

January 9, 2009

E: Helen.stevenson@ontario.ca

Ms Helen Stevenson
Assistant Deputy Minister and Executive Officer
Ontario Public Drug Programs
Ministry of Health and Long-Term Care
Hepburn Block, 9th Floor
80 Grosvenor Street
Toronto, Ontario M7A 1R3

Dear Ms. Stevenson:

On behalf of the Canadian Association of Chain Drug Stores and the Ontario Pharmacists' Association, we are writing to provide input on the Public Consultation to Review the Definitions of Professional Allowance and the Codes of Conduct.

Our comments and proposals are based on the practical experience of our members following enactment of the *Transparent Drug System for Patients Act* (TDSPA) in June 2006, and subsequent regulatory amendments to the *Ontario Drug Benefit Act* (ODBA) and the *Drug Interchangeability and Dispensing Fee Act* (DIDFA). These reforms have brought sweeping change to the business and practice of pharmacy.

In formulating our submission, we considered the intent of these reforms in improving Ontario's drug system by creating a drug system that is efficient, transparent, accountable and fair. It is important to note that Ontarians have benefited in many positive ways from these regulatory reforms, including coverage for new products, improved access to innovative drugs, the introduction of the exceptional access program, conditional listings, and the introduction of MedsCheck programs.

As we look ahead to the future, we need to consider how pharmacy's position as the face of community health care is to be maintained, and ultimately built upon. Ontarians rely on pharmacy care and assume it will always be there for them with the accessibility they've come to expect. Governments in every province rely on pharmacy to provide health care services, and pharmacists have readily offered that care.

The fact that needs to be confronted through the regulatory review is that the cost of pharmacy care has not been fully recognized by Canadians, by patients, by provincial governments or by other drug plan payors in the public and private sectors. While on the one hand there is a willingness to respect and rely upon pharmacies as the face of community health care, on the other hand is a reluctance to reconcile the value of pharmacy services with the need to fund pharmacy appropriately, and to enable pharmacies to use the funds they obtain to support a full range of patient care services.

It is clear that when the reforms associated with TDSPA were implemented there was no clear understanding of the total pharmacy funding model, comprised of direct ministry

and private payor funding and indirect funding through pharmaceutical manufacturers, and the regulations were drafted based on a belief that pharmacists were taking inappropriate rebates. It has now been demonstrated through the reporting of professional allowances, that the vast majority of pharmacies used these funds, and continue to use them, to support their businesses in providing patient care.

Against this backdrop, the transition from rebate revenues to professional allowances was done without precedent or experience. Now, two years later, there is an opportunity to apply the knowledge and experience gained on how allowances are used to adjust the regulations to ensure they fit the business and practice realities of providing pharmacy services. Further, the 2007 Annual Report of the Executive Officer¹ states *“Before, the true cost of dispensing drugs to Ontario Drug Benefit recipients was not reflected in the pharmacy reimbursement structure.”* The reimbursement structure in place today still does not fully fund the cost of providing services, as evidenced by the 2008 Cost of Ontario Community Pharmacy Services (COCPs) study, which demonstrated that the cost of providing dispensing and related services is at a median price of \$13.77 not fully covered by direct Ontario Drug Benefit (ODB) funding, but rather leaving a funding gap of \$5.07 per prescription dispensed². It is well recognized that the allowances received by pharmacies from manufacturers is subsidizing the costs of providing dispensing and related pharmacy services to both ODB recipients and non-ODB recipients.

Meeting these challenges requires a shift in thinking. It demands preparedness and a willingness to revisit and reconsider assumptions and past practices in how pharmacy care is funded, and it calls for creativity and resourcefulness by those who make pharmacy policy decisions as well as those who implement the business and practice of pharmacy. On the government side, there is an opportunity to strengthen the commitment to provide health care through community pharmacies by improving funding for pharmacy services and ensuring that funding obtained by pharmacies can be reinvested in providing a full range of patient care services. On the pharmacy side, there is an opportunity to engage government as a full partner in ensuring that patients are receiving the benefits of pharmacists' training and unique experience, while delivering efficiencies to the healthcare system.

The review of the regulations affords the Executive Officer the opportunity to make reasonable changes that reflect the current understanding of how allowances are used, and how pharmacy and pharmacist services contribute to the promise made to Ontarians through the TDSPA of delivering better value for money. Just as the Drug System Secretariat took a leadership position in 2006 with drug reform proposals that led to TDSPA, we urge the Executive Officer to take a leadership position and recognize the true value and purpose of allowances as a means of indirect funding for pharmacies that, in conjunction with direct funding, not only support services to ODB recipients, but support pharmacy services for Ontarians. In addition, in consideration of the recommendations made in this submission, CACDS and OPA are requesting a formal stakeholder engagement process to discuss the details of this submission, and to discuss potential solutions.

Our recommendations focus on issues identified in previous submissions that continue to be problematic to organizations and pharmacists providing pharmacy patient care

¹ Improving Ontario's Publicly Funded Drug System: Results for Ontarians

² According to the most recently available ODB report card, 2005/2006, reimbursement to pharmacy averaged \$9.19/Rx. Current data suggests that the average is less than \$8.70/Rx and declining. The study found that the median cost to provide pharmacy services is \$13.77, creating a funding gap of \$5.07.

services, and on areas where further development of the definitions would result in clarity, remove current restrictions on innovation and healthy competition in adopting and implementing new patient care services, promote enhanced operational implementation, and promote the evolution of a broad range of healthcare services designed to meet specific patient care needs depending on local patient demographics.

They are grouped under the four categories which you identified for consideration. Other relevant comments, as requested in your communiqué, are included as Section 5.

ISSUE IDENTIFICATION AND PROPOSED SOLUTIONS

1. Further clarification of the definition of professional allowance

a) Definition of patient care services

Discussion

The definition of professional allowance describes eight items for which professional allowances may be used (an *inclusionary* list), and the Code of Conduct defines fourteen items for which professional allowances cannot be used (an *exclusionary* list). In August 2006, we identified in our submissions on the proposed draft regulations that this prescriptive approach is far too limiting to achieve the ministry's stated intent of benefiting patient care. We predicted that the approach would lead to confusion and ambiguity about elements that are neither explicitly included, nor specifically excluded. In practice, we have indeed found that this "black and white" approach to defining pharmacy health care services has led to ongoing issues and concerns:

- Not all activities related to patient care are encompassed in the inclusionary list, neither are they itemized in the exclusionary list. The regulations as written have been a source of ongoing confusion, causing significant questioning and second-guessing about meaning and intent. This creates uncertainty for practicing pharmacists and pharmacy businesses.
- In an attempt to provide clarity, a communiqué issued December 18, 2006, indicated that the Executive Officer had, in collaboration with the OPA, established a process to regularly review requests for clarification around the definition of professional allowances. While the initial objective was well intended, the reality is that no regular process was established, and that some requests for clarification have been left unanswered, or perhaps were communicated back to individual organizations but not shared across the sector. The approach, therefore, is not working to remove ambiguity and enable patient care.
- The regulations do not recognize the current scope of practice, nor do they anticipate some of the new patient care services being contemplated as part of the expanded scope of practice for pharmacists put forward by HPRAC. The definition of professional allowances should enable pharmacy to use allowances to invest in and fully support the evolution of practice. Under the current definition, ongoing amendments to regulation will be required to recognize all

current as well as new and innovative services as being eligible for professional allowance usage.

- Pharmacy innovation and healthy competition in adopting and implementing a broad range of patient care programs is restricted by the confines of regulatory definition of which services may be supported by allowances.
- The resource supports and infrastructure required to implement patient care services should be eligible uses for professional allowances. For example, technology is not in the definition, even though pharmacy has been an eager and early adopter of technology to support the delivery of patient care. In fact, one of the conditions in the HNS Agreement requires pharmacies to use technology. This is in contrast to the funding provided by the ministry and channeled through Ontario MD to encourage family doctors to adopt technology in their practice. This exclusion restricts innovation and healthy competition in adopting and implementing new patient care services.

The definition of professional allowances in the regulations has been fraught with ongoing issues. Approaches devised to provide clarity have not worked. It is apparent that a new approach is required.

Recommendation

The knowledge and experience gained on how allowances are used should inform amendment to the regulations, to ensure they fit the business and practice realities of providing pharmacy services.

The definition of professional allowances should be amended in line with the ministry’s stated intent that professional allowances benefit patient care, and enable the sustainable evolution of professional, community-based pharmacy practice and patient care services. The definition should enable pharmacists to deliver all current patient care services, and be flexible enough to allow the evolution and implementation of new and innovative patient care services in line with the current expanding role and future expanded scope of practice for pharmacists. It must clearly recognize the need to apply allowances against business costs required to deliver services for all patients, as legitimate indirect funding to balance the gap in direct funding provided by payors.

Current definition	Recommended definition
<p>“professional allowance”, in the definition of “rebate”, means, subject to subsections (9) and (10), a benefit, in the form of currency, services or educational materials that are provided by a manufacturer to persons listed in subsection 11.5 (1) of the Act for the purposes of direct patient care as set out in paragraphs 1 to 8 of this subsection:</p>	<p>“professional allowance,” in the definition of rebate, means, subject to subsections (9) and (10), a benefit, in the form of currency, services or educational materials that are provided by a manufacturer to persons listed in subsection 11.5 (1) of the Act for the purposes of supporting pharmacy practice to provide direct patient care.</p>

b) Calculation of professional allowances

Discussion

Section 1(9) of the regulations under the ODBA defines the value of professional allowances, and states that benefits that are in excess of this value are considered a rebate and not a professional allowance. In our submissions to the ministry in August 2006, we identified that the calculation in the then proposed regulatory amendment, on the net price to government, would be unworkable in practice, and that it would restrict the availability of professional allowances. We proposed that the 20% cap be based on the drug benefit price. This proposal was not accepted.

In a subsequent submission to the ministry on Competitive Agreements in July 2008, we provided further evidence that the calculation of professional allowances, $X=20\% (P-V)$, was unworkable. In this example, the government does not intend to disclose the value of rebates it receives from successful bidder(s) in a Competitive Agreement process. The lack of transparency on volume rebates creates an unworkable situation for pharmacy. If only the successful bidder(s) and the ministry are privy to the value of "V", then pharmacy owners are unable to calculate the value of "X".

Pharmacy cannot reasonably be expected to comply with legislation when it does not have access to information necessary to make compliance possible.

Further, in regard to Competitive Agreements, pharmacy businesses cannot be expected to operate in an environment where they make financial and business plans based on projected allowances, only to lose the potential for significant revenues from allowances, with little lead-time to adjust, as a result of Competitive Agreements.

As indicated in our July 2008 submission, Competitive Agreements entered into by the ministry will significantly decrease the amount of professional allowances available to pharmacies, although the ministry's stakeholder presentation on the matter indicated that pharmacy reimbursement would "remain whole". If a generic manufacturer was a successful bidder, there would be a *de facto* reduction in the maximum amount of professional allowances paid to pharmacies according to the ministry's allowance calculation formula. In fact, as a brand manufacturer is the sole successful bidder for the only effectively tendered molecule to-date (enalapril maleate), manufacturer allowances for this molecule are expected to be *virtually eliminated* from pharmacy revenue, at an estimated reduction of \$5.9 million.

This situation further compounds the significant direct funding gap that already exists between community pharmacy costs and funding by the Ontario Public Drug Program.

Recommendation

Amend the regulations in Ontario such that the calculation for the 20% cap on professional allowances in the public sector is based on the Ontario Drug Benefit price (the gross price to pharmacy).

(9) Where the value of all of the benefits provided for in subsection (8) exceeds, with respect to all of a manufacturer's listed drug products or listed substances, the value of X in the formula below, then the benefits that are in excess of X are a rebate and not a professional allowance:

$$X = 20\% \text{ of } \{ P \}$$

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,

The regulations should be amended to make it clear that a rebate is only the amount of a benefit that is provided in excess of the 20% cap.

If the calculation of the formula in regulation remains as is, then the regulation should be amended to make it clear that benefits determined to be a rebate will only be a rebate in respect of the manufacturer, as the manufacturer is the only party outside government that is able to calculate the 20% Cap. This is especially true given that the discount amounts that may be granted by manufacturers to the ministry may not be published.

The issue arising out of this regulatory element should be included as a factor when considering fair, equitable dispensing fees and funding for the procurement of services from pharmacies.

c) The definition of rebate and commercial business arrangements

Discussion

The definition of professional allowances is informed by the definition of "rebate" in the Act. Rebate is defined in section 11.5(18); *"rebate, subject to the regulations, includes, without being limited to, currency, a discount, refund, trip, free goods or any other prescribed benefit, but does not include, (a) a discount for prompt payment offered in the ordinary course of business, or (b) a professional allowance"*

In our August 2006 submissions on the draft regulations, we identified that many commercial business arrangements are currently entered into between manufacturers and pharmacies in the ordinary course of business, which are not

and should not be considered “rebates”. Amounts paid for services that are customary in many retail distribution industries, including cost sharing initiatives, reimbursement for warranty obligations, reimbursement for expired product, late payment penalties, backorder fees, fees for inability to supply, and fees for sales information should be permitted. Cost sharing initiatives that are unique to different business models should be recognized, for example, those specific to providing pharmacy services to long term care facilities.

Also, certain ordinary commercial business practices that may be unique to the pharmacy supply industry should be permitted. For example, current industry practice for distribution of generic drugs is that the drugs are purchased from the manufacturers and sold to retail pharmacies at the drug benefit price. To compensate for this distribution function the generic manufacturer pays a distribution allowance to the wholesaler that may be based on a percentage of the drug benefit price. This practice allows pharmacies to be able to purchase at the book price and obtain the full allowable mark-up. If the distribution fee were classified as a rebate, wholesalers and distributors would have to add a wholesale mark-up to the generic purchases made by retail pharmacies. This would eliminate the price parity between the wholesale and direct-from-manufacturer channels. In turn, this would encourage pharmacies, in an effort to retain the full mark-up, to purchase directly from the generic manufacturers which may result in escalating costs and inefficiencies throughout the supply chain.

The current language creates a number of “grey areas”, leaving businesses attempting to operate under unclear regulation. For example, several questions remain outstanding, including whether a fee for service constitutes a prohibited rebate, and whether there are limits on prompt payment discounts.

Recommendation

The regulations should be amended to include the following clarification of the definition of the term “rebate”:

A “rebate” does not include any property, fees, currency or services, whether payable or paid in kind, when provided as an ordinary commercial practice including, but not limited to, fees for service and leasing arrangements, cost sharing initiatives, payments or free goods provided pursuant to warranty obligations, product withdrawals or product recalls, distribution allowances, payments or goods provided for expired drug products, fees charged for late payments, backorders or failure to supply and fees charged for preferred listing arrangements and allowances for volume commitments, provided that: (i) any such property, fees, cash or services are provided pursuant to a written agreement; and (ii) the value of any such property, fees, cash or services received reflects the fair value for an arm’s length transaction and is duly recorded in the financial records of the party providing such property, fees, cash or services and the party receiving such property, fees, cash or services.

If a revised definition such as this is not accepted, then a process should be established through a mechanism such as the Pharmacy Costing Working Group to inform discussion on which commercial business terms can and should be excluded from the definition of “rebate”.

2. Provisions in the Code that require further clarification

Discussion

In our August 2006 submissions, we identified that to enable the Code of Conduct to work in practice an alternate approach to that being proposed should be implemented. We maintain that an industry review committee and a guidance document referenced in the Code of Conduct, as detailed in that submission, would be a reasonable approach. Furthermore, it would be preferable to have one approach across industry sectors. Rx&D member companies currently operate under a guidance document, and CGPA has developed a similar document which has been introduced in Ontario and Quebec, with the intent to implement across all jurisdictions. At the same time, stakeholders are complying with legislative requirements in several jurisdictions to achieve the same objective.

However, we feel that changes to the definition of professional allowance as outlined in Section 1(a) of this submission would mean that substantive changes to the Code of Conduct would not be necessary. This change in definition would enhance the ability to implement the Code of Conduct in practice, and would align with the voluntary approaches taken by Rx&D and CGPA.

If the definition recommended in 1(a) is adopted, we recommend two changes to the Code of Conduct, pertaining to delivery services and inventory costs.

The inclusion of delivery services in the prohibited uses for professional allowances fails to recognize the significant patient care and caregiver benefit of this service. Inventory costs are another example of the current reimbursement structure established under the TDSPA being insufficient to meet the need of pharmacies. Many pharmacies are required to pay shipping and handling charges on brand name medications purchased from wholesalers. Under the TDSPA, the mark-up paid by ODB decreased from 10% to 8% and the actual acquisition price (including the wholesaler's fee) was replaced by the ODB formulary price. The mark-up on drugs effectively decreased far below 8%. With inventory costs currently listed as a prohibited use for professional allowances under the Code of Conduct, pharmacies are unable to apply professional allowances to address the inequity in the reimbursement structure. These issues should be addressed.

Neither the ODBA nor DIDFA provide authority for the ministry to require disclosure of information to other stakeholders. Confidential business information is included in the data pertaining to the flow of funds between a manufacturer and an operator of a pharmacy, or companies that own, operate or franchise pharmacies. The requirement to make other stakeholders aware of the flow of funds could reveal confidential information and negatively affect competition in the marketplace.

In addition, the obligation in the Code of Conduct to make the Executive Officer aware of the flow of funds in the private sector is inconsistent with the statement in the December 18, 2006 communiqué which identified that the Executive Officer has

no role in pricing other than as stated in the ODBA, for ODB-eligible recipients. While DIDFA relates to interchangeability and dispensing fees in the private sector, it does not refer to private sector pricing. Therefore, the requirement to report the flow of funding as it relates to pricing, which includes professional allowances, is questionable.

Recommendation

The definition of professional allowances should be broadened as recommended in section 1(a) of this submission. Delivery services and costs associated with inventory should be removed from the list of prohibited uses for professional allowances in the Code of Conduct.

The obligation in the Code of Conduct to make the Executive Officer aware of the flow of funds should pertain only to those funds in the public sector. The restrictions under the TDSPA relate to rebates, and the Executive Officer has adequate investigative and enforcement rights under the legislation to ensure that these restrictions are complied with.

The reference to stakeholders should be deleted from the Code of Conduct.

3. Are there any categories that should be added or specific categories that should be excluded under permitted uses for professional allowances?

Recommendation

The definition of professional allowances should be broadened as recommended in section 1(a) of this submission.

4. Comments on the current reporting framework for professional allowances and recommendations to improve and facilitate the reporting process

Discussion

The reporting requirements have taken up significant management time and added legal and accounting expenses for the ministry, for key stakeholders including OPA, CACDS and CGPA, as well as for each and every pharmacy in Ontario. While pharmacies have been diligent in trying to understand and attempting to fully comply with the new reporting requirements for professional allowances, CACDS and OPA have not yet received any feedback from the ministry on the findings or learnings from the reports it has received. Although individual follow up may be completed with specific organizations, an appropriate level of reporting to CACDS, OPA and CGPA would be informative, and could be used as an ongoing issue identification and quality improvement tool.

When the reporting framework was developed there was no clear understanding of the total pharmacy funding model, comprised of direct ministry and other payor funding, and indirect manufacturer funding that supports the provision of pharmacy services, and the framework was developed without precedent or experience in attempting to categorize patient care services into very specific groups.

The regulatory review should be used to revisit the framework and its intent, and to establish a revised process that fits the business and practice realities of providing pharmacy services. The framework used in Quebec provides a viable alternative, which has been found in practice to work well in operations, and across sectors. In addition, if the recommendations made in section 1(a) are accepted, the framework will need to be adapted accordingly.

The framework is particularly difficult to apply to specialty practices such as long term care, sterile compounding and the provision of methadone services. This issue needs to be considered and an alternate approach developed.

To facilitate the reporting process and to ensure regulatory compliance, pharmacy owners seek transparency. We ask that the ministry, along with pharmacy stakeholders co-develop criteria for audits of professional allowances. Furthermore, as there is currently no appeals process for audits, we recommend one be established. We request a commitment to review both the audit criteria and appeals process with pharmacy stakeholders on a regular basis.

The timeframes associated with reporting have been dynamic since inception, and we recommend that a simpler, annual reporting period of public professional allowance dollars now be implemented.

We also reiterate our previous request of the Executive Officer that bonuses be allowed to be reported as part of pharmacy staffing costs rather than broken out of staffing costs as a separate line item. As reported in the COCPS Study analysis provided to the ministry, bonuses represent 1.26% of total pharmacy personnel compensation, and this does not warrant separate reporting.

Recommendation

The framework should be redefined. The model used in Quebec should be adopted in Ontario, that is, the total amount spent by manufacturers would be reported. In addition, pharmacies would report the total amount of allowances received. Pharmacies would continue to maintain usual business records that support the expenditure of professional allowances, and would include on their report of expenditures a statement that expenditure is in accordance with all applicable legislation.

Reporting should follow the precedent set by the ministry in extending the reporting period to a reasonable timeframe. Reporting was originally required quarterly, then semi-annually. Annual reporting should now be sufficient for the ministry's information needs.

A process should be established to provide timely feedback of appropriate information to pharmacy and the generic industry on the payment and usage of professional allowances to support patient care.

If the above recommendations are accepted, the need to review the reporting framework and adapt it appropriately for use in long term care and other specialty practices is negated.

A process should be established to ensure that pharmacies have access to audit criteria for professional allowance reviews. A fair appeals process should be developed. Both processes should involve pharmacy stakeholders and be reviewed on a regular schedule.

The use of professional allowances to support payment of pharmacy staff bonuses should be reported with other pharmacy staffing costs, and no longer required to be broken out separately.

5. Other Relevant Comments

a) Fee for Dispensing Services

Discussion

We have made many submissions and have had many discussions with the ministry indicating that the fee paid to pharmacy for dispensing services is significantly below the cost to provide these services, and it is well known that manufacturer allowances have been bridging this gap and sustaining service.

Compounding this issue is the continuing downward pressure on generic drug pricing, including tendering initiatives such as Competitive Agreements. The latter has proven to remove generic manufacturers completely from eligibility, or may in the future include them as a benefit but with an unknown discount paid to the ministry (refer to section 1(b) in this submission). This significantly widens the gap between the funding for services that the ministry procures from community pharmacies and the cost to provide those services.

The studies we have provided to the ministry provide a real understanding of the actual cost of providing pharmacy services to patients. Coupled with information about the levels and sources of direct and indirect funding for pharmacy, these studies set the stage for discussions about the fairness and appropriateness of current funding, and the implications for the future of pharmacy and the patient care it provides.

Informed by these findings, we want the ministry to make a constructive commitment to maintaining and building on the pharmacy care Ontarians value, trust and need. As part of our engagement with government, we will seek changes that ensure predictability and sustainability for pharmacy business models, while enabling pharmacists to utilize their training and expertise in providing optimal care to patients and delivering efficiencies to the healthcare system.

Recommendation

Fair funding for the pharmacy services that the ministry procures through community pharmacies is a reasonable expectation. A process, with reasonable timelines, must be established for further discussion on this issue.

b) Short term dispensing

Discussion

The August 2008 regulation limiting the payment of dispensing fees to twice per calendar month has had a tremendous impact on the provision of compliance dispensing services for many vulnerable Ontarians, in spite of the exemptions to the policy. Standard practice includes compliance dispensing in increments of seven days based upon the construction of packaging and on efficiencies relating to medication management. With the exception of February, pharmacists cannot provide accurate and predictable service for each calendar month under the terms of the current regulation.

To efficiently operationalize the process for those patients who can safely receive a 14 day supply of medication, a switch to a bi-weekly policy is necessary. Under the current regulation, pharmacies are effectively being asked to absorb the costs of service for two billing cycles each year; in addition, regulations prohibit pharmacies from directly charging ODB patients for unpaid fees. Furthermore, where a patient or their agent requests more frequent dispensing, Section 9 of the *Drug Interchangeability and Dispensing Fee Act* expressly obligates the pharmacist to honour the request. It is unreasonable to expect that pharmacies will continue to provide these essential, but resource-intensive, services in the absence of compensation. These issues need to be quickly addressed through this regulatory review process so that patient care is not adversely affected.

To date, the ministry has been receptive to suggestions and comments put forth by pharmacy as they relate to the exemptions to the dispensing fee regulation. However, with a view toward optimal patient care, gaps still remain within the patient population that need to be addressed collaboratively in order to prevent negative health outcomes and increased strain on the system. There are patients with increased needs living in residences outside of those exempted by the Long Term Care Act and Homes for Special Care Act. These patients live in homes that generally have fewer, if any, staff trained to administer medications; accordingly, they rely on the expertise of their community pharmacist to provide compliance packaging on a weekly basis and to monitor the use of their chronic medications. There are other patients who desire to live independently in the community. Many of them proudly struggle with daily activities such as shopping, cooking, and cleaning; however they are at increased risk of harm secondary to non-compliance with multiple medications. Through pharmacists' provision of compliance dispensing services, these individuals will be less likely to suffer negative consequences of medications mismanagement and will not be causing any additional strain on the healthcare system.

While discussions are underway with OPA, it is imperative that the ministry works with pharmacy and patient groups to establish a patient-centred approach to compliance dispensing. In the long term, this would be irrespective of a specific drug or place of residence, focusing instead on the individual's personal and medical circumstances and substantiated by pharmacist's professional judgment. This would eliminate the complexity of establishing facility-based criteria for exemption purposes. In the short term, we offer to work collaboratively with the ministry to consider an interim expansion of the exemption list to include retirement homes, group homes and others not currently exempt, but where patients have special needs.

Recommendation

In line with practice, the regulations should be amended to reimburse one dispensing fee every fourteen days.

As a short-term measure, we recommend that there be an expansion of the exemptions to include patients living in settings that include, but are not limited to, private retirement residences and group homes. These locations can be exempted from the policy either through pre-defined criteria for the facilities as a whole or through criteria for identified patients within those facilities. These location-specific criteria are meant solely as an interim measure to ensure that the most vulnerable of patients have access to compliance dispensing services.

In parallel, the ministry should consider a patient-centred policy as proposed by OPA, relying on the pharmacist's professional judgment, which could be implemented on an exception basis for those patients whose medical condition(s) and care plan may require more frequent dispensing. Concurrently, the Pharmacy Costing Working Group could consider alternate reimbursement mechanisms for daily or weekly dispensing.

The legislative restriction that prohibits pharmacies from charging, or accept payment from, a person other than the Executive Officer, including private third party drug plans, in respect of supplying a listed drug product for an eligible person pursuant to a prescription, should be addressed. The regulations should be amended to allow pharmacies to charge for services that are not reimbursed by the Executive Officer, should the patient request those services, as is the case with the recent agreement in BC.

c) Implementation timeframes and transition strategy

Discussion

We have submitted on many occasions that both practice and business transition strategies need to be identified to successfully implement significant policy changes. This includes necessary adaptation of business and operational plans, and implementation of practice supports.

As one example, a recent article in the Canadian Pharmaceutical Journal³ identified several barriers to implementing the MedsCheck program, including:

- The need for an additional pharmacist to cover the dispensary while MedsChecks were being conducted,
- Having to conduct MedsChecks outside regular shifts,
- Training technicians,
- Lack of time,
- Frequent interruptions,
- Documentation requirements, and
- Lack of a private room.

These are issues that can be addressed through consultation with front-line stakeholders during policy development and with accompanying transition strategies, including the enabling and adoption of the necessary supporting infrastructure.

Recommendation

Transition and implementation strategies should be incorporated as a part of the change management process for significant policy changes, and timelines for policy change should incorporate these processes. Pharmacy is creating a framework for the funding of pharmacy services and the implementation of professional services, which includes a transition strategy to ensure that the necessary infrastructure is in place to allow new policies to be successfully implemented. We request the opportunity to review this document with the ministry to inform future policy change and implementation.

d) Payment of applicable markup on Cost-to-Operator Claims

Discussion

In a communiqué from December 18, 2006, the Executive Officer stated that after March 1, 2007, cost-to-operator claims will be restricted to situations where a pharmacy is unable to acquire a generic product and must dispense the original product or a higher priced generic product.

While the provision for cost-to-operator claims remains, the funding provided to pharmacies for dispensing these claims does not reflect the recognized funding formula for pharmacy, in that it does not include a markup; section 6(3) only reimburses pharmacy for the acquisition cost. However, the cost to the pharmacy for procuring product and dispensing these claims is the same, if not higher, than those for regular claims, as the pharmacies must source and procure product outside of the regular pharmacy formulary. It should be noted that the markup is provided to pharmacies to ensure that certain costs and expenses incurred in stocking inventory of interchangeable listed drug products is compensated.

³ Initial pharmacist experience with the Ontario-based MedsCheck program; L Dolovitch, A Gagnon, C McAiney, L Sparrow, S Burns, Vol 141 No 6

Recommendation

A change should be made to the regulations to permit a markup on cost-to-operator claims.

e) Notice of update to the formulary

Discussion

The lead time between the release date and the effective date of updates to the Ontario Drug Benefit Formulary does not allow for the appropriate management of patients or inventory systems, which requires:

- adequate inventory levels for patients, including the brand product while sourcing the interchangeable product
- time to make the required adjustments to computer systems, which must occur during standard business hours in a certain sequence
- selling through of the brand product in pharmacy inventory

Recommendation

To ensure that Ontarians have uninterrupted access to medications, while maximizing savings to the ministry, we recommend that the approach used in Alberta be implemented in Ontario, whereby the generic is listed but the brand is still reimbursed for 60 days. Using this approach, as soon as brand stock is depleted the generic is dispensed and reimbursed, and the ministry benefits from savings while allowing natural depletion of brand stock at pharmacies. This solution allows generic manufacturers adequate time to increase production, and allows pharmacy to manage inventory levels and ensure appropriate patient care.

f) Pricing of Off Formulary Interchangeable (OFI) products for private sector sales

Discussion

The Executive Officer has the ability to designate products as interchangeable, but to select not to include them as reimbursable products on the ODB Program. The Executive Officer has also chosen to include prices in the formulary for OFI products, which is inconsistent with a statement in the December 18, 2006 Executive Officer communiqué which identifies that the Executive Officer has no role in pricing other than as stated in the ODBA, for ODB-eligible recipients. While DIDFA relates to interchangeability and dispensing fees in the private sector, it does not refer to pricing. Therefore, the inclusion of prices for OFI products dispensed to patients with private sector or cash paying patients is questionable.

Recommendation

Prices should not be included in the ODB Formulary for OFI products.

Thank you for the invitation and opportunity to comment on the Definition of Professional Allowances and the Codes of Conduct, and we look forward to participating in the stakeholder consultations which will be held to discuss written proposals.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Nadine Saby".

Nadine Saby
President and Chief Executive officer
Canadian Association of Chain Drug Stores

A handwritten signature in cursive script, appearing to read "Dennis A. Darby".

Dennis A. Darby, P. Eng.
Chief Executive Officer
Ontario Pharmacists' Association