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NEIGHBOURHOOD PHARMACY ASSOCIATION OF CANADA SUBMISSION IN RESPONSE TO HEALTH SECTOR PAYMENT TRANSPARENCY ACT DRAFT REGULATIONS

The Neighbourhood Pharmacy Association of Canada (Neighbourhood Pharmacies) appreciates the opportunity to provide input during the consultation period ending April 6, 2018, in response to the draft regulations under the Health Sector Payment Transparency Act (the Act).

In recent years, Ontario's pharmacy and the pharmaceutical sectors have provided the government guidance to deliver on the policy objective of enhanced access to affordable quality community based care. Neighbourhood Pharmacies and its members remain committed to continued dialogue and collaboration to ensure that Ontarians have access to services in pharmacy to optimize pharmacotherapy and improve health outcomes.

While we agree that transparency in healthcare is important to ensure unbiased patient care, we believe that the spirit of these proposed regulations reaches far beyond the protection of the public, and poses undue burden on the payors and recipients defined in the Act. We believe that the underlying objective of achieving transparency in healthcare should be the assurance of public safety through the prevention of commercial influence on prescribing and healthcare decisions. This is the perspective that other jurisdictions have taken when enforcing such transparency regulations. We feel, however, that the objective of the proposed Health Sector Payment Transparency Act is unclear and seems to be an excessively broad, information-gathering initiative that seeks to uncover private business practices with no clear benefit to the public. The regulations, and indeed the Act itself unnecessarily target the pharmaceutical, medical device and pharmacy sectors, while the Government of Ontario and various other sectors are engaged in commercial transactions whereby there are significant transfers of value.

We ask that the Ministry reconsider the purpose of this Act to ensure that the proposed regulations have a narrower scope and truly address specific concerns rather than what currently seems to be a broad imposition of disclosure requirements that have a plethora of unintended consequences without clear benefit to the public and may inadvertently subvert competition within the sector and disclose competitive intelligence. We have outlined some of our primary concerns below.

INADEQUATE CONSULTATION AND IMPLEMENTATION TIMEFRAME

With respect to the draft regulation for the Health Sector Payment Transparency Act, we again request that the consultation period be extended and implementation be delayed to ensure a robust consultation and reasonable time to conduct an impact analysis. The number of transactions that will be captured by this regulation is significant and to provide a proper assessment, more time is required. The regulations define a total of 31 "recipients", representing at least 31 distinct groups of stakeholders who are impacted.

If this regulation is adopted hastily, without a comprehensive review of its implications, Neighbourhood Pharmacies believes that there will be unintended consequences that will not enable patients to make more informed decisions about their healthcare or increase public trust and confidence in the care provided to them.

Furthermore, to ensure compliance with the *Reducing Regulatory Costs for Business Act*, and in order for us to determine the impacts on members of the related costs of implementation for new equipment, IT purchases, training, recordkeeping, reporting and other administrative activities imposed by the proposed regulation, more time is needed.

UNDUE ADMINISTRATIVE BURDEN ON IMPACTED STAKEHOLDERS

Neighbourhood Pharmacies believes that disclosure activities for the list of recipients defined, when considered in conjunction with the definitions for transfers of value, encompass a plethora of standard daily transactions that occur within the stakeholders impacted. Several of the definitions in the regulations are opaque and may lead to unnecessary business uncertainty and a lack of predictability on compliance.

Primarily, we feel the \$10 threshold on transactions is unrealistically low and seems designed to do little more than assert government's regulatory authority without real purpose. This threshold would force payors to report on literally every transfer of value beyond an inconsequential amount. This will impose an enormous burden on payors and require them to make major new investments in resources, estimated to cost upwards of millions of dollars per organization, to administer and report on. A regulation is only effective if it is in the public interest and is enforceable. We suggest that a \$10 threshold accomplishes neither objective. It seems unclear to Neighbourhood Pharmacies why the government would want to exempt the reporting of "medical products", which we interpret to include medical samples, while imposing a reporting requirement on transfers of value of as little as \$10.00 – which we feel is unlikely to have any impact on public safety. Additionally, the majority of stakeholders in the industry are national in scope, and these regulations are being imposed only in Ontario, which will pose additional challenges in reporting and administration.

We are therefore challenged to understand how these proposed regulations align with the commitment made in Ontario's Reducing Regulatory Costs for Business Act (RRCBA) and feel this will make Ontario less competitive in attracting new businesses and innovation, when compared to other jurisdictions.

INADEQUATE TIMEFRAME FOR REPORTING

The timeframe for reporting is insufficient for industry, given the broad scope. We understand that the timeframe was selected based on the experience with similar regulations in other jurisdictions, however, it should be noted that the scope of these regulations is much broader and involves many more stakeholders, and significantly more exhaustive reporting.

BREADTH OF THE PROPOSED REGULATIONS – DEFINITIONS OF PAYORS, RECIPIENTS AND TRANSFERS OF VALUE

Although the Act was initially said to have been informed by similar transparency legislations in other jurisdictions, the Ministry has broadly defined recipients and transfers of value, irrespective of their impact on public safety and therapy decisions. We therefore feel that the breadth of these definitions does not achieve any significant value for the public, and so should be re-evaluated to ensure that only those recipients and transfers of value that directly impact patient care decisions be included in these regulations.

Although there are 24 distinct “Transfers of Value” listed in this section, Neighbourhood Pharmacies believes that these could be construed to include other transfers that should otherwise be exempt, including but certainly not limited to, the following:

- Services that directly impact patient care
- Liability insurance
- In-house training
- Internal meeting expenses
- Staff parties and investment in professional development
- Costs of distribution

Regarding research funding in particular, most investments made by pharmacy organizations in the healthcare sector are made through unrestricted grants that support research and development in a variety of clinical areas without direct disclosure of expenditure from the research organizations to the donors. This process ensures objectivity of research while preventing donors’ involvement and interference in the studies. The reporting requirements of these proposed regulations will complicate this relationship and may result in a chill effect leading to a reduction of clinical trials conducted in Ontario – a province that, today, is a leader in research and development in healthcare.

Additionally, we feel that membership fees and dues paid to Associations, both provincial and national, professional and trade, Advocacy Groups or Regulatory Colleges should be excluded from the regulations. We feel that trade association dues are not only proprietary, as they are often based on members’ annual revenues, but also have no relation to the intended objectives of the Act. In many cases trade associations are national in scope and so disclosure of dues relating to activities in Ontario alone would be difficult if not impossible to determine. Furthermore, it appears to be an unwarranted intrusion into the not-for-profit operations of a pharmacy trade association which in no way impacts the ability of patients to make more informed decisions about their healthcare.

We firmly believe that pharmacy should not be included under the definition of payor in regulations in which the transfers of value are so broadly defined. Further, we stress a focus on the underlying objective of the Act and argue that the majority of the transactions that would be captured and reported under the Act are routine business transactions that have absolutely no impact on public safety or therapy decisions.

Overall, we urge the Ministry to re-evaluate the definitions with a narrower scope focused on the underlying objectives of the Act, and that transfers of value that provide direct patient benefit, such as patient support programs and services be exempt from these regulations.

Finally, we suggest that some key recipients are missing as the proposed regulations stand. Should these regulations move forward, we envision the need to broaden the scope of the regulations to include Transfers of Value between manufacturers and the Ontario Government. The recent report by the Auditor General noted that the Ministry of Health received rebates of \$1.1 billion from drug manufacturers. The goal of achieving transparency will be advanced through the reporting of these rebates.

DEFINITION OF DRUG AND EXCLUSION OF CONSUMER HEALTH PRODUCTS

Neighbourhood Pharmacies questions the rationale for the definition of “**Drug**” for the purposes of the Act. We recognize the importance of transparency for products listed in the Ontario Drug Benefit Formulary and other products that may not be listed, e.g. products reimbursed under the Exceptional Access Program (EAP), because they are publicly funded, and have a clear “fair market price” – the Drug Benefits Price (DBP), as defined under the ODBA. However, we feel that the inclusion of hundreds if not thousands of over-the-counter (OTC) consumer healthcare products that are not publicly funded drug products would lead to unnecessary reporting and may actually diminish competition among businesses. To include consumer health products while exempting natural health products is arbitrary and inconsistent application of policy.

Therefore, we request an exclusion of consumer health products in addition to the currently excluded natural health products. The only drug products to which this definition should apply should be those reimbursed by the Ontario Public Drug Programs. This can be accomplished by removing the references to the *Drug and Pharmacies Regulation Act* in Section 3 and replacing it with references to the *Ontario Drug Benefit Act* and the *Drug Interchangeability and Dispensing Fee Act*.

The above represents a subset of the critical concerns we have with the breadth of the current definitions; however, the unintended consequences are abundant, and require a thorough review to ensure that the undue burden placed on stakeholders is outweighed by the overall benefits of the Act. The scope of the proposed regulations is broad sweeping. As such, monitoring and enforcement will be challenging without exhaustive allocation of new resources and likely significant burden to Ontario taxpayers.

ANTI-COMPETITIVE NATURE OF UNNECESSARY DISCLOSURE OF BUSINESS PRACTICES

We believe that actions that disrupt the competitive nature of the pharmacy, pharmaceutical and medical device sectors, may be at odds and undermine federal competition law. The regulations as proposed, require the reporting of commercially sensitive information, and public disclosure of organization-specific transactions, without aggregation or redaction. We believe that these requirements for reporting and disclosure will dis-incentivize and in many cases, prevent commercial agreements which ultimately help to reduce overall costs of products and services to patients. Additionally, we feel that public disclosure of commercial transactions may lead to reduced competitiveness between organizations, which will also ultimately lead to increased prices for the end consumers.

CONCLUSION

Neighbourhood Pharmacies understands the intent of the Ontario government to increase transparency in the healthcare system. However, in fulfilling that mandate, the government also has an obligation to develop and implement public policies based on information and evidence that will serve the public interest and not impair the ability of pharmacy and the larger healthcare sector to serve Ontario's 13 million residents and help grow the provincial economy. Ensuring a level playing field for business to operate in Ontario beyond its borders is critical. Ensuring regulatory measures are balanced and do not enact intra-provincial trade barriers is critical, especially as businesses face the economic headwinds of increased competitiveness from the US, and potential trade barriers.

According to data from the Ministry of Economic Development and Growth, Ontario thrives through its unique combination of manufacturing expertise, exports, innovation and resources, and generates 37% of Canadian GDP. Ontario is home to almost 50% of all employees in high tech, financial services and other knowledge-intensive industries. It is therefore vital that the government not exert its statutory authority that singles out the one industrial sector that provides essential healthcare products and services for increased transparency.


Overall, we feel that the scope of disclosure is too broad, and the threshold for reporting is too low, when compared to other jurisdictions with similar regulations. We respectfully urge the Government to lead the way forward on transparency disclosure, and as a first step, disclose all provincially supported research grants and financial support to stakeholders, similar to the Sunshine Act, to determine the feasibility for businesses to adapt and implement the processes required for disclosure and to ensure a level playing field.

We acknowledge and recognize the importance of transparency, as it pertains to maintaining objectivity in the delivery of patient care, and in ensuring that commercial practices do not impact the level of patient care provided; but we fail to see how many of the recipients, payors or transfers of value named in these regulations would impact care. The perspective and benefits not considered in the design of the current draft regulations are that in many cases, these so called "transfers" or rather investments do positively impact patient care through better education, greater patient support services, and ultimately better health outcomes.

We remain concerned that the Act and draft regulation is narrowly focused on the health sector while excluding every other sector in Ontario. The Ontario government collects tax revenues and then procures and pays for hundreds of millions of dollars' worth of goods and services from the food, automotive and dozens of other industries to serve the Ontario public, should these "transfers of value" also be captured for the benefit of the consumer and taxpayer?

We thank the Ministry, and Government, in advance for its consideration, and welcome the opportunity to meet to further discuss the significant impacts of these proposed changes and discuss the opportunities to collectively deliver better care in every community served by our members daily across the province and Canada.

Sincerely,



Justin J. Bates
Chief Executive Officer