies. (“allocations professionnelles”)

~~“rebate”, subject to the regulations, includes, without being limited to, currency; “rebate” means a discount, refund, trip, or free goods or any other prescribed benefit, but does not include a professional allowance or a discount for prompt payment offered in the ordinary course of business. (“rabais”)~~

## Regulations

(11) The Lieutenant Governor in Council may make regulations clarifying ~~the definition of “rebate” in this section, including providing that certain benefits are not rebates, prescribing benefits for the purpose of that definition and clarifying~~ how the calculations are to be made in this section.

### Rules re s. 12.1

**12.2** (1) The following rules apply with regard to an order made or a notice given by the executive officer under section 12.1:

1. The order or notice must be in writing, and set out in brief the reason for which it is made.
2. An order must set out how any amount required to be paid under the order was calculated, specify any right of reconsideration that is available, and the time within which reconsideration is available.
3. The order or notice may be served by leaving a copy of the document with an officer, director or agent of the manufacturer, or with a person at any place of business of the manufacturer who appears to be in control or management of the place of business.
4. An order must specify the time period with respect to which the order is made, which may include a time period with respect to which a previous order was

made, if the previous order has not been complied with.

5. An order must set out the time period in which the manufacturer is required to comply with the order.

6. An order must specify the consequences for failing to comply with the order.

#### **Same, publication of enforcement action**

(2) The executive officer may publish on the Ministry's website the corporate names of manufacturers against whom the executive officer has taken action under section 12.1 and may also publish any information he or she considers appropriate about the action that has been taken.

#### **No appeal**

(3) There is no appeal from a decision or action of the executive officer under section 12.1, except as provided for in that section.

#### **Non-application of SPPA**

(4) The *Statutory Powers Procedure Act* does not apply to anything done by the executive officer under section 12.1.

#### **5. (1) Subsection 14 (1) of the Act is amended by adding the following clause:**

(d) defining any word or expression used in this Act but not defined in this Act.

#### **(2) Clause 14 (2) (a) of the Act is repealed and the following substituted:**

(a) it does not contain a drug or drugs in the same amounts of the same or similar active ingredients in the same or similar dosage form as the other product; or

**(3) Subsections 14 (2), (3), (4) and (5) of the Act are repealed.**

**(4) Section 14 of the Act is amended by adding the following subsection:**

#### **Retroactive**

(9) A regulation is, if it so provides, effective with reference to a period before it is filed.

## **PART II**

### **AMENDMENTS TO THE**

#### *Ontario Drug Benefit Act*

**6. The *Ontario Drug Benefit Act* is amended by adding the following section:**

## Principles

**0.1** In this Act, the following principles are recognized:

1. The public drug system aims to meet the needs of Ontarians, as consumers and taxpayers.
2. The public drug system aims to involve consumers and patients in a meaningful way.
3. The public drug system aims to operate transparently to the extent possible for all persons with an interest in the system, including, without being limited to, patients, health care practitioners, consumers, manufacturers, wholesalers and pharmacies.
4. The public drug system aims to consistently achieve value-for-money and ensure the best use of resources at every level of the system.
5. Funding decisions for drugs are to be made on the best clinical and economic evidence available, and will be openly communicated, to the extent possible.

[6. The Minister has an obligation to ensure that eligible persons have uniformly timely access, at the point of dispensing, to listed drug products and interchangeable products.](#)

**7. (1) The definition of "designated" in section 1 of the Act is repealed and the following substituted:**

**"designated"** means designated in the Formulary by the executive officer;  
(**"désigné"**)

**(2) Section 1 of the Act is amended by adding the following definitions:**

["Appeal Board" means the Health Services Appeal and Review Board under the Ministry of Health Appeal and Review Boards Act, 1998 \("Commission d'appel"\)](#)

**"executive officer"** means the executive officer of the Ontario public drug programs appointed under section 1.1; ("administrateur")

["designated pharmaceutical product" means a product prescribed as a designated pharmaceutical product;](#)

["extemporaneous preparation" means a drug or combination of drugs prepared or compounded in a pharmacy according to a prescription;](#)

**"Formulary"** means the Formulary that the executive officer is required to keep, maintain and publish under section 1.2; (**"Formulaire des médicaments"**)

["professional services" means any of the following services provided by a member of the Ontario College of Pharmacists to a patient:](#)

(a) medication use reviews, including with a patient's other health care providers;

(b) implementation of patient care plans;

(c) chronic disease management;

(d) monitoring patient outcomes and assisting with adherence to medications;

(e) specialized primary care services;

(f) any additional services that are prescribed; and

(g) any additional services that are agreed to by the executive officer and the committee referred to in clause 1.1 (2) (j).

**(3) The definition of "Minister" in section 1 of the Act is repealed and the following substituted:**

~~"Minister"~~ means the Minister of Health and Long-Term Care or any other member of the Executive Council to whom the administration of this Act is assigned under the *Executive Council Act*; (~~"ministre"~~)

**(4) Section 1 of the Act is amended by adding the following definition:**

~~"prescribed"~~ means prescribed in the regulations; (~~"prescrit"~~)

**8. The Act is amended by adding the following sections:**

#### **Executive officer**

**1.1 (1)** The Lieutenant Governor in Council shall appoint an executive officer for the Ontario public drug programs.

#### **Functions and powers**

(2) Subject to this Act and the regulations, it is the function of the executive officer, and he or she has the power, to perform any functions or duties that he or she may have under this Act and the regulations, under the *Drug Interchangeability and Dispensing Fee Act* and its regulations and under any other Act or regulation, and without in any way restricting the generality of the foregoing,

(a) to administer the Ontario public drug programs;

(b) to keep, maintain and publish the Formulary;

(c) to make this Act apply in respect of the supplying of drugs that are not listed drug products as provided for in section 16;

(d) to designate products as listed drug products, listed substances and

designated pharmaceutical products for the purposes of this Act, and to remove or modify those designations;

(e) to designate products as interchangeable with other products under the *Drug Interchangeability and Dispensing Fee Act*, and to remove or modify those designations;

(f) to negotiate agreements with manufacturers of drug products, agree with manufacturers as to the drug benefit price of listed drug products, negotiate drug benefit prices for listed substances with suppliers, and set drug benefit prices for designated pharmaceutical products;

(g) to require any information that may or must be provided to the executive officer under this Act or the regulations or any other Act or regulation to be in a format that is satisfactory to the executive officer;

(h) to make payments under the Ontario public drug programs;

(i) to establish clinical criteria under section 23; and

(j) to negotiate and agree on the payments to be made to operators of pharmacies for professional services and the conditions under which such payments may be made, with a committee comprised of two members of the Ontario Pharmacists' Association and two members of the Ontario Chain Drug Association, and to pay operators of pharmacies for such professional services, ~~and to determine the amount of such payments subject to the prescribed conditions, if any.~~

## **Regulations**

(3) The Lieutenant Governor in Council may make regulations,

(a) clarifying, modifying or restricting the functions and powers of the executive officer;

(b) providing for additional functions and powers of the executive officer.

## **Formulary**

**1.2** (1) The executive officer shall keep, maintain and publish a Formulary.

## **Contents**

(2) The Formulary shall set out,

(a) the listed drug products and listed substances for the purposes of this Act;

(b) the drug benefit price for listed drug products, listed substances and designated pharmaceutical products;

(c) the products that are designated as interchangeable for the purposes of the

*Drug Interchangeability and Dispensing Fee Act*; and

(d) any other information required under this or any other Act.

### **Other information**

(3) In addition to anything mentioned in subsection (2), the Formulary may set out any other information or material the executive officer considers necessary or advisable.

### **Publication**

(4) The executive officer shall publish the Formulary on the website of the Ministry and may publish it in any other format the executive officer considers advisable.

### **Where conflict**

(5) In the event of a conflict between what is posted on the Ministry's website under subsection (4) and what is posted in another format, the Ministry's website prevails.

### **Listing**

**1.3** (1) A drug product becomes a listed drug product on the effective date of its being designated in the Formulary as a listed drug product, and ceases to be a listed drug product on the effective date of that designation being removed.

### **Requirements for listing**

(2) The executive officer may designate a drug product in the Formulary as a listed drug product where the executive officer considers it to be in the public interest to do so, but shall not do so if the prescribed conditions under clause 18 (1) (b) have not been met.

### **Modification**

(3) Any modification of a designation takes place on the effective date of its being designated in the Formulary as a modification.

### **Transitional**

(4) A drug product that was a listed drug product immediately before October 1, 2006 continues to be a listed drug product until it is removed from the Formulary as a listed drug product under this section.

### **Pharmacy Council**

**1.4** (1) **The Minister shall establish a Pharmacy Council whose duties shall be to provide expert advice to the Minister, to ensure the involvement of pharmacists in the development of pharmaceutical and health policy including in the development of reimbursement models for pharmacists, and to identify support**

and training mechanisms for medication management reviews.

(2) Subject to subsection (4), the Pharmacy Council shall be composed of one representative nominated by each of the following: the Minister, the Ontario Pharmacists' Association, the Ontario College of Pharmacists, the Ontario Chain Drug Association, the Canadian Society of Hospital Pharmacists- Ontario Branch, the Faculty of Pharmacy at the University of Toronto, the Ontario Medical Association and the Citizens' Council.

(3) The Pharmacy Council shall be chaired jointly by the representatives of the Minister and the Ontario Pharmacists' Association.

(4) The chairs may jointly agree to expand the composition of the Pharmacy Council by inviting another organization or organizations with an interest in pharmacy or pharmaceutical and health policy to nominate a representative.

### Citizens' Council

1.5 (1) The Minister shall establish a Citizens' Council whose duty shall be to ensure the involvement of patients in the development of pharmaceutical and health policy.

(2) The Citizens' Council shall be composed of <\*> members nominated by <\*> and <\*> members nominated by <\*>.

**9. Subsection 2 (1) of the Act is amended by striking out "designated" and substituting "prescribed".**

**10. (1) Subsection 4 (1) of the Act is amended by striking out "the Minister" and substituting "the executive officer".**

**(2) Subsection 4 (2) of the Act is amended by striking out "the Minister" and substituting "the executive officer".**

**(3) Subsection 4 (3) of the Act is amended by striking out "the Minister" and substituting "the executive officer".**

**(4) Subsection 4 (4) of the Act is amended by striking out "the Minister" and substituting "the executive officer".**

**(5) Paragraph 4 of subsection 4 (5) of the Act is repealed and the following substituted:**

**4. ~~Subject to the prescribed conditions, if any, if~~ the acquisition cost, for the operator of the pharmacy, of the drug product dispensed is greater than the ~~sum of the~~ drug benefit price for that product ~~and the mark-up referred to in paragraph 3 of subsection 6 (1)~~, determine the amount by which they differ.**

**11. (1) Subsections 5 (1) and (2) of the Act are repealed and the following substituted:**

## **Payment of claim of operator**

(1) Subject to subsection (2), an operator of a pharmacy who submits to the executive officer a claim for payment in respect of supplying a listed drug product for an eligible person pursuant to a prescription is entitled to be paid by the executive officer the amount provided for under section 6.

## **Alternative payments**

(2) The executive officer may pay the operator of a pharmacy an amount different from the amount provided for under section 6 in respect of a claim or claims under subsection (1) for prescribed classes of eligible persons, subject to any prescribed requirements. [Payment pursuant to this subsection shall not be less than the amount provided for under section 6.](#)

## **Transitional**

(2.1) Any agreement that was in place under subsection (2), as it existed before October 1, 2006, that was in effect immediately before that date continues in force, with the executive officer substituted for the Minister, until it is terminated under its terms.

**(2) Subsection 5 (3) of the Act is amended by striking out "the Minister" wherever it appears and substituting in each case "the executive officer".**

**12. (1) Subsection 6 (1) of the Act is repealed and the following substituted:**

### **Amount executive officer to pay**

(1) The amount the executive officer shall pay under subsection 5 (1) in respect of a listed drug product is the amount calculated by adding the amounts determined under paragraphs 1, 2 and 3 and subtracting from that total the maximum co-payment that may be charged in respect of the supplying of a listed drug product for an eligible person, as provided for in the regulations:

1. The dispensing fee determined under subsection (2).
2. The drug benefit price for the drug product, but, if there are other listed drug products that are interchangeable with the drug product, the drug benefit price shall be deemed to be the lowest of the drug benefit prices for the drug product and the listed drug products that are interchangeable with it.
3. The prescribed mark-up on that price.

**(2) Subsection 6 (2) of the Act is amended by striking out "the Minister" in the portion before clause (a) and substituting "the executive officer".**

**(3) Clause 6 (2) (a) of the Act is repealed.**

(3.1) Clause 6(2)(c) of the Act is amended by adding “Subject to subsection 6 (2.1)” before “in all other cases”.

(3.2) Section 6 of the Act is amended by adding the following subsections:

**Premium Dispensing Fee**

(2.1) The executive officer shall pay the operator of a pharmacy a premium dispensing fee that exceeds the prescribed dispensing fee, where the prescribed conditions have been met and in the prescribed amount, for performance of the following services:

- (a) methadone dispensing and maintenance therapy;
- (b) intravenous infusion services;
- (c) specialty compounding;
- (d) compliance packaging;
- (e) needle and syringe exchange programs; and
- (f) any additional services that are prescribed.

**Review of Dispensing Fee and Mark-up**

(2.2) Not more than three years after the coming into force of this Act, and not more than every three years thereafter, the executive officer shall review the prescribed dispensing fee, the prescribed premium dispensing fees payable pursuant to subsection (2.1) and the prescribed mark-up, and shall recommend to the Lieutenant Governor in Council that they be increased by a percentage that is not less than the percentage increase in the cost of living since the previous review, as measured by the Consumer Price Index in Ontario.

**(4) Subsection 6 (3) of the Act is repealed and the following substituted:**

**Same, high acquisition cost**

(3) ~~Subject to the prescribed conditions, if any, if~~ the acquisition cost of a listed drug product for an operator of a pharmacy is greater than the ~~sum of the drug benefit price for the drug product determined under paragraph 2 of subsection (1) and the mark-up on that price, referred to in paragraph 3 of subsection (1),~~ the executive officer shall also pay, under subsection 5 (1), the difference between the acquisition cost and the drug benefit price for the drug product ~~and that sum.~~

**(5) Subsection 6 (5) of the Act is amended by striking out "the Minister" and substituting "the executive officer".**

**(6) The Act is amended by adding the following section:**

**6.1 An operator of a pharmacy who submits to the executive officer a claim for**

payment in respect of professional services is entitled to be paid by the executive officer, for such professional services, the amount that the executive officer has negotiated and agreed to with the committee referred to in clause 1.1 (2) (j), subject to the conditions for payment that have been negotiated and agreed to between the executive officer and the committee.

**13. Section 8 of the Act is repealed.**

**14. (1) Subsection 9 (1) of the Act is amended by striking out "The Minister" at the beginning and substituting "The executive officer".**

**(2) Subsection 9 (2) of the Act is amended by striking out "the Minister" and substituting "the executive officer".**

**(3) Section 9 of the Act is amended by adding the following subsection:**

**Transitional**

**(4) Any agreement under subsection (1) that was in effect immediately before October 1, 2006 continues in force, with the executive officer substituted for the Minister, until it is terminated under its terms.**

**15. (1) Subsection 11 (1) of the Act is amended by striking out "the Minister" wherever it appears and substituting in each case "the executive officer".**

**(2) Subsection 11 (2) of the Act is amended by striking out "the Minister" wherever it appears and substituting in each case "the executive officer".**

**16. (1) Subsection 11.1 (1) of the Act is amended by striking out "the Minister" wherever it appears and substituting in each case "the executive officer".**

**(2) Subsection 11.1 (2) of the Act is amended by striking out "the Minister" and substituting "the executive officer".**

**(3) Subsection 11.1 (3) of the Act is amended by striking out "the Minister" and substituting "the executive officer",**

**(a) in the portion before clause (a); and**

**(b) in clause (a).**

**(4) Subsection 11.1 (6) of the Act is amended by striking out "The Minister" at the beginning and substituting "The executive officer".**

**(5) Subsection 11.1 (7) of the Act is amended by striking out "The Minister" at the beginning and substituting "The executive officer".**

**17. (1) Subsection 11.2 (1) of the Act is amended by striking out "the Minister" wherever it appears and substituting in each case "the executive**

officer".

(2) Subsection 11.2 (2) of the Act is amended by striking out "the Minister" and substituting "the executive officer".

(3) Subsection 11.2 (3) of the Act is amended by striking out "the Minister" and substituting "the executive officer",

(a) in the portion before clause (a); and

(b) in clause (a).

(4) Subsection 11.2 (5) of the Act is amended by striking out "The Minister" at the beginning and substituting "The executive officer".

(5) Subsection 11.2 (6) of the Act is amended by striking out "The Minister" at the beginning and substituting "The executive officer".

18. Subsection 11.3 (1) of the Act is amended by striking out "the Minister" wherever it appears and substituting in each case "the executive officer".

19. The Act is amended by adding the following sections:

#### **Supply to be at drug benefit price**

11.4 (1) A manufacturer shall not sell a listed drug product, for the purpose of supplying a drug product under this Act, for a price that is higher than its drug benefit price as listed in the Formulary.

#### **Agreement not to exceed drug benefit price**

(2) A manufacturer, in agreeing to a drug benefit price with the executive officer under section 22, shall agree to comply with subsection (1).

#### **Executive officer may make order**

(3) If the executive officer believes, on reasonable grounds, that a manufacturer is not complying with subsection (1), the executive officer may make an order requiring the manufacturer to pay to the Minister of Finance the amount calculated under subsection (4).

#### **How amount calculated**

(4) The amount that the manufacturer is required to pay under subsection (3) is the amount determined by the formula:

$$A = Q (P - DBP)$$

where,

"A" is the amount to be paid by the manufacturer,

"P" is the price for which the manufacturer is selling the listed drug product,

"DBP" is the drug benefit price, and

"Q" is the number of units of the listed drug product sold at the higher price.

### **Reconsideration**

(5) Within 14 days of being served with an order under subsection (3), the manufacturer may submit evidence to the executive officer as to its compliance with subsection (1), or that the amount calculated under subsection (4) is not correct, and the executive officer shall reconsider the order based on that evidence.

### **Actions of executive officer after reconsideration**

(6) After reconsidering the order, the executive officer may do one of the following, and shall promptly serve the manufacturer with notice of his or her decision.

1. Affirm the order.
2. Rescind the order.
3. Vary the order.

### **Executive officer may act**

(7) Where a manufacturer has not complied with an order under subsection (3) within 14 days of being served with it, or has submitted evidence within 14 days under subsection (5) and the order has been affirmed or varied under subsection (6) and the manufacturer has not complied with the affirmed or varied order within 14 days of being served with it, the executive officer may either issue a further order under subsection (3) requiring the manufacturer to pay a revised amount calculated under subsection (4), or do either or both of the following:

1. Remove the designation of the drug that is the subject of the order as a listed drug product.
2. Not make further designations of any of the manufacturer's drug products as listed drug products under section 1.3, nor consider any of its drug products for approval under section 16, nor designate any of its products as interchangeable under the *Drug Interchangeability and Dispensing Fee Act* until such time as the executive officer is of the opinion that the manufacturer is selling the drug product for the drug benefit price.

### **Limit on reconsideration**

(8) Subsections (5) and (6) do not apply to a further order mentioned in subsection (7).

## **Required notice**

(9) Where the executive officer proposes to act under paragraph 2 of subsection (7), the executive officer shall serve the manufacturer with at least 30 days notice.

## **Rebates, etc.**

**11.5** (1) A manufacturer shall not provide a rebate to wholesalers, operators of pharmacies, or companies that own, operate or franchise pharmacies, or to their directors, officers, employees or agents,

(a) for any listed drug product or listed substance; or

(b) for any drug in respect of which the manufacturer has made an application to the executive officer for designation as a listed drug product, while that application is being considered.

## **May not accept rebate**

(2) No person shall accept a rebate that is mentioned in subsection (1), either directly or indirectly.

## **Professional allowance**

(2.1) Subject to subsection (2.2), a manufacturer may provide a professional allowance to wholesalers, operators of pharmacies, or companies that own, operate or franchise pharmacies.

## **Disclosure of professional allowance**

(2.2) A manufacturer that provides a professional allowance to wholesalers, operators of pharmacies, or companies that own, operate or franchise pharmacies shall inform the executive officer of the details of the professional allowance.

## **Executive officer may make order**

(3) If the executive officer believes, on reasonable grounds, that a manufacturer is not complying with subsection (1), the executive officer may make an order requiring the manufacturer to pay to the Minister of Finance the amount calculated under subsection (4).

## **Calculation**

(4) For the purposes of this section, the following rules apply to calculating the amount that is to be paid under subsection (3):

1. The amount shall be calculated by determining the difference between the expected value of all units of drug products and listed substances purchased and the actual cost of acquiring those units by the wholesaler, operator of a

pharmacy, or company that owns, operates or franchises pharmacies.

2. The expected value mentioned in paragraph 1 shall be determined by multiplying the drug benefit price by the volume of units provided by the manufacturer or wholesaler for all the listed drug products and listed substances.

3. The actual cost of acquiring those products and substances mentioned in paragraph 1 shall be determined by subtracting the monetary value of the rebate from the amount paid for the drug products and listed substances by the wholesaler, operator of a pharmacy, or company that owns, operates or franchises pharmacies.

### **Deemed drug benefit price**

(5) For the purposes of subsection (4), the drug benefit price of a drug in respect of which clause (1) (b) applies shall be deemed to be the price submitted by the manufacturer.

### **Reconsideration**

(6) Within 14 days of being served with the order, the manufacturer may submit evidence to the executive officer as to its compliance with subsection (1), or that the amount calculated under subsection (4) is not correct, and the executive officer shall reconsider the order based on that evidence.

### **Actions of executive officer after reconsideration**

(7) After reconsidering the order, the executive officer may do one of the following, and shall promptly serve the manufacturer with notice of his or her decision.

1. Affirm the order.
2. Rescind the order.
3. Vary the order.

### **Executive officer may act**

(8) Where a manufacturer has not complied with an order under subsection (3) within 14 days of being served with it, or has submitted evidence within 14 days under subsection (6) and the order has been affirmed or varied under subsection (7) and the manufacturer has not complied with the affirmed or varied order within 14 days of being served with it, the executive officer may either issue a further order under subsection (3) or do either or both of the following:

1. If the drug that is the subject of the order is a listed drug product, remove its designation.
2. Not make further designations of any of the manufacturer's ~~drug~~ products as listed drug products under section 1.3, nor consider any of its ~~drug~~ products for

approval under section 16, nor designate any of its products as interchangeable under the *Drug Interchangeability and Dispensing Fee Act* until such time as the executive officer is of the opinion that ~~the~~ manufacturer is no longer offering the rebate.

### **Limit on reconsideration**

(9) Subsections (6) and (7) do not apply to a further order mentioned in subsection (8).

### **Required notice**

(10) Where the executive officer proposes to act under paragraph 2 of subsection (8), the executive officer shall serve the manufacturer with at least 30 days notice.

### **Definition**

(11) In this section,

“professional allowance” means a benefit in the form of money that is provided by a manufacturer in the ordinary course of business to wholesalers, operators of pharmacies or companies that own, operate or franchise pharmacies. (“allocations professionnelles”)

~~“rebate”, subject to the regulations, includes, without being limited to, currency;~~ “rebate” means a discount, refund, trip, or free goods ~~or any other prescribed benefit~~, but does not include a professional allowance or a discount for prompt payment offered in the ordinary course of business. (“rabais”)

### **Rules re ss. 11.4 and 11.5**

**11.6** (1) The following rules apply with regard to an order made or a notice given by the executive officer under section 11.4 or 11.5:

1. The order or notice must be in writing, and set out in brief the reason for which it is made.
2. An order must set out how any amount required to be paid under the order was calculated, and specify any right of reconsideration that is available and the time within which the reconsideration is available.
3. The order or notice may be served by leaving a copy of the document with an officer, director or agent of the manufacturer, or with a person at any place of business of the manufacturer who appears to be in control or management of the place of business.
4. An order must specify the time period with respect to which the order is made, which may include a time period with respect to which a previous order was made, if the previous order has not been complied with.

5. An order must set out the time period in which the manufacturer is required to comply with the order.

6. An order must specify the consequences for failing to comply with the order.

#### **Same, publication of enforcement action**

(2) The executive officer may publish on the Ministry's website the corporate names of manufacturers against whom the executive officer has taken action under section 11.4 or 11.5 and may also publish any information he or she considers appropriate about the action that has been taken.

#### **No appeal**

(3) There is no appeal from a decision or action of the executive officer under section 11.4 or 11.5, except as provided for in those sections.

#### **Non-application of SPPA**

(4) The *Statutory Powers Procedure Act* does not apply to anything done by the executive officer under sections 11.4 and 11.5.

#### **20. Section 12 of the Act is repealed and the following substituted:**

##### **Minister and executive officer to consult**

**12.** The Minister and the executive officer may consult with persons or organizations representing eligible persons, manufacturers, operators of pharmacies, physicians, suppliers of listed substances, wholesalers and companies that own, operate or franchise pharmacies with respect to the amounts payable under this Act and other matters of mutual concern arising out of this Act and the regulations, and the *Drug Interchangeability and Dispensing Fee Act* and its regulations.

**21. (1) Subsection 13 (1) of the Act is amended by adding "and the executive officer" after "The Minister" at the beginning.**

**(2) Subsection 13 (2) of the Act is amended by adding "and the executive officer" after "The Minister" at the beginning.**

**(3) Subsection 13 (3) of the Act is repealed and the following substituted:**

##### **Disclosure**

(3) The Minister and the executive officer shall disclose personal information if all prescribed conditions have been met and the disclosure is necessary for purposes related to the administration of this Act or for such other purposes as may be prescribed, but shall not disclose the information if, in his or her opinion, the disclosure is not necessary for those purposes.

**(4) Subsection 13 (4) of the Act is amended by adding "and the executive**

officer" after "the Minister".

**22. The Act is amended by adding the following section:**

**Requirement to provide information**

**13.1** (1) For the purposes of determining compliance with this Act or the regulations or with the *Drug Interchangeability and Dispensing Fee Act* and its regulations, the executive officer may require a manufacturer, wholesaler, supplier of a listed substance, operator of a pharmacy or a company that owns, operates or franchises pharmacies to provide information other than personal information to the executive officer, either in response to a specific request, or at regular intervals.

**Time and form**

(2) The executive officer may specify the time at which and the form in which the information must be provided.

**Publication**

(3) Where the executive officer requires that information be provided at regular intervals, the executive officer shall publish the manner and form that are required on the website of the Ministry, and may publish them in any other format that he or she considers appropriate.

**Compliance required**

(4) ~~The~~[Subject to subsection 14.1 \(1\), the](#) manufacturer, wholesaler, supplier of listed substances, operator of a pharmacy or company that owns, operates or franchises pharmacies shall comply with every requirement to provide information under this section.

**Where conflict**

(5) In the event of a conflict between what is posted on the Ministry's website under subsection (3) and what is posted in another format, the Ministry's website prevails.

**23. Subsections 14 ~~(2), (3)~~, (4) and (5) of the Act are repealed and the following substituted:**

**Examine books**

(2) Subject to subsection (5), an inspector may examine records relating to a claim for payment under this Act, in whatever form, in the possession or under the control of an operator of a pharmacy or a physician, if the inspector believes on reasonable grounds that the records will assist the inspector in determining the accuracy and completeness of a claim for payment of the operator or

physician or of information they are required to submit under this Act or the regulations, or in determining whether they have complied with this Act and the regulations.

### **Same**

(3) ~~An~~Subject to subsection (5), an inspector may examine records relating to a claim for payment under this Act, in whatever form, in the possession or under the control of a wholesaler, manufacturer, supplier of a listed substance, operator of a pharmacy or a company that owns, operates or franchises pharmacies, if the inspector believes on reasonable grounds that the records will assist the inspector in determining the accuracy and completeness of a claim for payment of an operator of a pharmacy or physician or in determining whether the wholesaler or manufacturer has complied with this Act and the regulations.

### **Copies**

(4) In carrying out an inspection under this section, the inspector may, upon giving a receipt for it, take away a record, including a sales or a marketing record, for the purpose of making a copy, but the copy shall be made and the record shall be returned as promptly as reasonably possible.

### **Notice**

(5) The inspector shall not carry out an inspection under this section unless the inspector has given the operator of a pharmacy, physician, wholesaler, manufacturer, supplier of a listed substance, or company that owns, operates or franchises pharmacies, as the case may be, seventy-two hours notice in writing of the inspector's intention to carry out an inspection under this section.

### **23.1 The Act is amended by adding the following section:**

#### **Review to Appeal Board and Stay**

14.1 (1) Any person who is affected by a requirement to provide information under section 13.1 or who is subject to an inspection under section 14 may request a review of the requirement under section 13.1 or of the decision to conduct an inspection or the conduct of the inspection, as the case may be, from the Appeal Board. A request for review under this section stays the obligation to comply under subsection 13 (4) or the inspection, as the case may be, until the disposition of the review.

#### **Powers of Appeal Board**

(2) After conducting a review, the Appeal Board may,

(a) confirm the requirement under section 13.1 or the decision to conduct an inspection under section 14 and make such order as it considers proper in regard to the scope of the requirement or the conduct of the inspection, as the

case may be; or

(b) relieve the applicant from the requirement under section 13.1 or order that there be no inspection under section 14.

### **Appeal to Divisional Court**

(3) Any party to the proceedings before the Appeal Board under this Act may appeal from its decision or order to the Divisional Court in accordance with the rules of court.

### **Powers of court on appeal**

(4) An appeal under this section may be made on questions of law or fact or both and the court may affirm or may rescind the decision of the Appeal Board and may exercise all powers of the Appeal Board under this section and as the court considers proper and for such purposes the court may substitute its opinion for that of the Appeal Board, or the court may refer the matter back to the Appeal Board for review, in whole or in part, in accordance with such directions as the court considers proper.

## **24. (1) Clause 15 (1) (b) of the Act is repealed and the following substituted:**

(b) submits to the executive officer a claim for payment where the executive officer is not required to make any payment or where the claim is in excess of the amount the executive officer is required to pay;

**(2) Clause 15 (1) (e) of the Act is amended by adding "or the *Drug Interchangeability and Dispensing Fee Act*" after "administration of this Act".**

**(3) Subsection 15 (5) of the Act is amended by striking out "the Minister" and substituting "the executive officer".**

**(4) Subsection 15 (6) of the Act is repealed and the following substituted:**

**Same**

(6) The minimum penalty for each offence under clause (1) (b) is two times the difference between the amount for which a claim was submitted to the executive officer and the amount the executive officer is required to pay.

## **25. Section 16 of the Act is repealed and the following substituted:**

### **Unlisted drugs, special case**

**16. (1) If a physician informs the executive officer that the proper treatment of a**

patient who is an eligible person requires the administration of a drug for which there is not a listed drug product, the executive officer may make this Act apply in respect of the supplying of that drug as if it were a listed drug product by so notifying the physician.

### **Same**

(2) The drug benefit price of a drug referred to in subsection (1) shall be the amount determined by the executive officer in accordance with the regulations.

### **Listed drugs, special case**

(3) If a physician informs the executive officer that the proper treatment of a patient who is an eligible person requires the administration of a drug for which there are one or more listed drug products but for which the conditions for payment under section 23 are not satisfied, the executive officer may make this Act apply in respect of the supplying of those listed drug products as if the conditions were satisfied.

### **Notice to operator**

(4) An operator of a pharmacy is not liable for contravening this Act or the regulations in respect of supplying a drug referred to in subsection (1) or a listed drug product referred to in subsection (3) unless the operator has received notice from the physician or from the executive officer that the executive officer has made this Act ~~applies to that supplying~~ apply in respect of the supplying of a drug referred to in subsection (1) or a listed drug product referred to in subsection (3).

### **Retroactivity**

(5) Where the executive officer may make this Act apply in respect of the supplying of a drug or a listed drug product under this section, the executive officer may make that application retroactive to a date determined by the executive officer.

## **26. Subsections 17 (2) and (3) of the Act are repealed and the following substituted:**

### **Determination of drug benefit price**

(2) The executive officer has the authority to,

(a) determine the conditions which must be met before a pharmaceutical product, including an extemporaneous preparation, is designated as a designated pharmaceutical product; and

(b) determine the drug benefit price of a designated pharmaceutical product, including determining a formula by which the drug benefit price may be calculated.

## Section 22 does not apply

(3) Section 22 does not apply for the purposes of this section.

## Publication

(4) The executive officer shall publish, on the Ministry's website and in any other format the executive officer considers appropriate, any conditions or formulas that the executive officer determines under subsection (2).

## Where conflict

(5) In the event of a conflict between what is posted on the Ministry's website under subsection (4) and what is posted in another format, the Ministry's website prevails.

## 27. (1) Subsection 18 (1) of the Act is amended by adding the following clauses:

(0.a) defining any word or expression used in this Act but not defined in this Act;

(0.a.1) governing prescribing additional services as professional services for the purposes of clause 1.1 (2) (j); ~~including defining "professional services", governing payments that may be made for professional services, including governing to whom payments may be made, and prescribing conditions to which the executive officer is subject in making payments for professional services;~~ and section 6.1;

(2) Clause 18 (1) (a) of the Act is amended by striking out "designating" and substituting "prescribing".

(3) Clauses 18 (1) (c) and (d) of the Act are repealed.

~~(4) Clause 18 (1) (e.1) of the Act is repealed and the following substituted:~~

~~(e.1) prescribing the manner of determining acquisition costs of drug products, for the purposes of subsections 4 (5), 6 (3) and 6 (4), and prescribing conditions for the purposes of paragraph 4 of subsection 4 (5) and for the purposes of subsection 6 (3);~~

~~(5) Subsection 18 (1) of the Act is amended by adding the following clause:~~

~~(e.1.2) prescribing classes of eligible persons and setting out requirements for the purposes of subsection 5 (2);~~

~~(65) Clause 18 (1) (e.2) of the Act is amended by striking out "the Minister" and substituting "the executive officer".~~

~~(76) Clause 18 (1) (e.3) of the Act is amended by striking out "the Minister" and substituting "the executive officer".~~

**(87)** Clause 18 (1) (g) of the Act is repealed.

**(98)** Clause 18 (1) (g.1) of the Act is repealed and the following substituted:

(g.1) prescribing the mark-up of the drug benefit price the executive officer will pay under subsection 6 (1);

**(409)** Clause 18 (1) (g.3) of the Act is repealed.

**(4410)** Clause 18 (1) (g.4) of the Act is repealed and the following substituted:

(g.4) prescribing the dispensing fee ~~and conditions for the payment of the dispensing fee~~ for the purposes of subclause 6 (2) (c) (i), the premium dispensing fees for the purposes of subsection 6 (2.1) and the conditions for the payment of the premium dispensing fees, and prescribing any additional services as services in respect of which premium dispensing fees shall be paid;

**(4211)** Clause 18 (1) (g.6) of the Act is amended by striking out "the Minister" and substituting "the executive officer".

**(4312)** Clause 18 (1) (h) of the Act is repealed.

**(4413)** Clause 18 (1) (k) of the Act is repealed.

**(4514)** Clause 18 (1) (k.1) of the Act is repealed and the following substituted:

(k.1) respecting how drug benefit prices are to be calculated for the purposes of section 16;

**(15)** Clause 18 (1) (k.2) of the Act is amended by striking out "the Minister" and substituting "the executive officer".

**(16)** Clause 18 (1) (k.23) of the Act is amended by striking out "the Minister" and substituting "the executive officer".

**(17)** ~~Clause 18 (1) (k.3) of the Act is amended by striking out "the Minister" and substituting "the executive officer".~~

**(48)** ~~Subsection 18 (1) of the Act is amended by adding the following clause:~~

~~(k.5.1) clarifying the definition of "rebate" in section 14.5, including providing that certain benefits are not rebates, prescribing benefits for the purpose of that definition and clarifying how the calculations are to be made in that section; clarifying the records which may be examined by an inspector for the purposes of subsections 14(2) and 14(3);~~

**(4918)** Clause 18 (1) (k.6) of the Act is repealed and the following substituted:

(k.6) prescribing conditions under which the Minister and the executive officer may collect or use personal information under subsection 13 (1) or (2), conditions under which the Minister and the executive officer shall disclose personal information under subsection 13 (3) and conditions under which the Minister and the executive officer may enter into agreements under subsection 13 (4);

**(~~20~~19) Clause 18 (1) (l) of the Act is repealed.**

**(~~21~~20) Subsections 18 (1.1), (1.2) and (1.3) of the Act are repealed.**

**(~~22~~21) Clause 18 (5) (d) of the Act is amended by striking out "the Minister" and substituting "the executive officer".**

**28. Sections 19, 20, 21, 22 and 23 of the Act are repealed and the following substituted:**

### **Decisions about listing, delisting**

**19.** In deciding whether or not to designate a drug product as a listed drug product or to remove such a designation, the executive officer may consider anything he or she considers advisable in the public interest, including, without limiting the generality of the foregoing, the drug benefit price of the drug product or other drug products or the price charged to operators of pharmacies for the drug product or other drug products.

### **Delisting**

**20.** (1) The executive officer may remove a drug product's designation as a listed drug product even if none of the conditions prescribed under clause 18 (1) (b.1) are breached, if he or she considers it advisable in the public interest to do so.

### **Effect of breach of continuing conditions**

(2) Despite a breach of a condition prescribed under clause 18 (1) (b.1), a drug product does not cease to be a listed drug product until its designation as a listed drug product is removed.

### **Advisors**

**21.** The Minister, the executive officer or any body or official who advises the Minister, the executive officer or the Lieutenant Governor in Council with respect to anything under this Act may, in formulating such advice, consider anything the Minister, the executive officer or Lieutenant Governor in Council may consider.

### **Drug benefit price**

**22.** (1) The drug benefit price for a drug product when it becomes a listed drug product shall be the amount agreed to by the executive officer and the manufacturer, subject to any conditions that may be prescribed.

### **Executive officer's agreement**

(2) In deciding whether to agree to an amount under subsection (1), the executive officer may consider any matter the executive officer considers advisable in the public interest, including, without limiting the generality of the foregoing, the drug benefit price of other drug products or the price charged to operators of pharmacies for the drug product or other drug products.

### **Request for change**

(3) A manufacturer may request, in writing, that the executive officer change a drug benefit price, but the executive officer is not obligated to act on the request.

### **Criteria for requesting change**

(4) The executive officer may establish rules, criteria and procedures that must be followed by a manufacturer in submitting requests for changes in a drug benefit price, including providing for how often such requests may be made, and shall post those rules, criteria and procedures on the Ministry's website and in any other format the executive officer considers advisable.

### **Manufacturer must comply**

(5) A manufacturer that submits a request for a change in a drug benefit price shall comply with the posted rules, criteria and procedures.

### **Where conflict**

(6) In the event of a conflict between what is posted on the Ministry's website under subsection (4) and what is posted in another format, the Ministry's website prevails.

### **Changing drug benefit price**

(7) Subject to any conditions that may be prescribed, the executive officer may change the drug benefit price of a drug product in consultation with the manufacturer if a request has been made under subsection (3) and the executive officer considers it to be in the public interest to make the change, and such a change is effective on the date that it is indicated in the Formulary as taking effect.

### **Documentation**

(8) In determining whether a change in the drug benefit price is in the public interest, the executive officer may require the manufacturer to supply any information, other than personal information, that the executive officer considers relevant, and the manufacturer shall comply with the request.

### **Transitional**

(9) The drug benefit price of a drug product that was a listed drug product immediately before October 1, 2006 shall be its drug benefit price as it existed under this Act at that time, until it is changed as permitted under this Act and the regulations.

### **Clarification**

(10) For greater clarity, the executive officer may change the drug benefit price of any drug product that was listed in the Formulary that existed immediately before October 1, 2006, and that was referred to in the regulations made under this Act or the *Drug Interchangeability and Dispensing Fee Act*, but only as provided for in this Act or its regulations, or the *Drug Interchangeability and Dispensing Fee Act* and its regulations.

### **Conditions of payment**

**23.** (1) The executive officer may require that, in respect of a specified drug product or class of drug products, specified clinical criteria must be met for the executive officer to pay an amount in respect of the supplying of that drug product or class of drug products for particular patients or a particular class of patients.

### **Publication**

(2) Where the executive officer specifies anything under subsection (1), he or she shall publish it in the Formulary.

### **Clinical criteria**

(3) Without limiting the generality of subsection (1), clinical criteria may include,

(a) considerations relating to the use or the possibility of the use of other drug products or therapies for particular patients or a particular class of patients;

(b) a requirement that the use of a drug product for particular patients or a particular class of patients require a prescription from a physician or member of a class of physicians specified by the executive officer;

(c) a requirement that a specified person or an expert panel recommend or approve the use of a drug product for particular patients or a particular class of patients.

### **When clinical criteria not met**

(4) If an operator of a pharmacy supplies a drug product for an eligible person and, because of the criteria set under this section, the executive officer is not required to pay an amount in respect of that supply, the operator may charge or accept payment from a person other than the executive officer in an amount equal to the sum of,

(a) the amount the executive officer would have paid under this Act, absent the criteria; and

(b) the amount the operator could have charged under this Act, absent the criteria.

### **Exception**

(5) Subsection (4) does not apply if, under section 16, the executive officer makes this Act apply in respect of the supplying of the drug product for the eligible person.

## **PART III COMMENCEMENT AND SHORT TITLE**

### **Commencement**

**29. (1) Section 3, subsections 5 (2), 12 (3) and 27 (10), this section and section 30 come into force on the day this Act receives Royal Assent.**

### **Same**

**(2) Sections 1, 2 and 4, subsections 5 (1), (3) and (4), sections 6 to 11, subsections 12 (1), (2), (3.1), (3.2), (4), (5) and (56), sections 13 to 26, subsections 27 (1) to (9) and (11) to (22) and section 28 come into force on October 1, 2006.**

### **Short title**

**30. The short title of this Act is the *Transparent Drug System for Patients Act, 2006*.**

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