CANADIAN PHARMACISTS ASSOCIATION
ASSOCIATION DES PHARMACIENS DU CANADA

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RE: *Notice to interested parties — Proposed regulations amending the* Narcotic Control Regulations, *the* Benzodiazepines and Other Targeted Substances Regulations and *the* Food and Drug Regulations — *Part G to modernize regulations with respect to pharmacists*

On behalf of the Canadian Pharmacists Association (CPhA), we are responding to Health Canada's Notice of Intent to amend the Narcotic Control Regulations (NCR), the Benzodiazepines and Other Targeted Substances Regulations (BOTSR) and the Food and Drug Regulations — Part G (FDR — Part G) in order to better support modern pharmacy practices and address gaps and inconsistencies.

CPhA is the national voice of Canada's 42,000 pharmacists, whose profession has undergone significant changes over the last two decades. Pharmacists have seen their scopes of practice evolve from one focused predominantly on dispensing medications to one of direct patient care and advanced medication management services. This shift has coincided with the enhanced education of pharmacists through the Doctor of Pharmacy degree, the regulation and expanded scope of practice of pharmacy technicians, changing demographics and health care needs of Canadians, as well as changing drug distribution models and technological advancements.

Health Canada has acknowledged in its consultation notice that various amendments have been made to the regulations over the years in a piecemeal fashion, and these may not all account for how the practice of pharmacy, associated technologies and drug distribution methods have evolved. Certain pieces of legislation and regulations may now act as barriers for pharmacists and regulated pharmacy technicians to achieve the best possible patient care and practice-level efficiencies. To address these barriers, we propose the following recommendations to Health Canada:

Pharmacists' value and recommendations with respect to opioids

1. Amend the Controlled Drugs and Substances Act (CDSA) to include pharmacists as "practitioners" authorized to adapt controlled drugs and substances.

2. Require that all products containing codeine be available by prescription only.

3. Review and assess the impact of the opioid warning labels regulations and provide support for pharmacy-led, opioid education and counselling programs.

Modernizing regulations specific to prescribing, record keeping and drug distribution practices

4. Include clear provisions within the regulations for electronic prescribing of narcotics, controlled drugs, benzodiazepines and targeted substances, along with modernized record keeping requirements to reflect electronic record keeping processes.

5. Authorize pharmacists and regulated pharmacy technicians at the federal level to dispense a narcotic, controlled drug, benzodiazepine and targeted substance pursuant to a prescription or an order from another pharmacy to enable central fill.

6. Authorize pharmacists and regulated pharmacy technicians at the federal level to sell or transfer a narcotic, controlled drug, benzodiazepine and targeted substance to another pharmacist or regulated pharmacy technician outside of the current requirement that it be done only for emergency purposes.

7. Authorize pharmacy employees to possess, transport and deliver narcotics, controlled drugs, benzodiazepines and other targeted substances.

Regulated pharmacy technicians

8. Grant regulated pharmacy technicians the authority at the federal level to accept verbal prescriptions, receive orders, destroy and perform all other functions related to the distribution of narcotics, controlled drugs, benzodiazepines and targeted substances.

The amendments to the regulations must not only accommodate new and emerging pharmacy practice and business environments, but Health Canada should ensure that these amendments provide an improved level of clarity and consistency across the various regulations. As a final recommendation, we would ask that Health Canada hold targeted consultations with pharmacy stakeholders as the changes to the regulations are being considered.

1. ***Amend the Controlled Drugs and Substances Act (CDSA) to include pharmacists as "practitioners" authorized to adapt controlled drugs and substances.***

Opioid use disorder may be attributed to many factors, ranging from a person's environment, health, socio-economic situation, etc. However, prescribing and dispensing practices by health care professionals have played an undeniable role in the opioid crisis currently unfolding across Canada. As drug experts with an obligation to ensure safe and optimal use of medications, pharmacists want to do more to resolve this health crisis.

CPhA has repeatedly called for legislative changes to allow pharmacists to play a greater role in the prevention and treatment of opioid harms and dependency, including in the area of appropriate opioid prescribing and

dispensing. Pharmacists can accomplish this through increased monitoring and interventions of prescribing and dispensing practices. To enable such interventions, the Controlled Drugs and Substances Act (CDSA) must be amended to include pharmacists as "practitioners" authorized to prescribe controlled drugs and substances.

In most provinces across Canada, pharmacists have the authority to prescribe or adapt prescriptions. This can involve making adjustments to dosing, quantities, dosage forms or directions for a particular medication. And in the case of an adaptation to an original prescription, pharmacists are always required to communicate any changes to the original prescriber. As with other schedule 1 drugs, pharmacists should be enabled to use their professional judgement to make similar adaptations to controlled drugs and substances. However, the CDSA does not currently include pharmacists in the list of practitioners who can prescribe and adapt CDSA-scheduled drugs.

It is common for community pharmacists to receive prescriptions for inappropriate dosages and quantities of initial opioid prescriptions. By designating pharmacists as "practitioners" within the CDSA and ensuring pharmacists have access to the indication for opioid treatment, pharmacists would be authorized to adapt, reduce or taper the dosage of opioids for patients, where appropriate, and instead prescribe or recommend alternative therapies, while ensuring that the original prescriber is consulted and notified of any changes. With this authority, pharmacists would also be able to work more closely with patients and health care teams to manage opioid replacement therapies, such as methadone and buprenorphine/naloxone (Suboxone), to ensure continuity of care, achieve appropriate dosing and provide better overall patient support.

Pharmacists in Saskatchewan have recently been granted a temporary exemption from the CDSA and regulations in order to prescribe and provide methadone and buprenorphine to patients. Health Canada, the provincial ministry and regulatory colleges collaborated to enable this exemption in the wake of a severe shortage of Saskatchewan physicians able and willing to prescribe opioid dependency treatment. We commend Health Canada for taking this step to enable pharmacists to better care for patients left vulnerable by prescriber shortages. We hope this experience will demonstrate the value of pharmacists in opioid dependency treatment and in communities lacking access to prescribing physicians.

Given the toll that opioids have taken on our society, we must allow all health care practitioners to use their expertise to help solve this crisis. As the most accessible, community-based health care professionals, pharmacists are ideally positioned to close the care gap and improve drug therapy management, oversight and risk mitigation for patients receiving opioid therapy and dependency treatment.

2. Require that all products containing codeine be available by prescription only.

For some time, pharmacists have been challenged by the availability of non-prescription low-dose codeine products. The regulations state the pharmacists may, without a prescription, sell a preparation containing up to 8 mg of codeine per tablet or up to 20 mg per 30 mL in liquid preparation if the preparation contains at least two additional medicinal ingredients other than a narcotic (S.36.1 NCR). Despite the legality of dispensing such products without a prescription, these low-dose combination codeine products are known to have little benefit over non-codeine containing analgesics and are associated with considerable harms. Such harms include misuse

and dependence, but also serious adverse effects related to the additional medicinal ingredients, which are often non-opioid analgesics, such as acetylsalicylic acid (ASA) and acetaminophen. High doses these analgesics may also result in serious adverse effects. Those struggling with dependency to low-dose codeine products are at risk of ingesting dangerous amounts of these analgesics.

Taking into consideration the risks associated with high doses of simple analgesics, the addictive potential of codeine, as well as the overall effectiveness of analgesics containing codeine compared to non-opioid analgesics, there is limited evidence available that would support the use of low-dose codeine pain medication over non-opioid analgesics. Further, gaps in the current system that allow for the misuse of low-dose codeine products include limited access by pharmacists to patient medical histories through electronic health records (EHR), medication histories through drug information systems (DIS) and prescription monitoring programs (PMP), which are specifically designed to detect drug misuse and diversion. Without these key monitoring tools, pharmacists are unable to know if a request for low-dose codeine is appropriate for the patient. Patients who misuse codeine may also be quite savvy to the system's monitoring flaws; convince pharmacists that no other analgesics have worked to manage their pain; and be persistent by visiting multiple pharmacies until they are able to obtain the product.

By continuing to authorize the availability of codeine as a non-prescription product at the same time as we move further towards encouraging patient self-care, policy-makers are contributing to the idea that low-dose codeine products are safe and effective treatment options. Without considerable investments in integrated EHR, DIS and PMP tools, pharmacists will continue to be significantly challenged to prevent the growing misuse and dangers associated with non-prescription codeine. As such, and consistent with our submission to Health Canada's public consultation on this topic in September 2017, CPhA is urging Heath Canada to require that all products containing codeine to be sold by prescription only.

3. *Review and assess the impact of the opioid warning labels regulations and provide support for pharmacy-led opioid education and counselling programs.*

Opioid warning stickers and patient handouts are tools that can be effective in informing Canadians of the risks associated with opioids, but they should be used at the discretion of the pharmacist and in conjunction with other forms of patient counselling and education. Used alone, this simple messaging tactic could be interpreted incorrectly, reach the wrong audience and add administrative burden to pharmacy practices.

While CPhA understands and strongly supports the need for patient education around the dangers associated with opioids, we question the effectiveness of mandatory auxiliary labels and generic patient information leaflets for all opioid prescriptions and at each refill. We further believe that pharmacists, as highly educated health care practitioners, must be able to exercise professional judgment and apply individualized patient-centred care in determining what information to supply to their patients through regular counselling.

The warning labels and patient handouts mandated within the regulations are contributing to unnecessary waste at an added financial cost to pharmacy practices. These costs were estimated within Health Canada's impact

analysis to be $76,522,000 for pharmacies over a 10-year period when discounted at 7%. These costs are not insignificant, and we have heard from many within the profession who say this it is negatively impacting pharmacy practice.

Pharmacists have a critical role to play in all aspects of the opioid epidemic, from patient education and counselling to drug therapy management and identifying and treating addiction. In order for pharmacists to be successful in this task, they must be able to use their expertise and professional judgement in communicating information to patients and managing medication therapy. Strict regulations enforcing passive, wasteful and ineffective communication methods will not achieve a more educated patient population on the safe use and associated risks of opioids. We, therefore, urge Health Canada to review and assess the opioid warning labels regulations and support more wholistic, collaborative and patient-centred strategies, such as pharmacy-led comprehensive opioid prescription counselling programs, to ensure the safety and education of patients who are prescribed opioids.

4. *Include clear provisions within the regulations for electronic prescribing of narcotics, controlled drugs, benzodiazepines and targeted substances, along with modernized record keeping requirements to reflect electronic record keeping processes (e.g. organized by patient, not by date and time).*

Electronic prescribing is an evolutionary practice that governments, regulators and health care practitioners can agree has the potential to enhance patient care and improve patient safety. E-prescribing can reduce transcription errors, improve monitoring, improve interprofessional communications, reduce diversion and support health care practitioners with patient drug profiles and other alerts.

In their current form, the NCR, BOTSR and FDR regulations specify that prescriptions may be authorized by a practitioner either in “written” format or verbally. Unlike orders, the regulations do not provide a definition of how a written prescription may be transmitted. While this may allow for some level of interpretation, CPhA believes that an explicit provision for electronic prescribing and the receipt of such prescriptions by pharmacies may provide the clarity required to modernize and develop further provisions for electronic prescribing at the provincial level. CPhA, therefore, recommends that the language contained within the regulations be updated to explicitly include electronic prescribing as a legitimate means of communicating a prescription.

Further, Health Canada must ensure that the regulations do not act as barriers to electronic record keeping processes in pharmacies. For example, regulation 40(1) of the NCR specifies that pharmacists shall maintain a special narcotic prescription file in which dispensed narcotics will be filed in sequence by date and number. Tracking the controlled drugs and substances dispensed through pharmacies is an important requirement to which pharmacies must adhere in an effort to guard against loss or diversion. However, it is possible that modern record keeping technologies can produce different yet equally effective tracking methods for controlled drugs. We recommend that Health Canada consult further with pharmacy stakeholders to ensure that record keeping regulations are also conducive to modern pharmacy record keeping technologies and practices.

5. *Authorize pharmacists and regulated pharmacy technicians at the federal level to dispense a narcotic, controlled drug, benzodiazepine and targeted substance pursuant to a prescription or an order from another pharmacy to enable central fill.*

Central fill pharmacies (or centralized prescription processing pharmacies) provide a valuable service to retail pharmacies whereby they prepare and package prescriptions for retail pharmacies to dispense directly to patients. Prescription information is transmitted from the retail pharmacy to a central fill pharmacy where the prescription is filled or refilled. The filled prescription is then delivered to the retail pharmacy where the pharmacy team dispenses the prescription to the patient. Many pharmacies are taking advantage of central fill models and transferring time-consuming, repetitive and distributive duties to these practices in order to maximize efficiencies and save space and community pharmacy resources for more patient-centred care and services.

As stated in the regulations, however, the sale or provision of narcotics or controlled substances from one pharmacy to another is allowed only in emergency situations, and if required because of a delay or shortfall in an order for benzodiazepines or targeted substances placed with a licensed dealer. This restricts central fill pharmacies from filling or refilling prescriptions for drugs listed in the Controlled Drugs and Substances Act (CDSA) and accompanying regulations.

CPhA opposes these restrictions and believes that central fill pharmacies have the appropriate oversight and security to be authorized to fill controlled drugs and substances. These pharmacies must obtain accreditation by provincial regulators and are held to the same high standards as community pharmacies that service patients directly. CPhA recommends, therefore, that the regulations be updated and amended at the federal level to allow pharmacists and regulated pharmacy technicians to dispense a narcotic, controlled drug, benzodiazepine and targeted substance pursuant to a prescription or an order from another pharmacy to enable central fill.

6. *Authorize pharmacists and regulated pharmacy technicians at the federal level to sell or transfer a narcotic, controlled drug, benzodiazepine and targeted substance to another pharmacist or regulated pharmacy technician outside of the current requirement that it be done only for emergency purposes.*

A pharmacist or pharmacy technician's ability to transfer a prescription to another pharmacy on the request of a patient is an important service that promotes patient choice. This service, however, does not extend to narcotics and other controlled drugs. When pharmacies are not able to transfer these prescriptions, it adds a significant administrative burden on both the pharmacy team and the original prescriber, who must then issue a new prescription for the patient to provide to the new pharmacy. This may also contribute to unnecessary delays in a patient's treatment. In consideration of the rigorous record keeping requirements for controlled drugs and substances, CPhA believes that with the appropriate policies and procedures, the pharmacy team's ability to transfer such prescriptions would result in benefits to patients and health care practitioners while not imposing additional risks to the security of the drug distribution chain.

In addition to prescription transfers, pharmacists and pharmacy technicians should be authorized at the federal level to sell a controlled drug or substance to another pharmacy outside of the current regulatory requirement

that this be done only for emergency purposes. Beyond enabling central fill processing, instances may arise when a pharmacy may not be able to order controlled drugs and substances from a supplier. Rural pharmacies, for example, may team up to jointly purchase drugs from suppliers, who often have minimum order requirements. If one pharmacy runs low on a product, they will often sell stock to each other until a larger order must be made to the supplier. Enabling this practice for controlled drugs and substances would greatly improve patient access to their prescribed drug therapy.

Another case demonstrating the benefit of selling controlled drugs and substances between pharmacies is when one pharmacy offers specialty compounding. Vulnerable patients who require specialized drugs prepared in a compounding pharmacy may have difficulty accessing such pharmacies, especially patients in rural areas. If pharmacists and pharmacy technicians were authorized to sell controlled drugs and substances to other pharmacies, patients would be able to obtain specialized compounded narcotics from their regular community pharmacist, who has knowledge of and access to their full patient profile and medication history.

7. *Authorize pharmacy employees to possess, transport and deliver narcotics, controlled drugs, benzodiazepines and other targeted substances.*

Community pharmacy medication delivery is an essential service to any patient with mobility restrictions or who are otherwise homebound. Pharmacy home delivery services are growing in response to an aging population and an increasing burden of chronic disease. Where this service is available, the pharmacist will deliver medications directly to patients or counsel patients by phone and have an employee deliver the patient's medication. The legislation does not currently allow for the home delivery of controlled drugs and substances by pharmacy employees. The CDSA defines the transport or delivery of narcotics as trafficking and the NCR limit the transport of narcotics to licensed dealers only.

These regulatory barriers may pose direct and negative impacts on patient access to drug therapy. With the appropriate regulatory framework, safeguards and procedures, CPhA believes that pharmacists, pharmacy technicians and other pharmacy employees, such as delivery drivers, should be authorized to possess, transport and deliver narcotics, controlled drugs, benzodiazepines and other targeted substances. This would allow pharmacies to deliver such medications to vulnerable patients along with other schedule I medications.

8. *Regulated pharmacy technicians should be granted the authority at the federal level to accept verbal prescriptions, receive orders, destroy and perform all other functions related to the distribution of narcotics, controlled drugs, benzodiazepines and targeted substances.*

Regulated pharmacy technicians are an integral part of the pharmacy team. Where they are licensed and work to the full scope of their skills and training, they are responsible for the full technical aspects of drug distribution and delivery within a pharmacy practice. This can include ordering, receiving and managing inventory; counting, compounding, measuring and labelling drug products; ensuring that product and technical aspects of a prescription are accurate; dispensing, and managing drug and patient records.

Pharmacy technicians are expected to perform the distributive activities of a pharmacy by adhering to and applying federal and provincial legislation, regulations, by-laws and standards of practice. Their independent authority and liability conform to requirements of regulatory authorities within their respective provinces.

The ability of pharmacy technicians to work to full scope is an essential enabler to allow pharmacists to remove themselves from the technical aspects of a pharmacy practice and focus their efforts on therapeutic aspects of patient care, such as medication and chronic disease management. In the case of controlled drugs and substances, enabling pharmacists to devote their time and resources to direct patient care becomes even more important.

While full scope has been granted to pharmacy technicians at the federal level for distributive activities related to schedule 1 drugs, pharmacy technicians are still restricted from certain activities related to narcotics and controlled drugs, including receiving orders from licensed dealers, accepting verbal orders and destruction activities. Although the regulations allow pharmacy technicians to ensure the accuracy of prescriptions, dispense and witness the destruction of controlled drugs and substances, currently they place sole responsibility on pharmacists to ensure the security of the pharmacy's drug supply.

Allowing pharmacy technicians to perform *all* distributive functions related to controlled drugs and substances would enable technicians to practice to the full extent of their skills and expertise, take on an increased responsibility for the prevention of theft and diversion of controlled drugs and substances, and allow pharmacists to focus on patient care and treatment using controlled drugs, including monitoring and dependency prevention strategies. CPhA, therefore, recommends that Health Canada grant regulated pharmacy technicians the authority at the federal level to accept verbal prescriptions, receive orders, destroy and perform all other functions related to the distribution of narcotics, controlled drugs, benzodiazepines and targeted substances.

Thank you for allowing CPhA and the profession of pharmacy to provide input into Health Canada's efforts to modernize the regulations with respect to pharmacy practice. We look forward to participating in further consultations with Health Canada as the changes to the regulations are being considered. Should you have any questions related to this submission, please contact me at 613-523-7877 or by email at gdoucet@pharmacists.ca.

Sincerely,

Glen Doucet
Chief Executive Officer