



ONTARIO  
PHARMACISTS  
ASSOCIATION

Office of the Chief Executive Officer

November 27, 2019

Mr. Patrick Dicerni  
Assistant Deputy Minister, Drugs and Devices Division  
Executive Officer, Ontario Public Drug Programs  
Ministry of Health  
5700 Yonge St., 3<sup>rd</sup> Floor  
Toronto ON M2M 4K5

Via Email: [Patrick.dicerni@ontario.ca](mailto:Patrick.dicerni@ontario.ca)

Dear Mr. Dicerni,

**RE: Reducing Administrative Burden to Drug Manufacturers and Pharmacies**

We appreciate the opportunity to respond to the posting of proposed amendments under the *Ontario Drug Benefit Act (ODBA), 1990, O.Reg. 201/96* and the *Drug Interchangeability and Dispensing Fee Act (DIDFA), 1990, O.Reg. 935*.

The Ontario Pharmacists Association is committed to evolving the pharmacy profession and advocating for excellence in practice and patient care. With more than 10,000 members, OPA is Canada's largest advocacy organization and continuing professional development provider for pharmacy professionals across Ontario. By leveraging the unique expertise of pharmacy professionals, enabling them to practise to their fullest potential, and making them more accessible to patients, OPA is working to improve the efficiency and effectiveness of the healthcare system.

Ontario's community pharmacists and technicians – and the pharmacies in which they practise – play a critical role in ensuring that patients have timely access to the safe and effective medications they need to manage their health conditions and achieve positive health outcomes and an improved quality of life. For the people of Ontario, pharmacists are often the most accessible healthcare providers – playing a key role as a community resource for health information, particularly in rural or remote communities.

Ontarians rely on their pharmacists to offer trusted advice and guidance on matters related to health and wellness as well as to ensure a safe, secure and continued supply of medication. Patients have come to expect that their community pharmacists will continue to support them personally in any way they can while helping at the system level to reduce health costs through the management and prevention of illness and keeping patients out of hospitals. As our health system evolves and demand for healthcare continues to grow, pharmacies and other health centres also need to evolve in order to accommodate the needs of patients. With escalating costs of doing business, pharmacies need the flexibility to be able to address the growing demand for services while remaining viable



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and sustainable. It is for this reason that we welcome efforts of government to reduce regulatory burdens that may restrict the ability of pharmacy owners to be nimble, agile and competitive as they strive to enable the pharmacy professionals they employ to appropriately and effectively address the needs of their patients.

We appreciate the Ontario government's willingness to work with the Ontario Pharmacists Association and acknowledge this collaboration as a symbol of the government's trust in the profession. Notwithstanding the proposed regulatory amendments to the ODBA and DIDFA, there is still much work to be done, and OPA is encouraged by the recent high degree of collaboration in addressing budgetary reforms and that together, government and the Association can address and mitigate the barriers facing the business and pharmacy professionals that interfere with their provision of high-quality care.

### **Commentary on the Proposed Regulatory Changes**

1. Remove the requirement for the Drug Notification Form (DNF) from all ODB Formulary drug submissions.
2. Reduce requirements for biosimilar drug submissions to simplify and align with national processes.
3. Permit generic drug price adjustments.
4. Streamline drug submission requirements for generic line extension.
5. Revoke provisions authorizing Ontario to conduct price review of certain single source generic products as the required pricing assessment is already conducted through the current pan-Canadian generic pricing framework.
6. Facilitate the management of drug shortages by allowing Ontario to provide short-term public funding, through the exemption of certain drug submission requirements, for clinically-appropriate alternate drugs that are not currently funded.
7. Extend submission window for electronic drug claim reversals from 7 days to 90 days.
8. Amend the definition of the Pharmacy Reference Manual to facilitate the publication of new versions of the Manual.
9. Modify the cap for ordinary commercial term (OCT) payments from 10% to 25%

With respect to the nine proposed changes to the ODBA and DIDFA regulations, OPA acknowledges that items 1 through 6 relate more specifically to pharmaceutical manufacturers and will therefore defer commentary on them to other stakeholders. That said, item 6 relates to efforts being taken by the Ontario government to remove regulatory burdens that may facilitate the management of drug shortages in Canada. OPA is firmly supportive of any efforts being made to ensure that patients can continue to receive their needed treatments in an uninterrupted manner, whenever possible. Although item 6 does not address the cause of the shortages, it will provide manufacturers and pharmacists with options to ensure continuity of care and will restore patients' confidence in Ontario's drug supply.

On items 7 through 9 of the proposed regulatory changes, OPA offers the following comments and feedback. Regarding item 7, OPA is very pleased with the Ontario government's intent to extend the submission window for electronic claims reversals from 7 days to 90 days. This will be very welcome news both to community pharmacy professionals and government claims adjudicators alike as this will eliminate the labour-intensive process of completing and processing manual, paper-based reversal forms. Speaking from the community pharmacy perspective, the less time spent filling out paper reversal forms means more time available for direct patient interaction and care.



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As it pertains to item 8, OPA also welcomes the streamlining of publication and amendments to the Pharmacy Reference Manual for easier and more timely access to this important reference document.

Finally, on item 9, while OPA acknowledges that on the surface, elevation of the cap on Ordinary Commercial Terms (OCT) from 10% to 25% may seem positive, in fact it offers no real change in the amount of work and red tape required to process and document any receipt of funds as deemed eligible under OCT. This consultation is not the first time OPA has provided commentary on OCT; in fact, the Association has come to alignment on two key regulatory changes consistent with our initial proposal shared with the Ontario government exactly one year ago today on November 27, 2018:

- i. Removing the current 10 per cent restriction on ordinary commercial terms; and
- ii. Enabling private label generic products to be considered as listed products under the Ontario Drug Benefits Act (ODBA) and/or as interchangeable products in accordance with the Drug Interchangeability and Dispensing Fee Act (DIDFA).

OPA contends that these changes, when considered together, will bring Ontario in line with regulations and policies in other provinces, promote fair competition between large corporate and small independent pharmacy operators and deliver value for government. Most importantly, these changes will contribute to the Quadruple Aim of healthcare by helping to preserve and enhance patient access to new and current professional services (including those within an expanded scope of practice), stabilizing drug supply, reducing costs to government, improving provider experience in their delivery of healthcare services while simultaneously protecting jobs.

### **OPA's Recommendation on Item 9**

It is the strong recommendation of OPA that *Ontario Regulation 201/96* and *Regulation 935* of the ODBA and DIDFA, respectively, are amended to completely remove the cap on Ordinary Commercial Terms.

When private label generic products were prohibited in 2010, the previous government created Ordinary Commercial Terms (OCT). OCT are permitted if they relate to any of the following: a prompt payment discount, a volume discount or a distribution service fee, and only if the total value of any benefit does not exceed 10 per cent of the value of the listed drug.

The arbitrary cap imposed on these terms – whether it is at 10%, 25% or another figure – prohibits pharmacies from running their businesses effectively and competitively and prevents pharmacies from operating under a normal business practice that is widely accepted in any other retail business operation.

OPA's position is that the cap on OCT must be removed completely, thereby allowing the Ontario government to reduce red tape and ensure the competitiveness and sustainability of Ontario pharmacies.

By removing the cap on OCT and following through with the implementation of the regulation to allow for private label generics as posted in October 2018, the Ontario government can continue to support the sustainability of the pharmacy sector and ensure that pharmacists can continue to provide high-quality care to their patients across the province. These changes, when considered



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together, will bring Ontario in line with regulations and policies in other provinces, promote fair competition and deliver value for government.

We appreciate the opportunity to provide our feedback to *Ontario Regulation 201/96* and *Regulation 935* of the ODBA and DIDFA, respectively. OPA looks forward to continuing to work with the Ontario government and the Ministry of Health.

Should you have any questions or concerns related to this submission, please do not hesitate to contact me at your earliest opportunity.

Yours sincerely,

A handwritten signature in black ink, appearing to read "Justin J. Bates".

Justin J. Bates  
Chief Executive Officer

cc: The Honourable Christine Elliott, Deputy Premier and Minister of Health  
Ms. Harpreet Bassi, Director of Policy, Ministry of Health  
Ms. Jen Baker, Chair, Board of Directors, Ontario Pharmacists Association  
Mr. Allan Malek, EVP and Chief Pharmacy Officer, Ontario Pharmacists Association  
Ms. Sandra Hanna, Interim CEO, Neighbourhood Pharmacy Association of Canada