Canadian Pharmacists Association | Association des pharmaciens du Canada

Controlled Substances Regulations

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Introduction:

The Canadian Pharmacists Association (CPhA) appreciates the opportunity to provide feedback on the newly proposed Controlled Substances Regulations (CSR). We commend and appreciate Health Canada's ongoing commitment to support the evolving practice of pharmacy and are pleased to see recognition of the increasingly important role that pharmacy professionals play in supporting the primary care needs for people in Canada reflected in the new regulations. We support the consolidation of regulations and incorporation of exemptions in the CSR and applaud all efforts to streamline and simplify the overall regulatory framework to remove unnecessary regulatory barriers and improve understanding and readability of the regulations. Our submission focuses on areas that we feel require further clarity as well as the importance of designating pharmacists as practitioners. We have also included sections from our previous submission that have not been fully addressed in the new regulations and continue to be pain points for pharmacy teams.

1. Writing CSR to reflect pharmacy practice

In this draft of the CSR, there are several instances where what is written does not properly reflect actual pharmacy practice. Regulations should be written to align with community pharmacy workflow and processes, so they facilitate patient care and prevent disruption or discontinuation of key activities that pharmacists are currently performing. Examples of areas that need modification include:

- **Distinguishing between "pharmacy professionals" and "pharmacies":** The draft of the CSR does not clearly distinguish between a pharmacist and a pharmacy. As it is currently written, the CSR (sections 91-97) implies that a pharmacist or pharmacy technician (a single licensed individual) buys and sells drugs, when in practice, it is the pharmacy (the registered retail establishment) which is responsible for buying and selling. Additionally, security (sections 103 & 106-107) and record keeping requirements (sections 120 & 122) of the CSR put the onus on pharmacists and pharmacy technicians to ensure these requirements are met. In practice, it is the pharmacy that maintains responsibility for security and document retention. This distinction is crucial given that many pharmacy professionals (pharmacists, pharmacy interns, and pharmacy technicians) practice at multiple establishments and would not be maintaining records for various practice sites. All record keeping requirements should align with provincial and federal health information legislation.
- **Prescribing vs. modifying, extending and renewing:** Per provincial regulatory bodies, prescription renewals, extensions, and modifications are completed via pharmacist assessment, resulting in the pharmacist issuing a prescription under their license and taking

on the liability of the prescriber (i.e., prescribing). As the CSR is currently written, pharmacists cannot issue a prescription, since that may only be done by practitioners. This means that provisions for extending or refilling prescriptions (section 99) are ineffective, since the process of extending or refilling the prescription requires the pharmacist to issue a new prescription (become the prescriber). It is vital that the CSR be written to allow pharmacists to modify, extend, and renew prescriptions as these are essential elements of pharmacy practice, facilitating delivery and continuity of patient care and addressing gaps in our healthcare system.

- **Administration of controlled substances**: The draft CSR limits the administration of controlled substances to practitioners and hospital employees. This is inconsistent with the authority currently granted to pharmacists by most provincial regulatory authorities. Furthermore, some provinces also permit pharmacy technicians to administer controlled substances, such as Nova Scotia where this is a publicly funded service. To enable pharmacy regulatory authorities to continue to authorize pharmacy professionals to administer controlled substances in accordance with current provincial scope of practice, the CSR should be written to permit both pharmacists and pharmacy technicians to partake in administration of controlled substances.

We recommend modelling the sections of the CSR pertaining to pharmacists, pharmacy interns, pharmacy technicians, and pharmacies after the CSR framework used to delineate hospitals from their employees. This would mean that pharmacy professionals are considered employees and/or health care professionals who act under the authority of "a person in charge" of their practice site. This would also require a definition of "pharmacy" or other community-based pharmacy settings (primary care centers, stand-alone clinics, physicians' offices, family health teams, etc.) Additionally, this change will mitigate inequities across pharmacy practice, given that the proposed CSR allows hospital pharmacists to conduct activities in accordance with their provincial scope of practice, but does not allow community pharmacists the same right. In many provinces, this would give hospital pharmacists authority to partake in activities that community/primary care pharmacists are not permitted to. This creates inequality across the profession, impairs delivery of patient care, and could lead to worsening the pharmacy professional shortage.[1]

We also strongly urge Health Canada to list pharmacists as practitioners during the current modernization efforts. In addition to reworking the CSR to mimic the framework used for hospitals and their employees, listing pharmacists as practitioners would allow pharmacists to modify, renew, and extend prescriptions in accordance with the scope of practice granted by their provincial regulatory authority. In this regard, listing pharmacists as practitioners simplifies the legislation and prevents the unintended revocation of essential practices in community pharmacy, ensuring that pharmacists remain able to provide excellent patient care and ease the burden of healthcare's human resource crisis. The classification of pharmacists as practitioners is imperative in order to align with the current state of pharmacy practice; without this authority, the regulations would be considered outdated in many jurisdictions at the time of publishing. Section 2 below outlines additional considerations for and benefits of listing pharmacists as practitioners.

2. Pharmacists as practitioners:

While the CSR framework acknowledges ongoing discussions to expand the list of practitioners to include pharmacists, we believe that the current regulatory review provides a timely opportunity to make the necessary changes to increase access to care for Canadians. It is our strong belief that the New Classes of Practitioners Regulations (NCPR) should expand the definition of practitioner under the CSR to include pharmacists so that they are authorized to conduct activities, including the prescribing of marketed drugs containing a controlled substance, in accordance with all associated regulations. This classification is necessary to future-proof the regulations to enhance patient care, improve accessibility to medications, support pharmacy operations and enable the delivery of primary care services through pharmacies.

The proposed CSR framework unnecessarily limits pharmacists' ability to provide comprehensive care to patients by only authorizing them to renew, extend, or transfer an existing prescription for controlled substances. A recent study conducted in Ontario found that the exemption did not result in prescribing for controlled substances at higher rates.[2] Rather, the absolute rate of pharmacist prescribing was low for these medications and never exceeded two percent of the total prescribed claims. This study demonstrated that greater involvement of pharmacists in managing drug therapy for controlled substances does not lead to overprescribing or adverse patient outcomes.

With the widespread shortage of physicians and nurses, enabling pharmacists to provide an enhanced level of care is critical to address the current gaps within the system. Listing pharmacists as practitioners removes limitations for provincial regulatory authorities to enable pharmacists to intervene by using their professional judgment when necessary. Pharmacist scope of practice has evolved considerably, and prescribing authority is currently enabled in many jurisdictions across the country.[3] We recommend that pharmacists be added as practitioners within the CSR in order to enable a broad range of critical services, included but not limited to:

- **Supporting unattached patients:** Currently, over 6.5 million Canadians do not have a designated primary care provider.[4] As medication experts, pharmacists possess the competencies and capabilities to support improved access to primary care and address this gap. Provinces across the country are turning to pharmacy professionals to provide primary care and there are clear benefits to patients and the health care system in enabling them to fully utilize their education to effectively provide medication management. In Nova Scotia there is evidence to show the impact that pharmacists have had when it comes to providing care for the growing number of unattached patients and why it's important that we continue to enable them by removing regulatory barriers.[5] Recent government reporting revealed that pharmacy clinics in Nova Scotia have contributed to a nearly 10% decline in emergency room visits for non-urgent or less-urgent cases, which further reinforces the vital impact of pharmacists in alleviating the burden on traditional health-care facilities.[6] Pharmacists operating in primary care clinics should be granted the authority to manage medications regardless of the drug classification so that they can provide comprehensive care. By listing pharmacists as practitioners under the new CSR, provincial regulators can have the option to enable care through pharmacist-led primary care clinics to support the

needs of patients in their jurisdictions and further alleviate burdens on Canada's healthcare system.

- **Initiation of Opioid Agonist Treatment (OAT)**: Pharmacists are ideally positioned to play a more proactive role in the management of opioid use disorder (OUD) through the initiation of OAT (e.g., methadone or suboxone).[7] The CAMH guidelines recommend that individuals with OUD have access to OAT within 48 hours.[8] By providing pharmacists with the authority to initiate OAT, they could proactively respond to patients exhibiting signs of opioid overuse in a timely manner. This approach would increase access to care, particularly in rural and remote communities and reduce the burden on other healthcare resources (e.g. physicians and addiction treatment centers). This is particularly important given that people with opioid use disorder are less likely than others to have a primary care physician[4] and access to OAT has been an ongoing challenge in many parts of the country (particularly in rural and remote areas) as demand has continued to outpace the capacity to provide support.[9,10] A recent study exploring patient perspectives on community pharmacies as treatment access points for OUD revealed that location distance and office hours were among factors that most influenced their decision to receive methadone from a pharmacy rather than an opioid treatment program.[11]

  Case example: An individual with a history of OUD who is receiving treatment is released from a correctional facility late on a Friday. Upon release, they are not provided with a discharge prescription for OAT. This oversight leaves them vulnerable to relapse as it would be nearly impossible to get an appointment with a specialist until the following week. The abrupt discontinuation of methadone could lead to severe withdrawal symptoms and potentially fatal consequences if they turn to street-drugs as a solution. Recognizing the gap in care, a pharmacist under specific protocols could prescribe a short-term supply of methadone or buprenorphine to bridge the treatment until the individual can see a specialized healthcare provider.

- **Therapeutic substitution**: The role of pharmacists in therapeutic substitution is well established across all drug classes and is a foundational element of their education. Where therapeutic substitution has not yet been enabled, pharmacists are often involved in the decision-making process regarding drug substitutions, providing advice and recommendations to prescribers and taking into consideration the specific needs of patients. Their ability to substitute drugs at the point of care has also become a cornerstone of Canada's drug shortage crisis. Their drug knowledge and expertise can lead to significant healthcare savings by streamlining prescribing (i.e. not going back and forth with physicians) while ensuring that patients receive the most suitable medication for their needs. The ability to conduct therapeutic substitutions should not be restricted. A pharmacist's ability to use clinical judgement remains the same regardless of the medication in question. The necessity of therapeutic substitutions by pharmacists is especially clear during incidents of drug shortages.

Case example: An ADHD medication (e.g., Biphentin) goes on backorder with no clear timeline for restock. The pharmacy team is now faced with switching all patients taking this medication to an appropriate alternative. The ability to independently prescribe a substitute agent (e.g., Concerta, Adderall XR) would allow the pharmacist to make the change at the point of care to support continuity and prevent the patient from experiencing harms from any gaps in therapy.

- **Emergency response:** The increasing and unpredictable occurrence of natural disasters and emergencies (e.g., forest fires and floods) have had a significant impact on pharmacies. These events displace families and communities from their homes, often without access to their medications. In these cases, pharmacists play an even greater role to ensure medication continuity and should not be limited by regulations to aid in these life-altering circumstances.[12] Federal regulations should be written to enable provincial regulators to enable pharmacists to act.

- **Deprescribing:** The ability for pharmacists to review, modify and deprescribe opioids is a critical step in tackling the opioid crisis and helping to reduce medication waste.[13] Pharmacists, in collaboration with patients and other healthcare providers, should be empowered to regularly assess a patient's pain management needs, and, where appropriate, decrease or substitute opioid prescriptions with more suitable alternatives, which in some cases may also be controlled drugs. The goal is to manage pain effectively while minimizing the risks associated with opioid use (e.g. dependency and overdose). Pharmacists' extensive knowledge of medication management and training in opioid stewardship make them uniquely qualified to guide this process, ensuring a patient-centered approach to pain management. This authority would assist with discontinuing other controlled drugs such as benzodiazepines, which have been associated with physical dependence, falls, functional impairment and motor vehicle accidents.[14,15]

  Case example: A pharmacist notices that an older patient has been using a high dose of a benzodiazepine medication to treat their insomnia for many years. Working with the patient on their therapeutic goals, they decide to slowly wean the patient off the drug. The authority to independently adjust dosages would allow the pharmacist to support the safe and effective transition while monitoring for withdrawal symptoms and the risk of rebound insomnia.

- **Chronic pain and palliative care:** Approximately 20% of adults in Canada suffer from chronic pain, with prevalence increasing with age.[16] Giving pharmacists the authority to prescribe under the CDSA would allow pharmacists to adjust medications for chronic pain and palliative care patients, directly improving a patient's quality of life. It would also provide opportunities for pharmacists working in collaborative settings (i.e., family health teams) to take responsibility for drug management activities that are currently

being handled by medical directives. This change would ease the workload of doctors and nurse practitioners, making healthcare more efficient. Overall, it promises more compassionate, streamlined, and effective care for those dealing with chronic or life-limiting illnesses.

> **Case example:** An elderly patient with mobility issues has been living with chronic pain for years. Her pain is worsening, affecting her sleep and daily activities. To treat the pain, she uses a short-acting 'as needed' opioid medication at regular intervals. Unfortunately, she will be unable to see her pain specialist to be reassessed for three weeks. Her family physician is not comfortable adjusting any pain medications which he did not prescribe. Her only option is to present to the emergency department to be evaluated and to get a new prescription. With authority to initiate medications under the CDSA, the patient's long-time pharmacist can adjust her long-acting opioid dosage to account for the increased use of breakthrough doses – this would help manage the patient's pain and reduce overall pill burden.

- **Reducing administrative burden:** Although medical directives can and are being used as work arounds to enable pharmacists to provide opioid related care outside of the regulatory framework, their use in practice place an unnecessary and administratively heavy burden. If a healthcare provider has a license, they should be able to own their actions, and not use or rely on someone else's license to govern their acts.

3. Clear Interpretation of the CSR:

Given that the objective of these revised regulations is to support pharmacy innovation in Canada and enable pharmacists and pharmacy technicians to more fully use their expertise as medication experts; as well as to further enhance the clarity and readability of the regulations by consolidating and improving alignment across the regulatory frameworks, we believe the following areas require further clarification, as there are a number of areas within the newly proposed CSR that remain open to misinterpretation.

- Overall, the CSR needs to be written in a way that is consistent with decreasing administrative burdens and streamlining pharmacy operations regardless of province or territory. It is important that we maintain the current workflows in pharmacy and avoid restricting processes in place in various jurisdictions.

- Section 1(1): Physicians and veterinarians are not defined in this section. It is important to define these roles to ensure they are properly delineated from other professionals (for example, physicians assistants).

- Section 1(1): The definition of pharmacist in the proposed CSR does not make reference to the existing breadth of pharmacist scope of practice nor the variability of scope of practice between provinces and territories. To ensure it is clear that pharmacists will be permitted to continue to work to their full scope, the definition of pharmacist should be modified. An

example of a definition that enables pharmacists to work in their provincially defined scope is "Pharmacist means a person who is entitled under the laws of a province to practise pharmacy and who is practising pharmacy in that province in a manner consistent with any applicable provincial or territorial pharmacy legislation and any applicable policies of a provincial or territorial licensing authority enabling pharmacist scope of practice and defining standards of practice."

- Section 1(1): The definition of pharmacy intern specifies that they must be working "in a pharmacy". This does not account for the many other practice sites in which pharmacy professionals may be employed (primary care centers, stand-alone clinics, physicians' offices, family health teams, etc.) This definition should be amended so that pharmacy interns are not unintentionally restricted to the settings where they practice.

- Section 99: This line states that "a pharmacist may extend a prescription after having fulfilled all refills authorized in the prescription". This wording implies that it must be the pharmacist extending the prescription must also be the one who filled all refills; however, there are instances where not all refills are fulfilled by one pharmacist. A common example of this is when prescriptions are transferred. This section requires rewording to avoid the stated misinterpretation.

- Sections 99 & 114: While the CSR allows for a pharmacist to accept a 'refill' for a controlled substance, it is unclear where the mechanism is that authorizes a prescriber to add refills to a prescription is referenced.

- The removal of the definition of a "Verbal Prescription Narcotic" (VPN; as previously referenced in sections 58 & 59 of the *Narcotic Control Regulations*) leads us to assume that any narcotic be authorized verbally – is this the intention?

- There is no clarity on **"**e-prescribing**"** and associated requirements for accepting electronically transmitted prescriptions.

- Additional clarification is required on the issue of part-fills as this continues to be a gap in legislation. There should be language enabling a pharmacist to dispense a supply of medication in shorter supply for purposes of safety or patient consideration where a smaller than authorized quantity by the physician is ordered.

  Case example: If a physician orders 100 tabs, partfill 30 every 30 days – the pharmacist has to fill that way. However, there are circumstances (LTC, compliance package, risk of theft) based on the patient where a shorter supply might need to be dispensed and a pharmacist should be able to do that and make that decision working with the patient.

- Section 100: For the transfer of a prescription, it is stated that a "written prescription" needs to be provided when transferring a controlled substance to another pharmacy. Given that the original prescription must stay with the original dispensing pharmacy, it should clarify that a "copy" of the original prescription should be made and transferred to the receiving pharmacy

– with a paper trail linking it to the original. For transfer of verbal prescription orders, we recommend adopting similar language to that used in the *Benzodiazepine and Other Targeted Substances Regulations* (section 54(2a): "in the case of a verbal transfer, record the information required by subsection 51(3)") to ensure administrative burdens are not increased in certain provinces depending on their interpretation and implementation of the current and future regulations pertaining to controlled drugs and substances.

- Further clarity regarding the scope of permitted pharmacist activities is required. Wording enabling pharmacists to modify formulations, manage part-fill intervals, or deprescribe, in accordance with their provincial regulations, is missing. If the CSR is meant to enable pharmacists to maintain the same authority as under the current separate regulations, additional provisions and/or rewording are required to ensure this is clear.

- We are pleased with the regulatory changes that enable distribution models such as central fill and wish to confirm whether the CSR is intended to permit central fill pharmacies to deliver directly to patients' homes or long-term care homes in addition to the originating pharmacy. Clarity here would be valued for consistent interpretation of the regulations.

Interpretation of the CSR will vary among provincial pharmacy regulatory organizations, and among Health Canada inspectors. Below are examples where this has posed issues with inconsistency under previous regulations and we hope the new streamlined approach to the CSR regulatory framework will help promote harmonization in pharmacy practice across jurisdictions nationwide:

- The BC College of Pharmacists interprets that delivery of medications under the CDSA, whether the individual is legally in possession of it or not, is illegal and constitutes trafficking unless it is transported by a wholesaler or pharmacist. This places unnecessary limitations on delivery for patients and pharmacies in BC.

- Some provincial regulatory authorities, for example, BC, SK, MB, and the Atlantic provinces, require the reporting of losses to the regulatory authority in addition to Health Canada, while other provinces do not. This creates unnecessary and duplicative processes – streamlining and standardization of administration should be encouraged across the country.

- Sections 106 & 107: Interpretation of security requirements under the CDSA has been inconsistent between pharmacy regulatory authorities and Health Canada inspectors. Modernization and additional clarity would facilitate more uniform interpretation of regulations. This would allow pharmacies and pharmacists to confidently use the security mechanisms that are best suited to their business and practices without worry of non-compliance. For example, the unnecessary requirement of time-delayed safes in highly secured facilities that are not patient-facing and have monitored /restricted access to employees only.

4. Transfer or sale of controlled drugs under the CDSA:

We support the authorization for pharmacists to compound, send, deliver and transport a controlled substance to a patient pursuant to a prescription, sell or provide a controlled substance to a practitioner or the Minister, and transfer a prescription to another pharmacist. We also commend Health Canada for recognizing the immense impact pharmacy technicians' authority has on improving patient care and granting them the authority to deliver, send, transport, destroy and compound controlled substances. We encourage further expansion of pharmacy technicians' authorization to include performing activities related to OAT, such as observing OAT doses following pharmacist assessment. Enabling pharmacy technicians to contribute to the delivery of OAT under pharmacist supervision will streamline pharmacy operations, making patient care more efficient and effective.

There are a number of operational situations that have been historically limited by regulations, and we support removal of barriers in these areas. We believe that enabling pharmacy professionals to use their professional judgment to support the management of controlled drugs will improve access to care as well as enhance pharmacy functioning in the following ways:

Efficient Inventory Management:

- Reduced restrictions on the transfer of controlled drugs allow pharmacies to manage their inventories more efficiently. Pharmacies could redistribute medications to where they are most needed, reducing wastage due to overstock and addressing shortages more effectively. This improved inventory management would be especially important in rural or remote areas, where access to medications can be a significant challenge.

Managing drug shortages:

- Beyond the current allowances for emergencies, expanded transfer rights would enable pharmacies to respond more robustly in other scenarios, such as drug shortages or other disruptions in the regular supply chains.
- Pharmacies could act as a network, supporting each other in ensuring that patients have uninterrupted access to essential medications during crises.

Streamlining pharmacy operations through central fill:

- We recognize Health Canada's desire to support the use of central fill distribution models to support patient care and see benefits to removing the requirement for locations to be licensed dealers to reduce barriers to pharmacy operations.

5. Advertising Restrictions:

The current advertising restrictions under the Food and Drugs Act significantly limit the ability of pharmacies to communicate effectively about the availability and nature of Opioid Agonist

Treatment (OAT) services to their patients. While we recognize the rationale to restrict advertising to the general public. Given the unique nature of OAT, we propose including exceptions to restrictions to allow for pharmacists, pharmacy technicians and practitioners to use specific terms related to valuable addiction treatments like 'methadone' and 'suboxone' in marketing materials. This change is crucial for several reasons:

Increasing Public Awareness and Reducing Stigma:

- There is a widespread lack of awareness among the general public about the availability of OAT services in pharmacies. By allowing the use of specific terms like 'methadone' and 'suboxone' in marketing, pharmacies can more effectively reach individuals who may benefit from these treatments. Clear communication is essential to inform individuals struggling with opioid use disorder (OUD) about accessible treatment options, which is a critical step in addressing the opioid crisis. Patients and their families often lack information about the types of treatments available for OUD. By allowing specific names of medications in marketing materials, pharmacies can provide clearer, more direct information about the treatment options they offer.
- Openly advertising OAT medications and the availability of OUD services in marketing materials can help normalize OAT as a legitimate and necessary medical intervention, thus reducing stigma. Decreasing stigma will encourage more individuals to seek help and adhere to treatment plans.

Targeted Outreach:

- Specific and clear marketing enables targeted outreach to populations that are most in need of OAT services. This is particularly important in communities heavily impacted by the opioid crisis.
- Targeted marketing can also reach healthcare providers who might refer patients to OAT programs, thereby expanding the treatment network and facilitating access to patient-centred care.

Supporting Integrated Care Models:

- Effective marketing of OAT services aligns with broader public health goals of creating integrated care models where pharmacies play a pivotal role in healthcare delivery, including addiction management. Through promotion of these services, pharmacies can position themselves as accessible points of care within the community.

Compliance with Ethical Marketing Practices:

- In the absence of these restrictions, pharmacies would continue to adhere to ethical marketing practices, ensuring that all promotional materials are accurate, informative, and in line with the intended objectives of the regulations as it pertains to pharmaceutical marketing. This approach balances the need for effective communication with the responsibility to provide truthful and non-exploitative

information.

6. Opioid Leaflet and Warning Label Policy:

We believe that the current one-size-fits-all approach to opioid management, particularly regarding the mandatory opioid leaflet and warning label, falls short in addressing the diverse and individualized needs of patients. To enhance the effectiveness of opioid management strategies, we propose two key changes: 1) granting pharmacists discretion in their use of these tools, and 2) implementing a comprehensive, government-funded education and counseling program to allow pharmacists to expand their services in opioid management. We request that the CSR provide specific wording to enable these changes.

- **Personalized Patient Care:** By allowing pharmacists to use the leaflets and warning labels at their discretion, they can use their professional judgement to tailor information to the specific context and needs of each patient. This individualized approach enhances patient education by addressing unique concerns or circumstances rather than using the one-size fits all approach.
- **Enhanced Patient Engagement:** Personalizing opioid management tools can foster better patient engagement and understanding. When patients feel that the information provided directly applies to them, they are more likely to adhere to safety guidelines and use their medications responsibly.

In a survey of pharmacists conducted in 2020, we found that:

- While 44% of pharmacists felt they were helpful, many pharmacists (33%) felt that they were not effective tools to communicate the risks of opioids. This is likely due to the wide range of circumstances when an opioid is dispensed, including a number of situations that may not require the pharmacist to provide additional counselling and education. Examples of which include:
    - Refills
    - Long term stable users
    - Chronic illness/palliative care circumstances

Environmental impact

It should also be noted that the opioid leaflets pose a significant environmental issue. Their production consumes a considerable amount of paper and after their brief usage, these leaflets often end up as waste.

Conclusion:

We believe that is it necessary to future-proof the regulations to keep up with the evolution of healthcare delivery in Canada. The role of the pharmacists as integral members of the primary care workforce needs to be recognized within the regulations, especially in the context of ensuring continuity of care when patients no longer have a physician or nurse practitioner. For unattached

patients, the ability of pharmacists to operate independently is critical to their care. Recognition of the role pharmacists as authorized prescribers in all provinces should be incorporated into the regulations. Pharmacists are prescribers for all other classes of medication and have a very intimate knowledge of the role of narcotic, controlled and targeted substances in medication therapy management. Limiting pharmacists' ability to prescribe is actually hindering patient care.

To achieve meaningful, consistent, and seamless integration into the interdisciplinary model of Canadian primary health care reform, we must all collaborate on a harmonized vision for innovation in primary care integration, and move toward unified implementation by enabling regulatory changes and policies that support our shared goals.[12] We believe that people living in Canada deserve to receive timely, equitable, and safe interdisciplinary care and that pharmacist within a coordinated primary health care system, including from their pharmacy team.[17]

The proposed changes we have discussed aim to modernize the Controlled Substances Regulations in a way that benefits patients, pharmacy and other healthcare professionals as well as the broader healthcare system. Given the current state of health care in this country, these changes need to be realized in the current revision process, as delays would result in many lost years spent waiting for the next opportunity for regulatory reform. We look forward to a constructive dialogue with Health Canada on these recommendations.

See Appendix A for further Questions and Answers previously posed by Health Canada

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APPENDIX A

1. **Would the pharmacist also be the one diagnosing patients, or would that still be done by a practitioner?**

This would be dependent on the competence of the individual practitioner and the authorized scope of practice in each jurisdiction. However, given the regulatory framework in each practice, it is not envisioned that pharmacists would initially be able to diagnose the patient. As practice evolves and if provincial governments deem it necessary, they could enable this.

2. **Would patients be charged a fee for any new prescription written by a pharmacist? If so, how much?**

Like all healthcare professionals, pharmacists are compensated for their professional time to conduct an assessment and write a prescription, if warranted. The payor for the pharmacist's professional services would be dependent on agreements in place in each jurisdiction. In some provinces, this would be covered as part of the public health plan, in other provinces, it may be a fee for service. The fee model for assessing and prescribing would typically follow existing guidelines but varies by jurisdiction. It is reasonable to assume that it would be comparable to, and likely less, than what is paid to other private primary care providers (e.g. family physicians).

The reimbursement model differs by province, however there are standards in place to ensure that there are no conflicts of interest between the assessment and prescribing activities. For example, in AB, remuneration for pharmacists is for their assessments regardless of whether the outcome produces a prescription. [18] Additionally, the BC College of Pharmacists code of ethics states that "in no instance should a pharmacist adapt a prescription in order to benefit financially or in kind".[19]

3. **What potential costs or benefits would this change have in terms of health care service delivery?**

There are multiple benefits for the patient, pharmacy workflow and for the health system including. In addition to the above (page 1), this would include:

- Improved access to chronic drug therapy management for drug regimens that include CDSA medication.
- Optimized medication therapy for patients whose drug regiment includes CDSA drugs (including deprescribing, therapeutic substitution, etc.)
- Improved continuity of care for patients without an "attachment" to a physician or nurse practitioner.
- Enhanced community screening to ensure that patients with OUD who would clearly benefit from OAT are identified and offered support.

- Pharmacists and pharmacy teams will be able to provide care and address issues without having to wait for responses from prescribers, which can take days especially on weekends.
- Alleviating pressures on other parts of the health care system. Pharmacists can manage routine aspects of OAT initiation and maintenance, freeing up time for other healthcare professionals to focus on more complex cases.

4. Are other regulatory colleges (e.g. the Colleges of Physicians and Surgeons) supportive of this change?

The current OSC exemptions have been very positively received by the various regulatory colleges across the country and across professions. In Nova Scotia, both the College of Physicians and Surgeons of Nova Scotia (CPSNS) and Nova Scotia College of Nursing have provided their support for the Nova Scotia submission to Health Canada.

In 2021, the college of physicians and surgeons of Ontario (CPSO) made changes to their methadone program standards and guidelines to increase OAT access by reducing significant oversight of this program. We anticipate that Colleges of Physicians and Surgeons would be supportive of expanding prescriptive authority of OAT to pharmacists for the following reasons:

- Expanded access to care especially in rural or remote areas. Even within larger populated areas community pharmacies are often access points for addiction treatment.
- Many regulatory colleges emphasize the importance of interprofessional collaboration and team-based care. In this context, allowing pharmacists to prescribe OAT can be viewed as a way to enhance collaboration between healthcare professionals and improve patient outcomes.

5. Would regulatory changes need to be made in the provinces and territories before pharmacists could initiate new prescriptions? If so, approximately how long would it take to make those changes?

Scope of practice currently varies across the country, ranging from prescribing for minor/common ailments in Ontario to full prescribing authority of all Schedule 1 drugs in Alberta. While CPhA believes that prescribing authority and other scopes should be standardized in Canada it remains that each province will enable pharmacist prescribing at its own pace. By adding pharmacists as practitioners or prescribers under the CDSA, Health Canada is essentially removing the barriers restricting provinces from expanding the scope of pharmacists as they see fit.

6. How would each province ensure that such a change would not result in the overprescribing of controlled substances or diversion of controlled substances to the illegal market? What systems would be put in place to prevent an individual from walking into multiple different pharmacies on the same day and requesting the same prescription, potentially with a view to then selling those substances on the street?

There are existing controls in place across the country to prevent the diversion of substances to the illegal market. In most provinces, pharmacists have access to a drug information system (e.g., PharmaNet in British Columbia etc) that allows them to view a patient's drug history. These systems have built in alerts for instances of suspicious activity (e.g., double doctoring).

A recent study conducted in Ontario found that the exemption did not result in prescribing for controlled substances at higher rates.[2] Rather, the absolute rate of pharmacist prescribing was low for these medications, and never exceeded two per cent of the total prescribed claims. This study demonstrated that greater involvement of pharmacists in managing drug therapy for controlled substances does not lead to overprescribing or adverse patient outcomes. The practice of pharmacy in Canada has evolved significantly from a model that presumes that pharmacists who are providing primary care would be doing so concurrent to processing and dispensing those same medications. In reality, pharmacists who are assessing patients and prescribing drug therapy are often in non-dispensary practice settings and/or the patients take their prescriptions to another pharmacy to be processed.

7. **Would there be any new educational programs put in place to support this change? How much would it cost to implement these programs?**

The topics of pain management, addiction and opioid use disorder are all covered as part of the standard entry-to-practice PharmD curriculum. Any practice change is evaluated for educational needs and offerings are developed with provincial associations and faculties of pharmacy. There are also a number of continuing education courses and clinical guidelines available for pharmacists to support their practice. Most provincial regulatory bodies have policies in place—some require mandatory education and training for members if they choose to practice in this space.

8. **Would this change apply only to the prescribing of certain controlled substances, or all controlled substances? Would there be any limitations in terms of what substances we would want pharmacists to prescribe?**

While we believe that pharmacists have the knowledge and expertise to manage all controlled substances. By removing prescribing restrictions at the federal level, each province can determine what is appropriate within their own jurisdiction. As drug experts, there is no rationale for establishing limitations on prescribing based on a formulary of medications. Rather, any limitation would be based on the condition being treated (i.e. if the condition has not yet been diagnosed and/or the standard of care for the condition is that the treatment is prescribed by, or in collaboration with, a medical specialist).

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