

**Written Submission for Health Canada's  
Consultations on the Modernization of  
Regulations with Respect to Pharmacists  
(Narcotic Control Regulations), the  
Benzodiazepines and other Targeted  
Substances Regulations (BOTSR) and the  
Food and Drug Regulations (FDR) – Part G**

**By: Neighbourhood Pharmacy Association of  
Canada**



**Neighbourhood  
Pharmacy**  
Association of Canada

Association canadienne  
**des pharmacies  
de quartier**

365 Bloor Street East, Suite 2003  
Toronto, ON M4W 3L4  
T : 416.226.9100  
F : 416.226.9185  
info@neighbourhoodpharmacies.ca  
[neighbourhoodpharmacies.ca](http://neighbourhoodpharmacies.ca)

## **Introduction**

The Neighbourhood Pharmacy Association of Canada (Neighbourhood Pharmacies) appreciates the opportunity to provide this Submission Brief to Health Canada on the modernization of regulations with respect to pharmacists.

Neighbourhood Pharmacies represents Canada's leading pharmacy organizations who deliver high value, quality care to Canadians in all models including chain, banner, long-term care, specialty and independent pharmacies as well as grocery chains and mass merchandisers with pharmacies. Our members are home to the most trusted providers of drug therapies, pharmacy-based patient services and innovative healthcare solutions. We advocate for community-based care through our members' high accessibility and proven track record of providing optimal patient care closer to where patients live, work and play. By leveraging over 10,500 points of care with pharmacies conveniently located in every community across Canada, Neighbourhood Pharmacies aims to advance sustainable healthcare for all stakeholders.

Neighbourhood Pharmacies broadly supports the work the government is doing to create a healthier and safer Canada. As a key stakeholder in Canada's healthcare framework, Neighbourhood Pharmacies has engaged extensively with government to improve individual and population health as it has undertaken changes to Canada's medical cannabis regime, changes to the Patented Medicine Prices Review Board (PMPRB), develops a made-in-Canada pharmacare program, and works to address the ongoing opioid crisis. We believe that solutions must be based on outcomes rather than on means to achieve those outcomes, so as not to introduce unnecessary red tape.

The following sections in this document outline the issues that must be considered in preserving, strengthening, and modernizing Canada's regulatory regime. There are three main areas where we wish to focus our comments on:

1. Optimizing the scope and value of pharmacists as medication experts;
2. Striking a balance to optimize practice and accessibility to care and pharmacy delivered services; and
3. Modernizing the regulatory framework with respect to pharmacists.

## **Recommendations**

**Recommendation 1:** That the government partner with pharmacies across Canada to mitigate the ongoing opioid crisis and reduce the potential harms and risks associated with accidental overdoses and increased usage. In doing so, Health Canada should adopt a regulatory change that enables de-prescribing and prescribing powers to pharmacists. This will make for a more comprehensive set of revisions, enabling a public health prevention approach and strategies to be utilized in addition to harm reduction initiatives, designed to effectively address the ongoing opioid crisis.

**Recommendation 2:** That the government dedicate funding support pharmacist-led pain management services aimed at addressing the prescription-related elements of the ongoing crisis, and engage with frontline pharmacy professionals as the opioid strategy continues to evolve.

**Recommendation 3:** That the government dedicate funding specifically to pharmacies in order to expand the availability, dispel stigma, and expand patient knowledge through education on appropriate use, of naloxone in community pharmacies across Canada, and to implement community-based programs to prevent overdoses.

**Recommendation 4:** That the government modernize the CDSA regulations by expanding the scope of regulated pharmacy technicians (or through standards and delegation in provinces that do not have regulated pharmacy technicians) to include receiving verbal prescriptions for controlled substances, performing the destruction of narcotics, and being authorized as designated narcotic signers for received deliveries of regulated substances.

**Recommendation 5:** That the government strike a balance on regulations related to the central-filling and compounding of controlled substances.

**Recommendation 6:** That the government amend the Cannabis Regulations to authorize pharmacies and pharmacists to distribute and dispense cannabis for medical purposes, consistent with the authorization of hospital pharmacists and physicians to do so, given their expertise in medication management and the importance of continuity of care for Canadians through transitions in care settings. Canadian pharmacies should be the primary dispensers for medical cannabis, as they can best ensure safe and responsible use.

**Recommendation 7:** That the government amend the Cannabis Regulations to authorize pharmacies to sell hemp-based CBD products with less than 0.3% THC content to be sold as over-the-counter health products without a medical authorization.

**Recommendation 8:** That the government commit to meaningful modernization of regulations in an era of increasing innovation by enacting a mandatory review period of regulations with respect to pharmacists of every three years.

## Capitalizing on the Value of Pharmacists

It is important to note the value of pharmacy to the health and well being of Canadians. With over 10,500 pharmacies in neighbourhoods across Canada, pharmacists are Canada's most accessible, frontline health service provider and foremost medications experts. Pharmacies are vital to solving Canada's most pressing healthcare challenges, from greater efficiency to more accessible care. In the face of the growing opioid crisis, pharmacies play a critical role in keeping Canadians safe, yet pharmacists are well positioned to do more. Canadian pharmacies need more open and modernized policies that allow them to meet Canadians' evolving healthcare expectations.

We continue to engage with government officials at all three levels to determine how pharmacies can best provide meaningful services that help deliver on Health Canada's harm-reduction approach to the opioid crisis. Pharmacies across Canada look forward to partnering with the government to mitigate the ongoing opioid crisis and reduce accidental overdoses and increased usage. **We recommend that Health Canada adopt regulatory changes that enable prescribing and de-prescribing powers to pharmacists by including pharmacists as "practitioners" within the CDSA.** Federal and provincial regimes often interact to delay access to pain management and create administrative burdens for physicians, nurses and pharmacists. Pharmacists having the ability to prescribe and de-prescribe would afford a more streamlined and secure method of caring for some of the most vulnerable patients and help to address the ongoing opioid crisis, and curb the potential harms associated with prescription opioids that have been prevalent for many years.

The Minister announced that the Government of Canada is removing barriers to accessing methadone for the treatment of opioid use disorder. By including pharmacists as practitioners in the CDSA, and enabling pharmacists to play a greater role in prescribing methadone and suboxone for the treatment of opioid use disorders, Canadians will have greater access to a comprehensive array of treatment options. Additionally, by removing certain marketing restrictions that make it difficult to communicate the availability of Opioid Dependence Therapy, pharmacies can increase awareness of these services and treatments. This will complement current harm-reduction approaches offered in pharmacy, including provision of naloxone kits and enabling illicit drug users' access to prescription treatments in all communities, including those at risk, through pharmacies.

On prescription-based issues with respect to the opioid crisis, the recently announced Federal Pain Management Task Force represents a good first step in moving forward to develop an effective pain management strategy and program which takes aim at the root causes of Canada's ongoing opioid crisis. We look forward to continuing to engage with them over the next three years to leverage pharmacy-delivered pain management services to support the broader pain management strategy, as they conduct a study and deliver reports on how best to move forward on pain management.

Pharmacist-led pain management programs have been implemented and proven to be effective in other jurisdictions. In a 2013 study by Bruhn et.al. published in the British Medical Journal (BMJ)<sup>1</sup> showed a statistically significant improvement in chronic pain management and

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<sup>1</sup> Bruhn H, Bond CM, Elliott AM, et al. Pharmacist-led management of chronic pain in primary care; results from a randomized controlled exploratory trial. *BMJ Open* 2013;3:e002361.

outcomes in the pharmacist-led pain management program group. Patients in this group received an in-depth medication review and one-on-one consultation, and were asked to keep a pain diary. As needed, pharmacists prescribed, de-prescribed and adapted prescriptions for pain medications. Significant improvements were seen in patient pain outcomes, and medication adherence due to improved education about optimal timing for administration of analgesic medications as well as due to optimization of medication therapies. Another 2013 study by Andrews et.al. published in the International Journal of Clinical Practice<sup>2</sup> demonstrated a significant improvement in patient safety and pain control with pharmacists' involvement in the co-management of acute pain and substance use disorder.

As presented to Suzy McDonald, Assistant Deputy Minister, Opioid Response team, in 2018, the Pharmacy Guild of Australia also launched a pharmacist-led chronic pain management program in community pharmacy. The Pain MedsCheck service involves professional pharmacist face-to-face consultations with patients to review their medication and analgesic use and develop a written action plan, incorporating education, self-management and follow up to support their clinical needs, with referral to physicians and other experts where needed.

As you know, Neighbourhood Pharmacies is an industry leader in the development of effective pain management programs. We have partnered with the Ontario Pharmacists Associations ("OPA") in formally proposing a pharmacy-delivered pain management program for Ontarians prescribed opioids to Assistant Deputy Minister and Executive Officer, Suzanne McGurn, informed by the 2017 Canadian Guidelines for Opioids for Chronic Non-Cancer Pain and the Health Quality Ontario Quality Standards for Opioid Prescribing, and aligned with current opioid strategies being pursued by several health professional colleges. While Health Canada has mandated the distribution of Opioid Leaflets with all dispensed opioid prescriptions, we believe Canadians require a more holistic and comprehensive education and counseling program. **We recommend dedicated funding from PHAC and Health Canada, to support pharmacist-led pain management services aimed at addressing the prescription-related elements of the ongoing crisis** to enhance the joint federal - provincial prevention strategies, by providing patients with one-on-one support to appropriately manage their pain while mitigating the potential risk of opioid dependence. By enabling pharmacists to prescribe and de-prescribe for opioids, pharmacists can provide patients with accessible pain-management services for acute and chronic pain, minimizing the quantity and dose of opioids, initiating dose titrations and preventing the potential harms associated with dependency. We welcome the chance to revisit this proposal with Suzy McDonald and other relevant officials on this plan.

Finally, while the work of the council is important moving forward, we must recognize that time is of the essence in taking concrete action to address the opioid crisis plaguing communities across the country now. To that end, **we recommend dedicated funding, from PHAC and Health Canada, as part of the next phase in the Opioid Action for pharmacies to expand the availability of naloxone in communities across Canada, and to implement community-based programs to prevent dependencies and reduce the risk of and harms associated with overdoses.** This should be done in a way that replaces provincial Naloxone Administration protocols with one, national protocol to provide consistency in the delivery and

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<sup>2</sup> Andrews LB, Bridgeman MB, Dalal KS, Abazia D, Lau C, Goldsmith DF and St John D. *Implementation of a pharmacist-driven pain management consultation service for hospitalised adults with a history of substance abuse. Int J Clin Pract.* 2013 Dec; 67 (12): 1342-9.

funding between provinces. Doing so will deliver a real, tangible change in the lives of Canadians struggling with substance abuse issues and create safer communities.

## **Creating Efficiencies in the Pharmacy Sector**

Healthy pharmacies ultimately deliver a less costly, more efficient healthcare system and Canadian pharmacies need modern policies that allow them to meet Canadians' evolving healthcare expectations. Neighbourhood Pharmacies advocates for a modern pharmacy model that allows more Canadians access to quality, convenient care that is efficient and cost-effective.

Pharmacies across Canada provide important, frontline health services to Canadians close to their homes and hold significant economic value for middle class and struggling Canadians. A recent series of reports by the Conference Board of Canada concluded that the community pharmacy sector generated more than \$16 billion in economic activity and supported nearly 250,000 jobs in 2016. The direct economic output of Canada's community pharmacy sector is comparable to that of the motor vehicle manufacturing sector. Your neighbourhood pharmacy is an important economic engine supporting thousands of middle-class jobs and helps create efficiencies in Canada's broader health system by providing valuable front-line health services in convenient retail locations, contributing to improved individual and population health. Yet, outdated regulations that have not been modernized to meet new demands. Additionally, the adoption and integration of innovations and tools that show significant promise of improving the way healthcare is delivered are difficult because of an excessively restrictive regulatory framework.

### **Striking a Balance on Oversight of Centralized Prescription Processing and Compounding of Controlled Substances**

Centralized prescription processing (central fill) refers to a repackaging or compounding service provided by one pharmacy to another where the central fill pharmacy processes a request from an originating pharmacy to prepare a drug order. Medications packaged or compounded by a central fill pharmacy are dispensed pursuant to a prescription from the originating pharmacy. Each participating pharmacy is required to be accredited within their given jurisdiction. Central filling, typically achieved through centralized automated dispensing or specialized compounding services, is not only associated with reduced dispensing errors, but also allows for operational efficiencies that enable pharmacists to dedicate more face-to-face time providing valuable one-on-one professional services to patients in the community.

Central fill pharmacies, however, while accredited by the accrediting body in their jurisdiction, must also comply with federal regulations as they relate to narcotics and controlled substances, and are required to hold both pharmacy licenses as well as narcotics dealers' licenses. We contend that this view leads to the imposition of additional regulatory burdens for central fill pharmacies simply because they are providing services to other pharmacies. Health Canada's current interpretation does not enable provisions of substances under the CDSA from central fill pharmacies. Pharmacies, and pharmacy professionals should be able to dispense a medication under the CDSA, pursuant to a prescription or an order from another pharmacy to enable central fill services, and to align the practice of central-filling controlled substances with that of other prescription medications.

Several other regulatory restrictions apply to central-fill pharmacies, that do not apply to other pharmacies. One such example is the designation, qualification and registration of a named alternate person in charge; the requirement to have a pharmacist on-site while technical activities such as restocking of robots are performed, present logistical challenges which limit the pharmacy's capacity to deliver accessible, timely access to Canadians. The requirement to store controlled substances and narcotics in locked safes at all times during operating hours limits the efficiency within pharmacy operations, as does the inability of technicians to re-stock dispensing robots without being under the supervision of a pharmacist on-site.

To further reduce the burden on central fill pharmacies, **we call on the government to amend the regulations to allow the sale, repackaging and compounding of narcotics between pharmacies, and to address the inconsistencies that currently limit the provision of these services.** This will promote innovation and improved efficiencies in the pharmacy sector and allow pharmacists to spend more time face-to-face providing much needed professional services to patients and creating capacity in the healthcare system.

#### Striking a Balance on Oversight of Controlled Substances Dispensed to residents of Long Term Care Facilities

The regulatory burden also extends to pharmacies servicing Long Term Care facilities, restricting pharmacies' ability to effectively support the needs of LTC facilities and their residents. The inability of pharmacists to receive verbal orders for controlled narcotics in emergency situations – such as overnight orders when physicians are unavailable to sign the prescriptions causes delays in treating vulnerable patients in pain. Similarly, the restriction on the transfer of controlled substances from one pharmacy to another necessitates duplication in administration to ensure that back-up prescriptions are available for patients in case of emergencies outside of the operating hours of a facility's regular pharmacy. Additionally, restrictions on the storage of controlled substances prohibit the use of night carts for the storage of narcotics and controlled substances for emergency purposes, while these restrictions do not apply to hospital pharmacies.

#### Expanding the Authorized Activities of Regulated Pharmacy Technicians, or Assistants under standards and delegation, in provinces where technicians are not regulated

In order to unlock the full potential of pharmacies as frontline health service providers and important economic drivers in Canada, **we call on the government to undertake regulatory modernization by expanding the scope of pharmacy technicians in-line with their training and expertise.** Specifically, we recommend enabling pharmacy technicians to accept verbal prescriptions and orders for controlled drugs and substances; to destroy expired or damaged medications listed under the CDSA; and to be authorized as designated narcotic signers for received deliveries of controlled drugs and substances. Additionally – in light of the ongoing opioid crisis, we recommend allowing pharmacy technicians to witness Opioid Dependence Treatment doses taken by patients to better enable pharmacists to evaluate patients clinically. By increasing the scope of authorized activities and undertakings of pharmacy technicians, we have the opportunity to enable pharmacists to optimize the care and services they deliver to patients while increasing the operational efficiency of the pharmacy sector.

### Harmonize Inter-provincial regulatory inconsistencies

Finally, inconsistencies between provincial regulation, as well as provincial interpretations of federal regulation significantly restricts the ability to provide inter-provincial services. In the case of central filling, some provinces require that both the originating pharmacy and the central fill pharmacy be accredited by the same regulatory body, others allow inter-provincial services but have different policies and requirements, while others have no defined policy at all. Inconsistencies also exist with respect to the interpretation of the requirements for prescription delivery under the CDSA – some provinces such as BC require that controlled drugs and substances only be transported by pharmacists or licensed wholesalers, while others enable the transport of controlled substances by agents of the pharmacies for the purpose of prescription deliveries, but have instituted policies to monitor these deliveries. Inconsistencies also exist with respect to consent provisions as well as access to electronic health records and other eHealth systems, such that providers cannot access records for patients in other provinces. These inconsistencies are reflective of the era in which the regulations were drafted, but no longer apply to the environment in which we currently operate, and do not allow for continued innovation and advancement of the provision of services that can improve access to care for patients across Canada.

## **Modernizing Regulations Pertaining to Pharmacies**

The undertaking being led by Health Canada to modernize the regulations pertaining to pharmacists is important and represents the first substantive action taken to modernize the regulations in several decades. It is important that Health Canada take this opportunity to not only enact meaningful change, but also ensure that the capacity of the pharmacy sector to deliver optimal care in our communities is optimized well into the future.

### Authorizing Pharmacies to Distribute and Dispense Cannabis for Medical Purposes

Canada has undergone significant change since the regulations relating to pharmacists were brought forward. Perhaps chief among them is that Canada has developed a world-leading medical cannabis regime, as recently upheld and strengthened by the 2015 Supreme Court ruling on *R. v. Smith*, which ruled that cannabis for medical purposes must be legal in all forms. Since then, Canada has taken yet another step as a global leader in the approach to cannabis by implementing a harm-reduction approach to legalizing and strictly regulating cannabis for adult recreational purposes. We commend the government for its bold approach to this process.

In a June 13, 2018 address to the House of Commons, Minister Pettipas Taylor noted that it was the government's intent, with respect to ensuring access to legal cannabis via home cultivation, to ensure that both the recreational and medical cannabis systems were consistent with one another. Yet, medical cannabis users have been left behind since Canada adopted its recreational cannabis regime and face ongoing access-related issues. In fact, a 2018 study found that prior to the legalization of cannabis for recreational purposes, only one in four medical cannabis users sourced their medicinal cannabis through the legal medical regime, with the rest getting it from the illicit market (cannabis dealers), friends, and illicit dispensaries. The experience of patients under the medical regime, its patchwork of regulations, and the limited ways in which they can legally obtain cannabis, has been such that they find it difficult to understand and navigate the system.

With such issues under the medical cannabis regime, there is a very present threat that persons using cannabis for medical purposes will engage in the recreational market to procure their cannabis and effectively self-medicate without the benefit or guidance of medication experts, pharmacists. This does not meet the spirit of the government's harm-reduction approach to cannabis, nor the spirit of the original Access to Cannabis for Medical Purposes Regulations (ACMPR). The government must take action to provide a more coherent, responsive approach to address the needs of patients through a formal pharmacist led retail channel that facilitates patient access to medical cannabis and prioritizes positive patient health outcomes. To ensure the affordable, equitable access of patients to their needed medical products, **Neighbourhood Pharmacies is calling on the government to amend the Cannabis Regulations by making the appropriate changes that will authorize pharmacies to distribute and dispense cannabis for medical purposes, consistent with the authorization of hospital pharmacists and physicians to do so.** Authorizing pharmacies to distribute and dispense cannabis for medical purposes is in line with the harm reduction pillar that Health Canada has included in its approach to cannabis legalization, will assist the government in providing solutions to ongoing issues with pain management, and will ensure continuity of care and a level playing field in accessing the advice of their pharmacist for patients transitioning between care settings (ex: community – hospital – long term care).

Further to authorizing pharmacies to distribute and dispense cannabis for medical purposes, **Neighbourhood Pharmacies is calling on the government to amend the Cannabis Regulations to authorize pharmacies to sell hemp-based CBD products with less than 0.3% THC content to be sold as over-the-counter health products without a medical authorization.** The growing evidence and medical community has recognized the potential health benefits of CBD when taken as indicated for: reduction in chemotherapy induced nausea and vomiting, , to treating neuro-inflammation, epilepsy, nausea, and anxiety, all without the unwanted psychoactive side effects of THC. Products containing CBD with less than 0.3% THC are not as susceptible to abuse and should not require controlled or restricted sale as other cannabis products, and patients are embracing the benefits of CBD in the wellness and natural personal care sectors.

#### Making a Commitment to Innovation in the Pharmacy Sector

Today, innovation and technological advancements occur at a more rapid pace than in decades past. When it comes to health services, new technologies have reinvigorated the innovation cycle in the development of new products and services, and internet connectivity, and mobile technology, have increased our capacity to reach Canadians closer to their own homes from coast to coast to coast. If we are to ensure that Canada's health care system and pharmacy sector remain as world leaders in the delivery and accessibility to care, it is essential that we amend the regulations pertaining to pharmacists to be as nimble as possible moving forward.

**To that end, we call on the government to commit to innovation by enacting a mandatory review of the regulations pertaining to pharmacists by the House of Commons Standing Committee on Health every three years.** It is essential that the government continuously study emerging trends and existing barriers to ensure the delivery of world class health services in Canada.

## **Conclusion**

Neighbourhood Pharmacies represents Canada's leading pharmacy brands who deliver high value, quality care to Canadians in all models including chain, banner, long-term care, specialty and independent pharmacies as well as grocery chains and mass merchandisers with pharmacies. Our members are home to the most trusted providers of drug therapies, pharmacy-based patient services and innovative healthcare solutions.

We are calling on the federal government to undertake a meaningful modernization of the regulations with respect to pharmacists to ensure that we unlock the full potential of the pharmacy sector in Canada to deliver accessible, high quality health services everywhere Canadians live. To ensure that Health Canada's meaningful modernization of the regulations with respect to pharmacist are lasting, it is essential that the government commit to enacting a mandatory review of the regulations pertaining to pharmacists by the House of Commons Standing Committee on Health every three years.

We look forward to working in partnership with Health Canada now and into the future to ensure that Canadians receive the health services that they need close to their homes.