SUBMISSION TO
ONTARIO MINISTRY OF HEALTH
AND LONG-TERM CARE

on

ONTARIO PUBLIC DRUG PROGRAMS PROPOSED
COMPETITIVE AGREEMENTS FRAMEWORK

CANADIAN ASSOCIATION OF CHAIN DRUG STORES
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SUMMARY

In 2006, the government of Ontario announced a plan to reform the drug system, with the stated intent to increase stakeholder consultation, transparency and access for patients. The governments commitment to reform, in particular to increase stakeholder engagement, was to improve the efficiency and cost effectiveness of the pricing, procurement and management of medications with a view to managing costs and improving the overall health and wellness of Ontarians. We applauded the government at the time for adopting this proactive approach and we continue to support these policy objectives.

On July 7, 2008, the Ministry of Health and Long-Term Care disclosed to pharmacy a proposed framework for Competitive Agreements within the Ontario Public Drug Program. Regrettably, this framework was developed without the engagement of pharmacy, the primary stakeholder in the delivery of services under the OPDP, and therefore without a full understanding of its consequences on community pharmacy and the patients it serves.

As representatives of both the pharmacists' profession and of pharmacy retailers we strongly support the Ontario government's objective of improving patient outcomes and improving the health and quality of life of Ontarians. However, we also must emphasize that developing reforms without consultation has two potential deleterious outcomes:

1. the stated objectives may not be realized
2. opportunities for creative reform through engaging with parties with diverse perspectives and experiences are lost.

The approach taken in respect of the announcements last week likely produces both outcomes.

In addition to failing to obtain input prior to developing the framework, the MOHLTC has offered an extremely short period for stakeholders to provide feedback on such a complex and far-reaching proposal, and has not provided a process for further consultation; rather, it has provided one session on July 15th for a "discussion with stakeholders". Such an approach suggests and perhaps confirms an unwillingness to truly engage with the stakeholders and to receive and consider seriously meaningful and comprehensive input from those best positioned to provide the Ministry with ideas and suggestions that may ensure that the government's objectives are realized and exceeded.

The framework will directly impact the ability of pharmacists to provide professional services to Ontarians, by decreasing the funding that enables their delivery, the result of which is patients being less well served. In the current environment pharmacy is highly dependent on manufacturer allowances, a transparent part of the reimbursement model and paid by manufacturers to support the continued provision of pharmacy services to patients.

Immediate action should be taken to delay this process. Pharmacy is requesting the opportunity to work with the MOHLTC and manufacturers, through a consultative approach and collaborative discussions, to fully assess the potential impact of the proposed framework on the provision of pharmacy services in Ontario, to review approaches taken in other provinces, and to discuss proposals that will assist government in meeting its objectives without significant negative consequences to community pharmacy, manufacturers, and in the medium to long term, to the health care system. This approach would almost certainly produce more lasting, effective and creative solutions focused on achieving the comprehensive policies of the Ontario government.

INTRODUCTION

The Canadian Association of Chain Drug Stores, the Independent Pharmacists' Association of Ontario and the Ontario Pharmacists' Association are pleased to provide these comments to the Ministry of Health and Long-Term Care (the "Ministry") regarding the proposed Competitive Agreements Framework (the "Framework").

We acknowledge and support the intent of the government of Ontario to move towards a transparent, sustainable and accessible drug system in Ontario. However, the proposed Framework, coupled with provisions in existing legislation, will have significant negative impact on the ability of community pharmacy and pharmacists to deliver pharmacy products and services effectively and efficiently to Ontarians. The proposed Framework seriously threatens the short and long term viability of community pharmacies: a cornerstone for healthcare delivery for Ontarians, a foundation of the business community in many of Ontario's smaller centers, and one of the most respected retail channels in the market. The proposed Framework would severely and immediately restrict the ability of many pharmacies to provide patient care services, proven to be critical elements of therapeutic protocols with significant impacts on the overall cost of the health care system and patient outcomes. Existing pharmacy economic issues must be addressed prior to introducing additional policies that will exacerbate the current situation.

The Framework introduced by the Ministry presents a new impediment into the system associated with the very tenets that predicated drug system reform; transparency and accountability. Specifically, this is related to the value of the rebates that the government will receive. While we can appreciate the desire of confidentiality around what are essentially business deals between manufacturers and the government, the desire for such confidentiality should not exempt government from their accountability and responsibility to taxpayers (patients) for conveying the value of the savings realized by such initiatives as well as the specific uses for those savings.

In addition, lack of transparency around the size of the rebates to government creates an unmanageable situation for pharmacy. In accordance with the Ministry's own regulations, professional allowances are calculated according to a formula which includes the value of volume rebates to the Ministry. In its effort to protect the business relationships with the two winning manufacturers, the Ministry is making it impossible for pharmacies to accurately calculate the amount of authorized manufacturer allowances. Pharmacy can no longer be held responsible for any professional allowances received in excess of the authorized amount if the Ministry chooses to withhold key information that would make compliance possible. Furthermore, pharmacy businesses cannot be expected to operate in an environment where they make financial and business plans based on projected allowances, only to find at a later date that the Ministry has obtained a volume rebate on specific molecules and effectively reduced income to pharmacy.

Limitations on both professional autonomy and patient choice will also result from the application of competitive agreements. Recognizing that there are subtle differences in non-medicinal excipients that may elicit not-so-subtle adverse reactions, physicians, pharmacists and patients lose their ability to choose the product that best suits their needs and improves adherence rates. In addition, the competitive activity between generic vendors is one of the leading factors enhancing the security of supply. Even today, generic vendors have supply issues with multiple source products. When it comes to the provision of pharmaceutical products, pharmacies have realized over the years that the security of supply through multiple choices of products outweighs the potential cost advantages of single sourcing or tendering. A dollar saved may become

a larger expense to the overall system when products are unavailable and patient care is impacted.

We are also concerned that the Framework could be emulated by private drug plans, which will result in a further negative impact on pharmacy services and patients.

To mitigate a negative impact on patient care, the Ministry must re-visit the Framework, amend legislation related to the calculation of manufacturers' allowances, and take steps to address long-standing pharmacy reimbursement issue. Pharmacy is anxious for the opportunity to work with the MOHLTC and manufacturers, through a consultative approach and collaborative discussions, to proactively assess the potential impacts of the proposed Framework on the provision of pharmacy services in Ontario, to review approaches taken in other provinces, and to discuss new proposals that will meet the government's objectives while optimizing therapy and promoting the health of Ontarians, without causing significant negative consequences to community pharmacy and manufacturers.

ISSUES AND RECOMMENDATIONS

1. Process and transparency

Issues

The Framework was developed in the absence of consultation with pharmacy, the primary stakeholder in the delivery of services under the OPDP, and therefore in the absence of obtaining a full understanding of the consequences of the proposed Framework on community pharmacy and the patients it serves. In addition, the MOHLTC has provided an extremely short period for stakeholders to provide feedback on such a complex and far-reaching proposal, and has not provided a process for further consultation; rather, it has provided one session on July 15th for a "discussion with stakeholders". With such extensive changes to Ontario's Public Drug Plan, stakeholders could reasonably expect that sufficient time and consideration be devoted to developing solutions. This would help ensure that those affected could offer comprehensive and 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.

The Framework introduces a new impediment into Ontario's drug system, as the government does not intend to disclose the amount of volume rebates it receives. While the legislation recognizes that there may be a need for confidentiality of information about agreements between the Executive Officer and manufacturers, the lack of transparency on volume rebates creates an unworkable situation for pharmacy when managing manufacturer allowances. Manufacturer allowances are calculated according to the formula in legislation;

> *X = 20% of (P - V)*
> *where,*
> *"X" is the total dollar amount of professional allowances that may be provided by a manufacturer to persons listed in subsection 11.5 (1) of the Act,*
> *"P" is the total dollar amount of a manufacturer's drug products reimbursed under the Act based on the number of units reimbursed at each product's drug benefit price,*

"V" is the total dollar value of any volume discount or any other amount of payment that was made to the Minister of Finance under an agreement entered into under this Regulation or Regulation 935 of the Revised Regulation of Ontario, 1990 (General) made under the Drug Interchangeability and Dispensing Fee Act for those products reflected in P.

If only the manufacturers and the Ministry are privy to the value of "*V*", pharmacy is not able to calculate "*X*".

Pharmacy cannot reasonably be expected to comply with legislation when it does not have access to information necessary to make compliance possible. As such, pharmacy cannot be held responsible for any professional allowances received in excess of the authorized amount if the Ministry chooses to withhold key information.

Furthermore, pharmacy businesses cannot be expected to operate in an environment where they make financial and business plans based on projected allowances, only to find at a later date that the Ministry has obtained a volume rebate on specific molecules and effectively reduced income to pharmacy.

- There has been no clarification from the Ministry on how the rebates it obtains will be invested back into the drug program. With the underlying principles of transparency and accountability with drug system reform, the Ministry has a duty to inform taxpayers of the aggregate savings achieved through changes to the system and on how those savings are going to be re-invested within the Public Drug Program. We encourage the Ministry to use these savings to ensure continued delivery of professional services that Ontarians deserve and have come to expect from their pharmacists, by using the savings to close the gap between the cost of providing services and reasonable compensation to pharmacy, and further investing in new pharmacy professional services such as Meds Check to contribute to the health and wellbeing of Ontarians.

Recommendations

- **Establish a fair and transparent process that will allow stakeholders to work with the Ministry through a well-coordinated consultative approach and with collaborative discussions. This will allow for a more fulsome assessment of the potential impacts of the proposed Framework on the provision of pharmacy services to Ontarians and on businesses. It will also allow for a critical review of approaches taken in other provinces and to discuss proposals that will help meet the government's objectives without causing significant negative consequences for community pharmacy and manufacturers. The current 6-day timeframe provided for stakeholder input on a policy change with such wide reaching patient care and economic implications is unworkable.**

- **Just as pharmacy must disclose the amount of manufacturer allowances obtained, and how they are invested directly back into patient care, the Ministry needs to disclose the amount of volume rebates obtained in order to allow pharmacies to comply with legislation regarding the calculation of professional allowances. In addition, the Ministry needs to uphold their promise of transparency and accountability in drug system reform, and report to taxpayers**

on how the savings from competitive agreements are going to be into the drug program to support patient care.

- **The calculation of the 20% cap on professional allowances should be based on the listed drug benefit price (the gross price to pharmacy). As currently defined in legislation, this 20% cap is based on the net price to the government and therefore restricts the full amount of professional allowances from being available.**

- **We encourage the Ministry to use the savings obtained through volume rebates to ensure continuity of pharmacy services for Ontarians, by using the savings to start filling the gap between the cost of providing services and reimbursement to pharmacy, and further investing in new pharmacy professional services such as Meds Check to contribute to the health and wellbeing of Ontarians.**

2. Impact on Patient Care

Issue
By decreasing manufacturer allowances to pharmacy, the proposed Framework will have a direct and negative impact on patient care services.

Pharmacy invests manufacturer allowances directly in patient care services, so it is clear that a decrease in allowances will result in a corresponding decrease in the provision of patient care services by community pharmacies in Ontario, services such as patient counseling, adherence management, compliance packaging, clinic days, education days and disease management and prevention initiatives. Manufacturer allowances are also used to fund continuing education for pharmacists. By decreasing allowances the Ministry would also be directly affecting the resources available to pharmacists to maintain and enhance their clinical skills.

There are issues with restricting the choice of medication available to patients and healthcare providers. Metformin, which is one of the four molecules selected for "phase one" is a good example. From a patient perspective, patients may prefer one manufactures formulation over another due to the flavoring of the tablets, which makes them more palatable, and as with any molecule allergies to excipients must be considered. From an operational perspective, dispensing coated versus uncoated tables can cause errors with electronic counting devices such as baker cells, and some manufacturers offer a 250 size of the bottle with child proof cap that eliminate the need to place the tablets in three or four separate prescriptions vials which reduces potential confusion and overdosing.

While the Ministry has defined a process in the proposed Framework to address out of stock issues, this process appears to be focused on penalties for the manufacturer, payable to the Ministry, rather than patient care concerns. As Ontario is the largest market in Canada, manufacturers who do not bid or who make an unsuccessful bid will ramp down production. Where does the Ministry intend to source product if both manufactures encounter an out of stock situation? What will be the process that is put in place to manage therapy, including temporarily switching patients to alternate medications if necessary? Recalls could also be problematic, for example, if a brand and generic were the two successful listings, and they use the same facility to produce product, a

three month stock provision is meaningless as all product would be quarantined.

Recommendations

- **Manufacturers' allowances are critical to patient care and to the current pharmacy model for provision of services. The Ministry must understand and take into account the role these allowances play in proving care to Ontarians and in the overall funding model for pharmacy, and understand the full impact of introducing dual-source tendering.**

- **The Ministry needs to define a workable process to address therapeutic and safety concerns, processing concerns, and out of stock and recall issues that may introduce the risk of interruption to patient care.**

3. Pharmacy Economics and Sustainability

Issue

By introducing the proposed Framework the Ministry is demonstrating its intention to both directly and indirectly decrease manufacturers' allowances paid to pharmacy, allowances that are a vital component of the current pharmacy economic model. Decreasing manufacturer allowances would further exacerbate critical pharmacy economic issues that have been heightened as a result of the governments plan to reform the drug system and the Transparent Drug System for Patients Act.

Pharmacy cannot absorb further cuts to revenues. This will be clearly demonstrated to the Ministry at our upcoming meeting on Thursday, July 25th when we will be presenting the results of the *Costs of Community Pharmacy Services Study.* This Study identifies a significant funding gap of up to $9.00 per prescription, depending on the nature and location of the pharmacy practice.

Pharmacy is currently attempting to operate while being expected to manage this cost-recovery gap. This is clearly not sustainable.

Compounding the substantial cost-recovery gap is a complete lack of return on investment for the provision of pharmacy services. Community pharmacies are private businesses, which depend on return on investment to deliver value to shareholders, re-invest in capital expenditure, invest in program development and innovation, support the current and evolving healthcare system, and promote competition to the benefit of consumers. While the Ministry recognizes the need for a return on investment as a component of reimbursement to pharmacy in its definition of the dispensing fee[1], its current reimbursement to pharmacies provides a negative return on investment. This is supported by the findings of the *Costs of Community Pharmacy Services Study* to be discussed on July 25th.

The Ministry is now intending, through the proposed Framework, to further exacerbate the untenable economic situation that has been imposed on pharmacy by further decreasing manufacturers' allowances. Under the Framework manufacturers allowances will be affected in several ways:

[1] http://www.health.gov.on.ca/english/public/pub/drugs/dispense.html

- The formula for calculating allowances in the regulations includes *the total dollar value of any volume discount or any other amount of payment that was made to the Minister of Finance.* Clearly, if a volume rebate is obtained by the Ministry, the value of allowances will decrease. For example, if a 20% volume rebate were obtained by the Ministry on a product valued at $100, the allowance would decrease from 20% to 16%

  The net affect of the implementation of the proposed Framework coupled with the calculation for allowances would be to directly remove between $1.8M to $3.3M from pharmacy reimbursement dependent on the level of rebates the government receives[2], and substantially more in phase two of implementation, when an additional four to twenty molecules would be added.

  NOTE: The MOHLTC is unable to provide sales data for the four molecules in question until end of day Monday July 14th. In the absence of ODB data, IMS total sales data for Ontario, supported by pharmacy data suggesting an estimated OPDP sales spilt of approximately 40%, has been used in this analysis.

- It is entirely likely that generic manufacturers will decrease the manufacturer allowances it pays to pharmacy to offset the volume rebate that it pays to the ministry, and to offset substantial losses if they are unsuccessful in the RFP process and lose business in Ontario for high volume molecules as a result. It is feasible that allowances could be decreased to zero.

  The net effect of the implementation of the first four molecules under the proposed Framework could be to remove $8.8M through the initial implementation of the Framework[3]

  The net affect of "phase two" will be significantly higher, for example, if the top 20 molecules by sales were tendered though competitive agreements, $64M could be removed from pharmacy reimbursement[4].

  NOTE: The MOHLTC is unable to provide sales data for the four molecules in question until end of day Monday July 14th. In the absence of ODB data, IMS total sales data for Ontario, supported by pharmacy data suggesting an estimated OPDP sales spilt of approximately 40%, has been used in this analysis.

- If a brand manufacturer is awarded a competitive agreement contract, it is unlikely that it will pay pharmacy a manufacturers allowance

  The issue of whether a brand manufacturer would be prepared to decrease a price to 50%, and then offer a manufacturer allowance, has national and international pricing repercussions. It is simply not reasonable to speculate

[2] Refer to appendix 1. For illustrative purposes and in the absence of information on the expected level of rebates to the Ministry, a range of volume rebate from 20% to 37% was used
[3] Refer to appendix 1. For illustrative purposes, and based on anecdotal information, an assumption that generic manufacturers could reduce pharmacy allowances to zero, to offset rebates to the Ministry, has been used.
[4] Refer to Appendix 1. For illustrative purposes, and based on anecdotal information, an assumption that generic manufacturers could reduce pharmacy allowances to zero, to offset rebates to the Ministry, has been used.

on a potential value of brand manufacturer allowances, and include this speculation as part of an economic model for the fair reimbursement of pharmacy services or provision of patient care.

In December 2007, the Ministry of Health and Long-Term Care committed to establish a Financial Working Group to address the economics of community pharmacy. While the MOHLTC spent six months conducting research and developing the Framework, the Working Group, which is critical to understanding pharmacy economics, and therefore assessing the impact of policy changes and the proposed Framework on Competitive Agreements on community pharmacies has not met.

Recommendations

- **The Ministry needs to address existing pharmacy economic issues prior to introducing additional policies that will further exacerbate the current situation and negatively impact patient care.**

  - **The Ministry has recognized the importance of pharmacy economic issues and the need to better understand and address pharmacy reimbursement through the establishment of the Financial Working Group. The work of this group must be expedited, and full assessment of the existing situation, and analysis of how the proposed Framework will compound this situation, must be completed as a priority.**

  - **To better inform further discussions, the Ministry should disclose the economic analysis that was conducted when drafting the Framework, including its assessment of the full impact of the proposed Framework on pharmacy reimbursement and therefore the continued provision of pharmacy services to Ontarians.**

  - **The dispensing fee paid by the Ontario Public Drug Program must be increased to fairly compensate pharmacies for the cost of dispensing and related services.**

- **The Ministry must understand the critical nature of manufacturers' allowances to supporting patient care and to the current pharmacy economic model, and take into account the role these allowances play in bridging the funding gap and contributing to the overall economic model for pharmacy.**

- **The calculation of the 20% cap on manufacturer allowances as currently defined in legislation, based on the net price to the government, restricts the full amount of professional allowances from being available. The calculation of the 20% cap should be based on the drug benefit price (the gross price to pharmacy)**

- **Any additional decreases in manufacturers' allowances as a result of the introduction of a competitive agreement Framework must be offset by corresponding increases to dispensing fees for pharmacy services.**

4. Private Sector Implications

Issue

The Competitive Agreements process will encourage privately insured drug plans, i.e. plan sponsors, to follow OPDP's lead in seeking similar volume rebates from manufacturers. The impact of the TDSPA reforms has already had the effect of creating two disparate markets for drug pricing and reimbursement, one public and one private, in Ontario, and this initiative will accelerate this trend to the detriment of both pharmacy and the millions of Ontarians not eligible for benefits under the OPDP.

Moreover, one likely consequence is that those patients with private plans would be required to absorb a higher cost degree of cost-sharing than the plan sponsor for their medications. The notion of undisclosed rebates to the government amounts to a tax on non-OPDP patients, runs counter to the Ministry's purported commitment to transparency, and is unfair and unacceptable. A dual-sourcing strategy may permit OPDP to achieve savings, but at the expense of the millions of Ontarians who either have no insurance at all or are beneficiaries under private drug plans. The OPDP has cited the case of New Zealand, among other countries, as a justification for competitive agreements. However, unlike Ontario, in New Zealand tenders are awarded on the basis of the lowest price actually charged, which is transparent. A policy in which the public payer saves money through the use of undisclosed rebates provided by brand or generic manufacturers under the Competitive Agreements framework is simply not in the larger public interest.

This issue was recently examined by Dr. Aidan Hollis of the Institute for Advanced Policy Research (IAPR) at the University of Calgary, who has pointed out that the use of sole sourcing in British Columbia for olanzapine, paired with secret rebates, "is causing higher drugs prices for patients and private insurers. While PharmaCare may be able to reduce its short-term drug costs through this approach, it is doing so by increasing costs for other payers, including uninsured and partially insured patients"[5]

Recommendation

- **The Ministry should be aware of the negative impact that the Competitive Agreements Framework is likely to impose on patients and pharmacies dealing with privately insured plans, and should take steps to mitigate negative repercussions by address pharmacy reimbursement issues and taking into full consideration and acting on the recommendations in this submission**

5. National Implications

Issue

Manufacturers will need to offset the volume rebate that it pays to the ministry, and to offset substantial losses if they are unsuccessful in the RFP process and lose business in Ontario for high volume molecules as a result. This situation will probably affect the way business is conducted in other provinces.

[5] The IAPR report is available at www.iapr.ca

Recommendation

- **A fair and transparent process must be established immediately to allow stakeholders the opportunity to work with the MOHLTC, through a consultative approach and collaborative discussions, to fully asses the potential impact of the proposed Framework on pharmacies**

6. Inventory Management

Issue

As a direct result of the Transparent System for Patients Act, pharmacies in Ontario have had to develop complex systems to manage two price points and therefore two "inventories", one for OPDP beneficiaries, and one for patients with a private plan, or who pay cash. This system was complicated to develop, expensive to implement, and requires ongoing maintenance. The proposed Framework will compound this situation, creating the requirement to create "a two tier system within a two tier system". To be clear the existing two tier system for public and private patients will still exist, and within that system, a two tier system for molecules that are tendered, and molecules that are not tendered will need to be developed.

Recommendation

- **A fair and transparent process must be established immediately to allow stakeholders the opportunity to work with the MOHLTC, through a consultative approach and collaborative discussions, to fully asses the potential impact of the proposed Framework on pharmacies**

Appendix 1

1. Potential Losses to Pharmacy as a Result of the Proposed Framework – Four Initial Molecules

Molecule	Total sales Ontario (IMS data)	ODB Sales (calculated as 40% of total)	20% PA	Loss to pharmacy if generics do not pay manufacturer allowances	37% rebate to ministry (Allowances at 12.6%)	Loss to pharmacy	20% rebate to ministry (Allowances at 16%)	Loss to pharmacy
METFORMIN	$43,174	$17,270	$3,454	$3,454	$2,176	$1,278	$2,763	$691
RANITIDINE	$32,784	$13,114	$2,623	$2,623	$1,652	$970	$2,098	$525
GABAPENTIN	$20,550	$8,220	$1,644	$1,644	$1,036	$608	$1,315	$329
ENALAPRIL	$13,433	$5,373	$1,075	$1,075	$677	$398	$860	$215
TOTAL	$109,941	$43,976	$8,795	**$8,795**	$5,541	**$3,254**	$7,036	**$1,759**

Numbers are in thousands

2. Potential Losses to Pharmacy as a Result of the Proposed Framework – Top Twenty Molecules by Sales

Top 50 Molecules	MAT MAY/08 DOL DRG	ODB sales (calculated as 40% of total)	Manufacturer allowance at 20%
RAMIPRIL	$ 90,267	$36,107	$7,221
VENLAFAXINE	$ 80,814	$32,326	$6,465
OMEPRAZOLE	$ 61,812	$24,725	$4,945
SIMVASTATIN	$ 56,764	$22,706	$4,541
OLANZAPINE	$ 48,343	$19,337	$3,867
CITALOPRAM	$ 47,976	$19,190	$3,838
METFORMIN	$ 43,174	$17,270	$3,454
ACETAMINOPHEN	$ 39,495	$15,798	$3,160
DILTIAZEM	$ 38,192	$15,277	$3,055
SERTRALINE	$ 34,407	$13,763	$2,753
RANITIDINE	$ 32,784	$13,114	$2,623
FENTANYL	$ 30,991	$12,396	$2,479
PAROXETINE	$ 30,414	$12,166	$2,433
ATENOLOL	$ 29,905	$11,962	$2,392
FLUOXETINE	$ 26,371	$10,548	$2,110
RABEPRAZOLE SODIUM	$ 24,235	$9,694	$1,939
ALENDRONATE	$ 23,455	$9,382	$1,876
PRAVASTATIN	$ 22,329	$8,932	$1,786
AMOXICILLIN	$ 21,673	$8,669	$1,734
GABAPENTIN	$ 20,550	$8,220	$1,644
	$ 803,951	$321,580	**$64,316**

Number are in thousands