



#### **Land Acknowledgement**

The HIV Legal Network works on the land now called Canada, which is located on treaty lands, stolen lands, and unceded territories of Indigenous groups and communities who have respected and cared for this land since time immemorial. We work to address the ongoing injustices and resulting health inequities faced by Indigenous Peoples that contribute to the disproportionate impact of the HIV epidemic on Indigenous communities. We are committed to learning to work in solidarity and to dismantling and decolonizing practices and institutions to respect Indigenous Peoples and Indigenous ways of knowing and being.

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#### **Acknowledgement**

A special thank you is reserved for the key informants who shared their knowledge and experience to help inform the development of this report and any subsequent knowledge resources on this subject.

The production of this document has been made possible through financial contributions of the Public Health Agency of Canada. The views expressed herein do not necessarily represent the views of the Public Health Agency of Canada.

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# Introduction

At the time of writing, the unregulated drug poisoning emergency in Canada has claimed the lives of at least 42,494 people since monitoring began in 2016,<sup>1</sup> primarily driven by a toxic and unpredictable supply of unregulated drugs.

Given the ongoing and escalating nature of this crisis, there is a dire need to implement measures that would facilitate access to a safe supply of quality-controlled substances for those currently risking their health and lives because they are compelled to consume illegal and therefore unregulated street drugs of unknown composition, purity, and potency.

Safe supply, in its simplest sense, refers to the provision of pharmaceutical-grade alternatives to the unregulated, illegal drug supply. Its primary purpose is to prevent drug poisoning deaths. And to that end, there is a growing body of evidence supporting this intervention. In a 2024 large-scale study in British Columbia, for example, researchers found that even minimal access to a prescribed alternative resulted in a significant reduction in risk of overdose and all-cause mortality in the subsequent week.<sup>2</sup> A scoping review of 24 publications on safe supply programs in Canada similarly validated positive outcomes, including reducing reliance on the **unregulated drug supply**. As detailed in research described further below, emerging evidence on safe supply programs demonstrates a reduction in fatal and non-fatal overdoses and improved health, while yielding cost savings for healthcare systems.



Safe supply generally refers to the provision of pharmaceutical-grade alternatives to the unregulated, illegal drug supply to prevent drug poisoning deaths. The current, predominant approach to safe supply in Canada is via clinician prescribing in a medical environment usually requiring frequent urine tests, daily pick-ups, short-term duration of prescriptions, and diversion protocols. One defining characteristic of prescriber-dependent programming is the requirement of the prescription recipient to demonstrate engagement in services through frequent assessments, follow-up appointments, goal setting, and other indicators of "adherence."

Prescribed safer supply can be witnessed or unwitnessed depending on the policy of the program. In witnessed dosing models, recipients must consume their dose on site under the supervision of trained staff. The medications offered in these models tend to be more potent and comparable to the unregulated drug supply, like the fentanyl tablet, injectable sufentanil, and fentanyl patch protocols, which may be prescribed or dispensed in a clinic setting, community-based pharmacy, or via outreach teams. They may also be prescribed or dispensed in a low barrier, "de-medicalized" environment that involves fewer strict program requirements and more closely resembles consumption practices in the community. Most unwitnessed prescribed safer opioid supply protocols use tablet hydromorphone and are intended to be lower barrier than witnessed programming. In these programs, recipients typically access their medications via a community pharmacy at least once per day.

Increasing the safety of the *unregulated* supply through some degree of quality control (e.g. through drug testing) is another approach to safe supply. This model may involve a compassion club or buyers' club that screens its members and procures and drug tests substances on their behalf.

Injectable Opioid Agonist Treatment (iOAT) and Tablet Injectable Opioid Agonist Treatment (TiOAT) programs also prescribe alternatives to the unregulated drug supply in supervised clinic and consumption service settings but can be distinguished from safe supply by the ways in which they are offered, including the flexibility of the program, the goals of care, the environment in which services are delivered, and the composition of the staff team.

Despite recent advancements in safe supply, accessibility remains low given the scale of the current crisis. One only has to look to B.C., the province that has done the most to scale up prescribed safe supply, where researchers have highlighted that access has been low considering the number of people who would benefit from the intervention.<sup>5</sup>

Moreover, safe supply programming to date has been predominantly medicalized and mired in capacity constraints. Indeed, the working group Canadian Civil Society Advancing Safe Supply published a policy brief in 2023 titled "Innovating Beyond Exclusively Medicalized Approaches" noting "existing prescriber-driven, or medicalized, safe supply programs ... are not an adequate standalone response to the urgent drug toxicity crisis" and "present barriers and exclusions for racialized and other marginalized populations." 6 In particular, the working group noted various preconditions for access to drugs in such programs including preconditions such as mandatory diagnostic and follow-up appointments, urinalysis screenings, and pharmacy attendance. As such, the working group recommended "urgent, visible support for, and upscaling of, non-medical safe supply through co-ops, buyers' or compassion clubs, and additional de-medicalized and community-based options for safe supply."7



In this report, supervised consumption services are defined as evidence-based health services that provide a safe, hygienic environment where people can use drugs under the supervision of trained staff or volunteers and are inclusive of low-threshold and/or temporary services often designated as Overdose Preventions Services (OPS).

One such de-medicalized option for safe supply is to scale up access within supervised consumption services (SCS). SCS are rooted in harm reduction principles and are meant to provide accessible and low-barrier access to people who use drugs, often also staffed by people with lived experience of drug use or "peers."8 Efforts to implement prescribed safe supply at SCS are already underway at several sites, and research shows promise related to participants' willingness to consume in a monitored setting<sup>9</sup> and to the co-location of safe supply programs within the low-barrier service delivery associated with SCS. This has facilitated connections between services given the physical proximity and connections between staff, although some participants also referred to challenges of limited operating hours, long wait times during peak hours, and sharing space with individuals not on safe supply as challenges of co-location.<sup>10</sup> While one study noted some participants' preference for consuming drugs alone versus at an SCS being shaped by experiences of gendered violence, pointing to the need to expand safer environment interventions, 11 many participants also described the convenience of having a safe supply program integrated within a service they already use - notably in a setting

they associated with safety, comfort, and reduced exposure to "forces of structural oppression and marginalization operating within the local drug scene (e.g., violence, police harassment)." Affirming the possibilities of enhancing access to safe supply via SCS, a 2024 report from the Provincial Health Officer of B.C. recommends that "[o]pportunities for enhancing access to on-site consumption of prescribed alternatives at existing harm reduction sites, for example at overdose prevention and supervised consumption sites, should be considered and supported." 13

Facilitating scale-up of safe supply at SCS requires a review of the legal and policy framework regulating both SCS and safe supply. As such, the HIV Legal Network examined those frameworks, explored legal and policy options that would enable scale up of safe supply via SCS, and devised a number of legal and policy options to bridge gaps between recommendations made by people who use drugs, clinicians, civil society and human rights organizations, and researchers working in harm reduction and safe supply and the existing legal and regulatory barriers that keep those recommendations out of reach.

# Methodology

The following roadmap was informed by a synthesis of available evidence, key informant interviews with people who use drugs, service providers (including those working in SCS), legal experts, and program and policy decision-makers, and applicable laws, policies, and human rights standards.

Key Informants (KIs) with unique experiences and perspectives on safe supply were sought out to inform this report. In the recruitment of KIs, concerted efforts were made to ensure geographic, racial, age, and gender diversity.

We interviewed 16 KIs, among whom 62.5% (n=10) identified as a person who uses drugs, 62.5% (n=10) also had experience managing, supervising, or coordinating an SCS, 31.3% (n=5) identified as a support or outreach worker, with the same number reporting experience as an SCS program operator, 25% (n=4) were prescribers (physician or nurse practitioner), 18.8% (n=3) had worked as systems navigators and/or social workers, 12.5% (n=2) identified as non-prescriber healthcare providers, one (6.3% or n=1) identified as running an unsanctioned SCS, and an additional one (6.3% or n=1) identified as an executive director. KIs primarily resided in British Columbia (n=6) and Ontario (n=5), from which most existing safe supply programming is coming, but

also included respondents from Alberta (n=1), Saskatchewan (n=1), Quebec (n=1), New Brunswick (n=1), and the Yukon (n=1).

Five additional KIs from the fields of pharmacy, law, and industry, and from Health Canada were recruited for focused interviews on legal and policy considerations.

In addition to KI interviews, we undertook a comprehensive review of the state of the evidence on safe supply by reviewing peer-reviewed research articles, literature reviews, program evaluations, and reports, which were appraised to identify emerging trends and validate information from key informants.

We have preserved the anonymity of all KIs to facilitate their participation and frank assessments of the benefits and limitations of safe supply models, including in the context of SCS.



We value the voices of lived/living experience, particularly those of people who use drugs and are most likely to use safe supply in SCS environments. They are the experts in their own needs and wants, and any work done to reduce barriers to safe supply access must be centred on their perspectives. As such, we have prioritized their expert opinions throughout our analysis, key informant interviews, and writing.

# A Brief Overview of the Current State of the Evidence on Safe Supply Programs

Given that most safe supply currently available in Canada is prescribed, the majority of peer-reviewed information is from prescribed safe supply programs.

While the evidence on safe supply is still emerging and longer-term outcomes are yet to be known, the documented benefits of prescribed safe supply already demonstrate:

- Reduction in fatal and non-fatal overdoses
- Improved physical, mental, and emotional health
- Improved wound care access and outcomes
- Improved connections to health and social services
- Improved overall function and reduced reliance on unregulated drugs
- · Fewer infections related to injection drug use
- Cost savings for healthcare systems.<sup>14</sup>

At the same time, the B.C. and Ontario Coroners have stated that there is no indication that prescribed safe supply is contributing to drug poisoning deaths. <sup>15</sup>

This burgeoning body of evidence tells us that safe supply has potential, but scalability, capacity, and other limitations of current programs are cause for concern. <sup>16</sup> Furthermore, reports from the BC Centre for Disease Control <sup>17</sup> and the Ontario Drug Policy Research Network highlight that inhalation now accounts for significantly more overdose deaths than injection in both provinces, yet no safe supply options exist for people who smoke their drugs <sup>18</sup>

Additionally, a 2024 scoping review of safe supply programming identified limitations of medicalized safe supply programs<sup>19</sup> – a conclusion that also emerges from grey literature, which emphasize the need to uplift and reflect drug-use culture to improve accessibility and acceptability of services.<sup>20</sup> A 2021 report on splitting and sharing at SCS, for example, highlighted that accessibility of services is improved when policies, settings, and staffing more closely honour and resemble drug-use culture.21 Notably, a study of the outcomes of a non-medical safe supply compassion club run by a collective of people who use drugs, the Drug User Liberation Front (DULF), demonstrated that a model that is not reliant on health professionals as prescribers is not only possible, but holds great promise, as outcomes from this intervention included "reductions in any type of non-fatal overdose."22

Some incongruence is worth noting between service design resources informed by people who use drugs, which call for flexible, harm reduction-based models for safe supply.<sup>23</sup> The reality has been the implementation of medicalized, and often rigid, programmatic safe supply models in Canada. This phenomenon is explored in depth with key informants.

#### Key informant insights on safe supply programs at SCS

#### **Benefits of safe supply at SCS**

All KIs acknowledged the value and potential of scaling up safe supply in SCS and among those associated with an SCS, almost all agreed that they could incorporate safe supply in their SCS. Among KI prescribers, all described a current process in which they meet participants in person or are connected virtually from a nurse on site. Prescribed safe supply was primarily required to be consumed on site, witnessed by a regulated health professional. KIs highlighted the benefits of scaling up safe supply in SCS given the existing infrastructure, trained staff, established trust with communities of people who use drugs, and low-barrier, harm reduction philosophy of practice.

One KI prescriber noted that the provision of safe supply at their SCS allowed for higher dose prescribing that corresponds to the need of participants because of the built-in safeguard of the SCS. Another KI prescriber described three primary benefits of care, connection, and access:

People are also saying they're saving money. And are able to save money on things that improve their lives in other ways. People are saying that they're overdosing less because they don't have to access the unregulated supply. People saying, it saves them time to be able to come to a single place instead of meeting in some [nondescript] location or some parking lot and risking all the things that come with trying to transact in the public or transact in some trap-house.

Other KIs who work at sites that offer safe supply highlighted benefits reflected in the literature review, including reduction in fatal and non-fatal overdoses, improved health and well-being, increased connections to care, reduced reliance on the unregulated supply, and more control over drug use. Several further highlighted a reduction in survival crime, improved overall functioning, and more broadly having basic needs met — allowing individuals to focus on other priorities and goals.

Prescriber KIs also noted the appeal of safe supply being a motivator to access SCS and addictions treatment. thereby improving accessibility and acceptability of existing services. There is an emerging body of evidence suggesting access to safe supply is having a positive impact on retention in opioid agonist treatment (OAT).24 According to one KI, "It's motivated some people to want to ... stabilize in their opioid use disorder, which they weren't wanting to do ... previous to participating in our program. Like, they've been on OAT before, they didn't like it. They didn't really see the benefit in it, until they started on their safe supply where they were getting something that was ... free and regulated and just predictable." Other KIs described the benefits participants experience when wraparound support is made available alongside the provision of safe supply.

#### Limits and barriers to current safe supply programs at SCS

### The three primary limits that KIs described in relation to current safe supply programs related to the:

- (1) lack of available and/or willing prescribers;
- (2) need for program flexibility and a greater variety of de-medicalized safe supply models; and,
- (3) need for more safe supply options, including for people who smoke their drugs or use stimulants.

KIs universally noted the lack of available and/or willing prescribers as the main limitation to scaling up safe supply, which results in long wait lists and limited capacity to serve high volumes of participants. To address this, some prescriber KIs suggested exploring the possibility of federal and provincial governments directing regulatory colleges to loosen restrictions on prescribers and ease fears of punishment in relation to safe supply.

In terms of program models, there was a notable incongruence between prescriber KIs and those who identified as people who use drugs. While prescribers extolled the benefits of safe supply in SCS as an opportunity to engage participants in care, other KIs expressed concern over being coerced or trapped into rigid, programmatic treatment settings. Kls described current, ongoing access to prescribed safe supply often being contingent on participants navigating multiple requirements, including frequent urine drug tests (UDT), daily pick-ups, short-term duration of prescriptions, follow-up appointments, goal setting, and participating in program evaluation. Missed-dose protocols dictate dose reductions to protect participants in case their tolerance has depleted during a period of non-use, and diversion protocols are enforced to address the perceived safety of communities. These safeguards create accessibility barriers and are not universally viewed as protective, particularly by people who use drugs. One KI expressed concern for the protected space of an SCS being used as an opportunity to "cherry pick" ideal safe supply candidates. Many KIs cautioned against replicating the existing prescriber-driven approach with rigid program requirements in SCS that could bar or ban participants deemed "non-compliant" and replicate medicalized trauma.

Many KIs also acknowledged that the current fixation on prescribed safe supply was detracting from the development and implementation of other models for safe supply including within the context of SCS. **As one prescriber KI reported:** 

It is still keeping an issue that is very much an issue rooted in social injustice within a medicalized model. So, I think the fact that there are prescribers involved and that it is situated within these respectable health care institutions ... in some way actually coverts and subverts and derails movements for justice for folks who use drugs and also movements to actually end the war on drugs.

Some recommended 24/7 distribution access and the use of vending machines for distribution to reflect the fact that drug use is not a "nine-to-five" activity. Kls described how drug use is a social behaviour to many, and how clinical environments would be a deterrent both for safe supply recipients and non-safe supply recipients who access the SCS. As one Kl put it, "Drinking a beer at your doctor's office might feel really strange compared to in a bar with your friend."

One KI who runs an SCS believed that a truly accessible safe supply may even negate the need for SCS. "What would be better is if we didn't have to have safe consumption spaces because the stuff people were using was safe," they said.

I don't think the medical model is that far of a stretch from the criminalized model around substance use and the drug war.

(KEY INFORMANT)

A recurrent theme was that there is no singular model or approach to safe supply, but that a continuum of options is needed. For example, KIs suggested buyers' clubs or compassion clubs and public health models that do not require an individual prescriber-patient relationship. As one KI with lived/living experience shared, "To take away some of the barriers, it would be cool to not have a medicalized model of safe supply, but, like, one that's more like buyer clubs or compassion clubs that are run by people who use drugs that have access to things like testing and different harm reduction strategies."

Most KIs noted that SCS environments should continue to reflect drug-use culture, and warned about injecting clinical programs and staff into settings that are intended to be culturally safe. For that reason, even KIs who support prescribed safe supply acknowledged that implementation in SCS would have to reflect some degree of de-medicalization. KIs thus urged SCS operators to remove medical elements from safe supply or make the medical elements voluntary/supplementary to the program. If medicalization and wraparound supports are available, KIs suggested creating separate spaces for service provision so the SCS remains a protected space for those who do not wish to engage with medical staff.

Additional caution was raised by KIs in terms of who should be responsible for the implementation and operation of safe supply in SCS. As one prescriber KI recounted, large systems and institutions are often not the best equipped to implement lower-barrier and harm reduction-based programming and are often unable to allow for individualized care. Overall, there was consensus from KIs that there is a need to address the woeful power dynamic between prescribers and participants created through medicalized models, and that safe supply programming, including at SCS, should be led and created/co-created by the community of people who use drugs who are intended to access the safe supply.

KIs described a range of safe supply substances being provided including tablet options like hydromorphone and oxycodone, fentanyl products including fentanyl patches, injectable sufentanil, dissolvable fentanyl pills, powdered fentanyl, and other injectable options like liquid hydromorphone and diacetylmorphine. Injectable options were primarily delivered in a model similar to an iOAT model, requiring participants to inject on site. KI prescribers discussed the unmet need for pharmaceutical opioids like diacetylmorphine and fentanyl in various formulations.

Multiple KIs across the spectrum of prescriber KIs and KIs with lived/living experience emphasized the need for viable safe supply options for stimulants, describing how people who use stimulants are often left out of conversations pertaining to harm reduction and safe supply yet risk many harms, including death, associated with the unregulated supply. At present, prescribed stimulant options are primarily either dextroamphetamine or methylphenidate, medications that often do not replicate the desired effects of their unregulated alternative. KIs also noted the lack of benzodiazepines in the current prescribed safe supply options. Another major theme was the inequity of current prescribed options that do not include smokeable formulations. This was discussed by multiple Kls, including one who contended the lack of smokeable options is an act of racism, since racialized communities may be more likely to smoke their drugs compared to other means of consumption. Other KIs noted that providing safer smoking spaces and access to regulated smokeable safe supply was imperative as most participants accessing their SCS were people who smoke their drugs. KIs thus recommended improving the selection of drugs available, including stimulants, smokeable options, diacetylmorphine, cocaine, and benzodiazepines.

Other discussions included multiple mentions of rural and remote inequities. Kls pointed out that in many localities, especially in remote and rural areas, SCS do not exist, highlighting the importance of having an array of options for safe supply that correspond to geographical disparities in harm reduction services. Concerns were also raised around the ethics of pilot safe supply programs. KIs underscored how the impermanence, precarious funding, and low capacity of pilot programs were cause for concern. Additional limitations raised were the lack of available and sustained funding, lack of physical spaces to develop safe supply programming, and unfamiliarity with technological requirements like online pharmacy databases and electronic medical records. Kls noted that securing sustainable funding was already challenging for many harm reduction services, with some SCS forced to self-fund their program because their provincial government would not support harm reduction. Adding safe supply programs may thus be a financial challenge for SCS providers who are already struggling with insufficient funding. KIs also indicated the failure to provide long-term funding prevents scale up of services and impedes innovation because program managers fear funding may be jeopardized if political ideologies shift.

# Legal and Policy Frameworks Relevant to Safe Supply at SCS

In order to understand how safe supply can be implemented and scaled up in SCS in Canada and to contextualize the barriers and opportunities identified above, a brief overview of the relevant legal and policy frameworks in Canada and internationally is necessary.

#### Federal control over drugs

#### Controlled Drugs and Substances Act (S.C. 1996, c. 19)

The Controlled Drugs and Substances Act (CDSA) is the overarching legislation that controls certain drugs, prohibits activities with controlled drugs or substances (listed in its Schedules), and creates offences punishable by way of imprisonment, fine, or both. These prohibitions restrict activities related to possessing, administering, or dispensing "controlled substances" including drugs that would be used for safe supply programs. As legal scholars have noted, for safe supply programs (including at SCS) to legally operate, both the supply and possession of substances would necessarily need to be free of criminal sanction, and "the full decriminalisation of drug use and the possession of drugs for personal use, across the board, should be regarded as a complement to any effective safe supply measure."<sup>25</sup>

Exceptions to prohibited activities may be authorized by regulation (section 55(1) of the CDSA) or through exemptions issued by the federal Minister of Health (section 56(1) of the CDSA). Section 56(1) of the CDSA gives the Minister broad powers to exempt the application of the CDSA and its regulations, with respect to any person or class of persons or any controlled substance or precursor for medical or scientific purposes, or "otherwise in the public interest." Section 56(1) exemptions have been granted, for example, to allow provinces to authorize overdose prevention sites on the basis that this is "in the public interest" and to relax rules for pharmacists and prescribers in dealing with controlled

substances in response to the COVID-19 pandemic to enable them to deliver controlled substances to patients in self-isolation.<sup>27</sup>

Section 56.1 of the CDSA specifically deals with exemptions of SCS from the CDSA for a "medical purpose" if specific criteria are met. Additionally, section 56.2 of the CDSA indicates that "[a] person who is responsible for the direct supervision, at a supervised consumption site, of the consumption of controlled substances, may offer a person using the site alternative pharmaceutical therapy before that person consumes a controlled substance that is obtained in a manner not authorized under this Act." This subsection was introduced in 2017 to support the offering of "replacement drugs" at SCS.<sup>28</sup>

Within this framework, only authorized persons set out in regulations or exemptions made under the CDSA may conduct activities with controlled substances that would otherwise be illegal. In particular, only "practitioners" can prescribe controlled drugs and substances under the CDSA. These include regulated health care providers such as doctors or dentists but also any other class of persons specifically authorized through federal regulation. Of note, certain controlled substances can only be prescribed by a limited class of practitioner. For example, outside of a hospital setting, diacetylmorphine can only be prescribed by medical doctors and nurse practitioners.

# Narcotics Control Regulations (C.R.C., c. 1041)

The Narcotics Control Regulations (NCR) were made under the CDSA. Section 2(1) of the NCR defines a prescription as "an authorization given by a practitioner that a stated amount of a narcotic be dispensed for the person named in it or the animal identified in it" and section 53(2) allows practitioners to sell narcotics to a person who is a patient under their professional treatment, if the narcotic is required for the condition for which the person is receiving treatment.

The NCR also include a section on "licensed dealers" who, under section 8(1) of the NCR, "may produce, assemble, sell, provide, transport, send, deliver, import or export a narcotic if they comply with these Regulations and the terms and conditions of their dealer's licence and any permit issued under these Regulations." Under section 9 of the NCR, only an individual who ordinarily resides in Canada, a corporation that has its head office or operates a branch office in Canada (which could include an SCS), or "the holder of a position that includes responsibility for narcotics" on behalf of the federal or provincial government, a police force, a hospital, or a university in Canada may apply for a dealer's licence. Section 25.4 of the NCR authorizes a licensed dealer to sell or provide a narcotic to a person who is exempted under section 56 of the CDSA with respect to its possession.

#### Food and Drugs Act (R.S.C., 1985, c. F-27)

All drugs are also subject to the *Food and Drugs Act* (FDA) and associated regulations, including drugs prescribed in safe supply programs. Where any inconsistency or conflict between the CDSA and the FDA and associated regulations arises, the CDSA takes precedence.<sup>29</sup> In order for a drug to be manufactured or sold in Canada, it must be authorized under the FDA.

#### Provincial/territorial jurisdiction over the administration of healthcare

Provincial and territorial governments are primarily responsible for the management, organization, and delivery of healthcare services, including the regulation of healthcare professionals, the administration of public drug plans, and the funding of harm reduction services. These governments consequently play a key role in the implementation of safe supply programs.

#### **Regulated Health Professions Legislation**

Provincial and territorial legislation regulating healthcare professionals (e.g. nurses, physicians, pharmacists, dentists, etc.) define "controlled acts" or "restricted activities" such as prescribing, which may be performed only by authorized regulated health professionals, and regulate how they conduct activities with controlled substances within the context of their scope of practice. The ach province and territory, regulatory colleges are also responsible for ensuring that regulated healthcare professionals provide healthcare services in a safe, professional, and ethical manner, including by setting standards of practice for healthcare professionals in a way that may impact the accessibility of safe supply programs (e.g. imposing additional training for safe supply prescribing).

#### **Publicly funded drug plans**

Each province and territory also administers a publicly funded drug plan, which provides coverage to its eligible population based on specific criteria, list of approved drugs or formulary, and reimbursed costs. All provinces and territories offer some form of drug coverage (including drugs prescribed in safe supply programs) to selected populations, such as those on social assistance, seniors, and individuals with conditions that are associated with high drug costs, with variation between provinces regarding who is covered and which drugs are covered. At least one public drug plan (Ontario) stipulates that "patient and societal impact" and "public interest" are among the factors considered in whether a drug should be reimbursed.<sup>31</sup>

#### **Emergency powers**

A declaration of emergency is a legal mechanism that allows governments to temporarily access extraordinary powers authorizing them to act quickly and easily to deal with a crisis.

# Federal Emergencies Act (R.S.C., 1985, c. 22 [4th Supp.])

The federal emergency power provides, under exceptional circumstances, the authority to undertake a broad array of temporary measures including directing any class of persons to render essential services. Under Section 3(a) of the Emergencies Act, a "national emergency" is defined as "an urgent and critical situation of a temporary nature that ... seriously endangers the lives, health or safety of Canadians and is of such proportions or nature as to exceed the capacity or authority of a province to deal with it." The Act defines four categories of "national emergency" including a "public welfare emergency" (section 5), which is defined as an emergency that is "caused by a real or imminent ... disease in human beings, animals or plants, or accident or pollution ... and that results or may result in a danger to life or property, social disruption or a breakdown in the flow of essential goods, services or resources, so serious as to be a national emergency." [emphasis added].

The unprecedented nature and magnitude of the unregulated drug poisoning crisis could support the declaration of a public welfare emergency. This would empower the federal government under section 8 of the *Emergencies Act* to direct "any person, or any person of a class of persons, to render essential services of a type that that person, or a person of that class, is competent to provide."

#### **Provincial emergency legislation**

Provinces also have emergency powers legislation allowing them to respond rapidly to crises, some of which also allow municipalities to declare local emergencies.<sup>32</sup> In B.C., for example, in response to the province's drug poisoning crisis, the Provincial Health Officer declared a public health emergency in 2016 pursuant to the province's *Public Health Act*.<sup>33</sup> This empowered the Provincial Health Officer to exceptionally authorize registered health professionals to perform activities that they would not otherwise be permitted to perform or provide under a health profession regulation and to "modify or waive a requirement, standard, limit or condition set under a health profession regulation."34 This declaration enabled subsequent public health orders, including one that has offered a pathway for B.C. nurses to prescribe safe supply.35

#### International treaties and human rights standards

Internationally, Canada is a party to the United Nations drug control conventions. Under these conventions, use of controlled or "scheduled" substances are permitted only for medical or scientific purposes, <sup>36</sup> though they specifically recognize that "the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes."<sup>37</sup>

At the same time, drug policy must be implemented in a way that respects, promotes, and protects human rights<sup>38</sup> and Canada has ratified international human rights treaties that require it to uphold the right to life and the right to the highest attainable standard of physical and mental health.<sup>39</sup> The former right has been interpreted by the Human Rights Committee (an oversight body tasked with reviewing states' compliance with the International Covenant on Civil and Political Rights) to require governments to "take appropriate measures to address the general conditions in society that may give rise to direct threats to life, or prevent individuals from enjoying their right to life with dignity"40 and in 2018, the Committee held in Toussaint v Canada that the right to life can require the government to provide emergency and essential healthcare, including essential medications to control diabetes and hypertension, which the claimant was denied as an undocumented migrant in Canada. 41 The right to health has been defined to include the provision of essential medicines in the International Covenant on Economic, Social and Cultural Rights (ICESCR), which also enshrines the rights to equality and the right to enjoy the benefits of scientific progress.<sup>42</sup> Notably, the Committee on Economic, Social & Cultural Rights (tasked with reviewing states' compliance with the ICESCR) has interpreted that right as "embracing a wide range of

socio-economic factors that promote conditions in which people can lead a healthy life," including measures to prevent and reduce "exposure to harmful substances" and as requiring health goods, services, and information to be available "in sufficient quantity," accessible, acceptable, and of good quality, meaning "scientifically and medically appropriate."

Similarly, the International Guidelines on Human Rights and Drug Policy has defined the right to life to encompass states' obligation to ensure access to overdose prevention services in taking "positive measures to increase the life expectancy of people who use drugs" and the right to health as requiring States to "[a]mend laws, policies, and regulations that unnecessarily restrict the availability of and access to controlled medicines."44 The Guidelines also assert that, as part of government efforts to ensure realization of the right to health, states "should repeal, amend, or discontinue laws, policies, and practices that inhibit access to controlled substances for medical purposes and to health goods, services, and facilities for the prevention of harmful drug use, harm reduction amongst those who use drugs, and drug dependence treatment," and that they "may utilize the available flexibilities in the UN drug control conventions to decriminalize the possession, purchase or cultivation of controlled substances for personal consumption." The Guidelines further define the right to benefit from scientific progress as requiring States to "[t]ake legislative and other appropriate measures to ensure that scientific knowledge and technologies and their applications - including evidence-based, scientifically proven interventions to treat drug dependence, to prevent overdose, and to prevent, treat, and control HIV, hepatitis C, and other diseases — are physically available and financially accessible without discrimination."45

In 2023, the UN Office of the High Commissioner on Human Rights noted that "[a]ffordable access to and adequate availability of internationally controlled essential medicines for ... drug dependency ... constitute core minimum obligations of the right to health."<sup>46</sup> The Office thus recommended that States "take control of illegal drug markets through responsible regulation" and "[c]onsider developing a regulatory system for legal access to all controlled substances."<sup>47</sup>

Under Canadian law, the Charter of Rights and Freedoms protects the rights of people who use drugs. In Canada (AG) v PHS Community Services Society, for example, the Supreme Court of Canada recognized that people who inject drugs are a historically marginalized group and preventing them from accessing the health services offered at an SCS violated their constitutional rights to life, liberty, and security of the person. <sup>48</sup> Courts have also repeatedly held that governments cannot discriminate against people who use drugs. <sup>49</sup> In 2023, in Black v Alberta, the court confirmed that a government's

restrictions on access to prescribed hydromorphone "may contravene the Charter s. 7 rights to life and security of the person" and can "have the effect of imposing an arbitrary or discriminatory disadvantage on those with opioid use disorder."50 The Court thus ordered that regulations restricting service providers from providing such access not apply until the resolution of the case. Additionally, all provincial and territorial human rights legislation prohibit discrimination in the provision of goods, services, and accommodation based on disability, which has been defined to encompass drug dependence.<sup>51</sup> To redress the legacy of residential schools and advance the process of Canadian reconciliation, the Truth and Reconciliation Commission has also called on governments to "recognize and implement the health-care rights of Aboriginal people as identified in international law, constitutional law, and under the Treaties" and to "close the gaps in health outcomes," including with respect to "addictions" and "life expectancy."52

# Policy and Practice Barriers to Implementation and Exploration of Pathways for Change

As detailed above, the literature review and KI interviews describe three main barriers to implementing safe supply at SCS:

- 1. Prescribed safe supply is limited by lack of available and/or willing prescribers.
- 2. There is need for program flexibility and a greater variety of de-medicalized safe supply options.
- The selection of drugs available is inadequate, with no prescribed safe supply options for people who smoke their drugs or viable stimulant safe supply options.

# Prescribed safe supply is limited by lack of available and/or willing prescribers

#### Regulatory college guidance

Confirming what KIs in this project described, studies have found that the provision of safe supply by clinicians has been met with reluctance, in part because of perceived inappropriate prescribing being grounds for reprimand and the burdensome nature of repeated audits issued by regulatory colleges for prescribing safe supply.53 Additionally, while some guidelines have been produced with respect to prescribed safe supply,54 prescriber reluctance may be related to the overall lack of clinical guidance on safe supply. According to Health Canada, "Although some opioid medications have been approved by Health Canada for treatment of opioid use disorder (OUD), there are no approved medications for substance use disorders involving stimulants or sedatives, as such, these medications are prescribed 'off label'"55 – meaning that a drug is being used in a way that has not been reviewed and authorized by Health Canada.

One way for regulatory colleges to increase clinicians' comfort and knowledge with prescribed safe supply, help alleviate prescriber hesitancy, and ease fears of punishment is to issue public statements and clinical guidance explicitly endorsing prescribed safe supply in the context of SCS and to offer training, so practitioners are equipped to prescribe safe supply. Health Canada's view that substance use dependence is medically complex to treat, including with respect to dosage, could be addressed by the development of clinical guidelines and decision support tools.<sup>56</sup> In a context where regulatory colleges have failed to provide such support or guidance, provincial authorities could direct regulatory colleges to do so, for which there is recent precedent in B.C. in the context of COVID-19.57 Additionally, Health Canada could play a leadership and convenor role to try to influence regulatory colleges to provide such guidance and support, as it has done before, by urging provincial health ministers, regulators of health professions, and organizations representing healthcare practitioners to provide such support and clinical guidance.58

#### **Medical directives**

Regulated health professionals who are legally authorized and competent to perform a controlled act (such as prescribing) can confer their authority to perform that act to another individual who is not so authorized. Delegating and accepting delegation of controlled acts is subject to regulatory college guidelines, standards, and regulations.<sup>59</sup> In the context of prescribing, directives are formal orders, typically authorized under the bylaws of professional colleges, given in advance by authorized prescribers to enable another healthcare provider to perform an activity for a range of clients with identified health conditions and when specific circumstances or criteria exist, without a direct assessment by the physician or authorizer at the time. 60 Such directives are generally developed by affected regulated professionals and relevant administrators within the province or territory and have essential components, including the client population to which the directive applies, specific client clinical conditions and situational circumstances that must be met before the directive can be implemented, scope of practice, description of the intervention(s), and identification of the healthcare professionals who can perform the intervention.<sup>61</sup> A medical directive may thus facilitate prescribing to a higher volume of safe supply participants, in line with recommendations made by clinicians to the Office of the B.C. Provincial Health Officer, who urged "an exploration of options [for prescribed safe supply programs] that are less resource intensive and don't require 1:1 prescribing."62 However, as noted above, the NCR define a prescription as "an authorization given by a practitioner that a stated amount of a narcotic be dispensed for the person named in it." [emphasis added] At least one nursing college has interpreted this as requiring orders for controlled substances to be client specific, thus precluding a directive for safe supply, <sup>63</sup> although medical directives for the administration of controlled substances such as opioids exist in the context of palliative care. <sup>64</sup> A medical directive for prescribed safe supply may thus require an amendment to the NCR definition of "prescription" allowing narcotic dispensation to a class of persons with identified health conditions.

In the context of SCS, a directive from a prescriber could be layered onto existing services. This could include an eligibility consideration requiring that an individual be an existing participant of that SCS (so that, for example, staff know that they are not opioid naïve) and a situational requirement that consumption happen on site. This is consistent with the spirit of section 56.2 of the CDSA described above, endorsing the provision of "alternative pharmaceutical therapy" at an SCS. Staff such as nurses at SCS (who are not permitted in most provinces to prescribe safe supply) are well trained to monitor for sedation and respond to overdose; a key public health and safety control could be witnessed consumption on site. Given these controls, a directive from a prescriber enabling a broader range of regulated healthcare providers<sup>65</sup> to provide safe supply for people who use drugs within the confines of an SCS may be one option to address the lack of available prescribers and limited capacity for serving high volumes of participants. Options that diffuse prescriber duties to a broad range of team members may also be necessary so as not to detract from existing staff responsibilities and to maintain the current operations of an SCS.

# **Expanded class of practitioners and prescribers**

Only practitioners can prescribe controlled substances, and practitioners who prescribe safe supply in Canada are predominantly physicians and nurse practitioners. Given the limited number of practitioners available to prescribe safe supply, expanding the definition of a "practitioner" who is authorized to administer, prescribe, or sell narcotics under the *Narcotics Control Regulations* to include other regulated professionals such as nurses and pharmacists may be one route to address the shortfall. This would require engaging the federal government, provincial governments, and health regulatory colleges.

Already, in 2012, the federal government expanded the list of practitioners via the New Classes of Practitioners Regulations SOR/2012-230 to include podiatrists, midwives, and nurse-practitioners. The regulation enables listed practitioners to prescribe a subset of controlled substances, subject to federal regulations and provincial/territorial laws and regulations. 66 Alongside the adoption of this regulation in 2012, Health Canada published a framework setting out the process by which it would consider amending the regulations to designate additional classes of health professionals as practitioners in the future, which includes engagement with provincial/ territorial ministries of health.<sup>67</sup> The framework specifies that in order for a class of health professional to be considered for inclusion in the "new classes," "the health profession in question must be regulated by an authority established under provincial/territorial legislation" (i.e. a professional college) and there must be mechanisms in place "to ensure compliance of the health profession in question" with this legislation and "to ensure that practitioners meet the security, record-keeping, and loss and theft reporting provisions" of CDSA regulations.

#### i. Nurses

Most SCS are already staffed by nurses; expanding the list of practitioners to include nurses would enable them to prescribe safe supply at SCS. Notably, some emergency provincial powers appear to permit a unilateral (i.e. without federal involvement) broadening of prescribers. In September 2020, B.C.'s Provincial Health Officer issued a public health order pursuant to the province's Health Professions Act acknowledging that, in the context of dual public health emergencies of drug toxicity deaths and COVID-19, there are "insufficient health human resources available to meet the needs of persons who use illegally produced and/or street procured drugs and who require pharmaceutical alternatives in order to mitigate the risks and harm of the dual public health emergencies." The order thus authorized registered nurses and registered psychiatric nurses who possess additional educational preparation and experience to "make a diagnosis of a problem substance use condition or substance use disorder" and to "prescribe specific drugs, including controlled substances, to manage or ameliorate the effects of substance use by a person who is diagnosed as having a problem substance use condition or substance use disorder" ... "in the public interest to increase access to health professionals who can prescribe pharmaceutical alternatives to the toxic drug supply."68 Following this order, in 2023, the B.C. College of Nurses and Midwives approved a series of new and amended standards, limits, and conditions to create a new designation of certified practice for registered nurses and registered psychiatric nurses to prescribe in relation to opioid use disorder.69

While this has yet to be fully implemented and scaled up in B.C., this approach holds promise and other provinces and nursing colleges in those provinces could follow suit to permit more registered nurses to prescribe safe supply.

#### ii. Pharmacists

Under provincial legislation, pharmacists are already among the regulated health professionals permitted to prescribe in limited circumstances, 70 and pharmacists in Canada have seen provinces expand their prescribing powers in recent years. 71 Should the federal government expand the list of practitioners to allow pharmacists to prescribe controlled substances to be used in safe supply programs, another option to facilitate safe supply at SCS is to have a prescribing pharmacist linked to an SCS. Already, in 2020, during the first year of the COVID-19 pandemic, Health Canada issued a temporary<sup>72</sup> s. 56(1) class exemption "in the public interest" for prescriptions of controlled substances authorizing pharmacists to prescribe, sell, or provide controlled substances in limited circumstances or transfer prescriptions for controlled substances. However, pharmacists were not allowed to initiate new treatments or drugs. A 2021 survey conducted by the Canadian Pharmacists Association of pharmacists implementing the CDSA exemption found that the majority of pharmacists are confident using the CDSA exemptions (71%) and believe the exemptions have had a positive impact on patients (79%), but most pharmacists (69%) also found it difficult to reach prescribers in a timely manner to extend, renew, transfer, or adapt prescriptions for patients.73

As with nurses, the inclusion of pharmacists as safe supply prescribers may require amendments to provincial legislation expanding their scope of practice<sup>74</sup> and defining the responsibilities of pharmacists and conditions under which pharmacists could prescribe safe supply. It would also require provincial regulatory colleges for pharmacists to work alongside pharmacists' associations to produce practice standards, educational tools, and other guidance for its members.<sup>75</sup>

#### There is need for a greater variety of de-medicalized safe supply

Given the overall limitations and unmet potential of the prescriber model, there is a need for complementary community-based models such as a co-op, compassion club, or buyers' club model<sup>76</sup> to access safe supply that may not require an individual prescriber-patient relationship, including within the context of SCS. This was affirmed in a recent review of B.C.'s prescribed safer supply programs, which acknowledged a need for programs "that are not dependant on an individual prescriber (e.g., access though ... Supervised Consumption Sites, multidisciplinary clinics with wrap around supports, including peer support, where patients have a relationship with the clinic versus an individual provider) and non-medical access models (e.g., compassion clubs)."<sup>77</sup>

# Scaling up prescribed safe supply models that permit greater access and user autonomy

#### Expanded Access program

In 2022, PHS Community Services Society launched a program in B.C. to sell pharmaceutical-grade fentanyl to individuals who would otherwise purchase substances from the unregulated market. Under the program, an individual is assessed by a medical team and if deemed suitable for the program, given a prescription that they can use to purchase fentanyl powder capsules at cost from one of the program's clinical sites, 78 permitting greater participant autonomy and fewer requirements of the prescriber and care team. This helps address a concern from some quarters that participants are selling (and diverting) safe supply, since people would ostensibly only purchase the drugs that they intend to use. Although the cost of purchasing safe supply would remain a significant obstacle, an expanded access approach may work in conjunction with a compassion club embedded within a SCS, whereby a medical team undertakes participant screening and either a compassion club (on behalf of its members) or individual consumers purchase and consume their safe supply on site. Operationalizing an expanded access program at an SCS in this way may facilitate the involvement of people who use drugs in a setting that more adequately reflects drug-use culture.

#### ii. Biometric Dispensing Machine approach

The MySafe program, which has been implemented at an overdose prevention site in Vancouver among other settings, provides prescription opioids to participants who have a history of overdose, use opioids, and have fentanyl detected in their urine drug screens. The staff team consists of a prescribing physician who completes a medical examination for all potential participants prior to

enrolment and program staff at each of the MySafe locations. Medications for MySafe participants are dispensed at a local pharmacy - staff place the medications inside the machine, and participants access their daily doses from the machine at a time they choose. In the context of a biometric dispensing machine at an SCS, participants would consume their safe supply on site, facilitating witnessed consumption. Placing a machine at an SCS would be simpler than embedding a pharmacy or retrofitting an entire medication room, while allowing participants to access an SCS booth in proximity to the machine. Research with MySafe participants describe the convenience and ease of accessing their safe supply from a biometric dispensing machine, which enhanced their autonomy while reducing negative experiences in other clinical or pharmacy settings; participants who were enrolled at the overdose prevention site also described the convenience of its proximity to where they resided.79

#### iii. Virtual care models

Virtual care models may be another option to reduce barriers to prescribed safe supply, especially in the context of prescriber scarcity as well as for patients in rural and remote communities. Evidence with respect to virtual OAT care suggests that virtual care prescribers have similar retention rates and treatment effectiveness compared to traditional, in-person appointments.80 As per B.C.'s review of prescribed safer supply programs, "Virtual models of substance use care should be supported as much as possible."81 While SCS remain out of reach for many rural and remote communities, one option for virtual care to address prescriber scarcity where SCS do exist may be for multiple facilities to establish a dedicated line to a prescriber, allowing them to assess and prescribe for individual participants at diverse locations.

# Expanding role of peers with prescribed safe supply

Expanding the role of peers within SCS is another option. Peers could operate a compassion club within an SCS, for example, and develop membership criteria and dispense safe supply to members after a primary prescriber has screened and prescribed to members.

Another possible legal pathway to expand prescribed safe supply is to permit peer experts to carry out a directive from a prescriber within the confines of an SCS. As noted above, this would require an amendment to the NCR definition of "prescription" since the regulations define a prescription as specific to "the person named in it." It would also require support from professional colleges to enable authorized prescribers to enable, via medical directive, a non-regulated category of peer experts to prescribe in a tailored way, e.g. in the context of an SCS for clients with an identified health condition. For the latter requirement, provinces could issue a public health order to colleges to support such a directive authorizing peer experts with extensive experiential knowledge of substances to prescribe safe supply in the context of an SCS. While this is an untested pathway, it is a possible route that removes key barriers (e.g. lack of available prescribers and inadequate de-medicalized safe supply options) to scale up safe supply.

# Expanding services at SCS to increase safety of unregulated supply and to facilitate access to pharmaceutical alternatives

#### i. Increasing safety of the unregulated supply

As described above, there is significant breadth to the CDSA's section 56(1) and section 56.1 exemption powers and the federal Minister of Health has full (but largely unused) authority to permit SCS to engage in activities to increase the safety of the unregulated supply. For example, SCS could provide on-demand drug checking (which Health Canada has already authorized at some SCS, though the cost of drug checking technology remains a significant barrier to other SCS seeking this authorization<sup>82</sup> ). SCS could also allow people with whom SCS participants have trusted relationships to sell their drugs on site, 83 which is not currently permitted, although an exemption could be sought under sections 56(1) or 56.1 to do so. In recent years, federal authorities have expressed willingness to allow SCS to apply to receive a federal exemption to permit splitting and sharing drugs on site.84 These additional options provide critical opportunities to improve accessibility and acceptability of SCS in a manner that respects and reflects drug-use culture.

Another route to facilitate safe (unregulated) supply in a de-medicalized physical space staffed by peer support workers (and often, integrated with healthcare and social services) is to enable SCS staffed by peers to procure and test substances from unregulated sources (as DULF did prior to the founders' arrests, with positive evaluations<sup>85</sup>), and provide this to SCS clients based on clear criteria. This could be achieved by the Health Minister granting either a blanket exemption pursuant to section 56(1) "in the public interest" from all applicable provisions of the CDSA and the regulations made thereunder, to all applicable entities involved in the operation of an SCS, to all applicable substances involved in the operation of the service, and in the course of carrying out the functions of the service, or under section 56.1 of the CDSA, for the purpose of allowing these activities to take place at a SCS "for a medical purpose."

#### ii. Facilitating pharmaceutical alternatives

As per the NCR, an SCS, being a corporation that has its head office or operates in Canada, could apply to be a "licensed dealer," which allows it to sell, provide, or deliver a narcotic if it complies with the NCR and the terms and conditions of its licence. While a licensed dealer is not permitted to provide or sell controlled substances to the general public, section 25 of the NCR outlines potential recipients of "Sale of Narcotics," which include another licensed dealer, a pharmacist, a practitioner, a hospital employee, the Minister, or an "exempted person" under section 56(1) of the CDSA86 Based on this provision, the Minister could potentially provide a section 56(1) exemption for a "medical or scientific purpose" or "in the public interest" to everyone who accesses a specific SCS that has a dealer's license (the terms of which permit the SCS to provide safe supply to individuals accessing the SCS). The SCS could then provide those exempted individuals with drugs procured from other existing licensed dealers, subject to certain conditions or public health decision-making tools and clear risk mitigation measures. This would be consistent with the spirit of section 56.2 of the CDSA endorsing the provision of "alternative pharmaceutical therapy" at an SCS.

This pathway reduces the need for a middle person (i.e. the practitioner) to prescribe safe supply and facilitates safer consumption through SCS oversight. In practice, this would require:

- A SCS to obtain a dealer's license that permits it to provide or sell safe supply to a class of section 56(1) exempted individuals under certain conditions (e.g. only those who access the SCS and meet defined criteria supported by public health decision-making tools).
- A SCS to procure safe supply from existing licensed dealers to meet the needs of SCS clients, and to then dispense safe supply to the exempted clients.

Notably, the conditions of a dealer's license established by Health Canada are stringent and require a secure environment for the storage of controlled substances. SCS would thus require resources to provide adequate safe supply options to exempted clients, absent provincial drug coverage (discussed below) or other provincial or federal funding, as well as resources to comply with the security requirements of a dealer's license. Moreover, safety and security are significant concerns and licensed dealers may be reluctant to sell controlled substances to SCS who are supplying individuals without a prescription. These concerns can be robustly dealt with through licensing, security, and SCS operational requirements. Further, in the context of a public welfare emergency, federal and provincial emergency powers confer broad powers on governments; the federal Emergencies Act, for example, empowers the federal government to direct persons to render essential services to others (such as directing licensed dealers to sell controlled substances to SCS that are also licensed dealers), to regulate the "distribution and availability of essential goods, services and resources," and to authorize emergency payments that could allow SCS to provide critical safe supply.

# The selection of drugs available is inadequate, with no prescribed safe supply options for people who smoke their drugs or viable stimulant safe supply options.

As discussed above, there is a need to improve the selection of drugs available for safe supply, including stimulants, smokeable options, diacetylmorphine, cocaine, and benzodiazepines to reflect the patterns and preferences of people who are accessing the unregulated drug supply.

One key challenge is related to the cost and the absence of certain safe supply drugs in publicly funded drug plans and provincial and territorial formularies and inadequate coverage of drugs in federally funded safe supply programs.<sup>87</sup> A review of the availability of safe supply options in all provincial drug plans is beyond the scope of this report. However, according to a 2020 Health Canada resource "Public Drug Plan Coverage for Medications for Substance Use Disorder and to Provide Pharmaceutical Alternatives to the Contaminated Illegal Drug Supply," some opioids are covered in most provincial and territorial drug plans (e.g. oral and, to a lesser extent, injectable hydromorphone, sustained release morphine, and slow-release morphine, though they may not be covered at the appropriate concentrations), while no province or territory includes diacetylmorphine in its public drug plan, despite being approved by Health Canada in February 2022 for severe opioid use disorder.88



#### **Advocating for diacetylmorphine**

#### As key informants have underscored, there is an unmet need for diacetylmorphine safe supply.

In B.C., amid repeated calls from advocates and a request from Fair Price Pharma, which procured diacetylmorphine from a licensed European supplier in 2021 and is set up to produce shelf-stable smokable options, the B.C. Ministry of Health has yet to confirm additional funding for diacetylmorphine treatment for patients beyond those already on treatment.<sup>89</sup>

In Ontario, advocates have long urged the province (to date, without success) to consider funding diacetylmorphine and to reimburse high-dose injectable hydromorphone through the Ontario Drug Benefit (ODB) program, noting that the "only significant barrier to implementing [injectable opioid agonist treatment] programs in Ontario is the lack of coverage for people insured by the ODB."90

Regulatory restrictions also persist in the NCR regarding who can prescribe, sell, or otherwise provide diacetylmorphine. Amendments would thus need to be made to those provisions to facilitate greater access to diacetylmorphine safe supply.

There is also no reference to fentanyl options in provincial drug plans in the 2020 Health Canada document, although various formulations of fentanyl have been covered in B.C. under time-limited federal funding<sup>92</sup> and provincial funding (e.g. via the Special Authority Drug List, when a patient meets specific criteria for Limited Coverage).<sup>93</sup> In B.C., most safe supply medications dispensed are on the provincial formulary or through special access programs (e.g. fentanyl options). Notably, when Ontario delisted high-strength fentanyl, hydromorphone, and morphine from the public drug formulary for non-palliative care prescribers in 2017 (though it is still possible to access these through out-of-pocket or private-payer programs), researchers observed a 98% decrease in the total number of publicly funded recipients of high-strength opioids between December 2016 and July 2017 for all prescribers.94

According to the same Health Canada document, all provinces and territories include the stimulants dextroamphetamine and methylphenidate, and the benzodiazepines diazepam, alprazolam, and clonazepam in their public drug plans. However, the resource notes some medications may not have indications for substance use disorder and that prescribing off-label is at the discretion of the medical practitioner.

Additions to provincial public drug plans necessitate clinical guidance, creating a "chicken and egg" situation: drugs cannot be added without more evidence, but that evidence is contingent in part on people accessing those drugs, including via public drug coverage. Nevertheless, there is an urgent need in the context of a public health emergency to develop guidance on other safe supply options, remove regulatory barriers that prevent their prescription and sale by a broader range of practitioners (e.g. with respect to diacetylmorphine), and to add those options to public drug plans.

### Recommendations

#### Recommendations to the federal government

- Decriminalize drug possession via the repeal of section 4 of the CDSA and amend section 5 of the CDSA to remove restrictions related to possessing, selling, splitting, sharing, dispensing, or otherwise administering the controlled substances that constitute safe supply.
- Legalize and regulate controlled substances, as per the 2021 recommendation of Canada's Expert Task Force on Substance Use, calling on Canada to "immediately develop and implement a single public health framework with specific regulations for all psychoactive substances, including currently illegal drugs" in order to "minimize the scale of the illegal market, bring stability and predictability to regulated markets for substances, and provide access to safer substances for those at risk of injury or death from toxic illegal substances."95
- Support the development of clinical guidance on safe supply, with a particular focus on viable stimulant safe supply options and virtual care approaches, and in collaboration with people who use drugs who will be the end user of safe supply.
- Provide urgent, visible support for non-medical safe supply through buyers' or compassion clubs, and additional
  de-medicalized and community-based options for safe supply. Support includes funding, authorizing, and otherwise
  endorsing these services.
- Employ federal emergency powers to direct provinces to guarantee sustained funding to the "essential services" of SCS and to adequately fund safe supply options.

#### In the interim, the federal government should:

- Reform the SCS-specific exemption regime to remove the need for case-by-case exemptions to the CDSA
  protecting SCS clients and staff from prosecution for drug possession or for activities related to possessing,
  selling, splitting, sharing, dispensing, or otherwise administering the controlled substances that constitute
  safe supply.
- Issue dealers licenses to SCS meeting minimum conditions and grant a class exemption to the CDSA to everyone who accesses a SCS with a dealer's license so they can access safe supply at SCS without risk of prosecution.
- Amend the definition of "prescription" in the NCR so orders for controlled substances need not be client specific
  and to allow medical directives for prescribed safe supply.
- **Expand the class of "practitioners"** who are authorized to administer, prescribe, or sell safe supply, to include other healthcare providers such as nurses and pharmacists, by amending the definition of practitioner in the CDSA or by regulation.
- Implement a nationwide section 56(1) exemption to the CDSA to facilitate community-based safe supply.

# Recommendations to provincial and territorial governments and other provincial and territorial authorities

- Guarantee sustained funding of SCS and ensure that remote and rural communities are adequately served.
- Remove unnecessarily restrictive requirements for SCS funding and support all SCS to provide inhalation services.
- Adequately fund safe supply programs, with an emphasis on flexible models that are tailored to consumer demand
- Ensure all safe supply options at appropriate concentrations are included in provincial and territorial public drug plans.
- Employ provincial emergency powers to direct provincial colleges regulating health professionals to:
  - develop clinical guidance and training on prescribed safe supply, including viable stimulant safe supply and virtual care options; and
  - authorize medical directives on prescribed safe supply, including for peer experts in the context of a SCS.

## Conclusion

There has been a growing willingness among federal policymakers to adapt legal frameworks, using existing flexibilities, to reduce barriers to health and harm reduction services for people who use drugs, prompted by the ongoing drug poisoning crisis and more recently the COVID-19 pandemic.

The experience of recent years has demonstrated that evidence-based, human rights-based analyses, combined with community capacity-building, mobilization, and knowledge translation engaging program and policy decision-makers can lead to important legal/policy shifts — creating a more enabling environment to protect the health of people who use drugs.

Safe supply is increasingly considered to be a key harm reduction intervention, including proposals to look beyond strictly medicalized models. In the context of an unprecedented drug poisoning crisis, it is imperative that novel and innovative approaches are explored to address the scalability of safe supply, as a matter of life and death. To meet the diverse needs of people who use drugs, it is also pragmatic and ethically imperative that innovative approaches are adopted to scale up access to safe supply beyond the existing medical model, including within SCS. Although safe supply at SCS is not without its limitations, including with respect to the absence of SCS in many communities and the lack of 24/7 access where they do exist, they are one viable option among the range of services that are desperately needed.

As described above, courts in Canada have repeatedly affirmed the right of people who use drugs to access harm reduction and other health services, and governments have a legal and ethical obligation to ensure access to safe supply and to SCS as a necessary component of the rights to life and to health, among other human rights. While policy and legislative reform requires time, all levels of government also have broad emergency powers allowing them to act swiftly — and to compel other entities to take action. As this report confirms, a diversity of tools is available for law and policy makers to eliminate barriers to safe supply at SCS and begin to fully realize a continuum of options that are accessible and honour the autonomy and human rights of people who use drugs. What we need now is political will.

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- See College of Nurses of Ontario, "No directives for controlled substances," June 7, 2022. Available at <a href="https://www.cno.org/en/learn-about-standards-guidelines/educational-tools/ask-practice/no-medical-directives-for-controlled-substances/">www.cno.org/en/learn-about-standards-guidelines/educational-tools/ask-practice/no-medical-directives-for-controlled-substances/</a>. See also Ontario College of Pharmacists, "Ontario's Physician Assistants: An Update," *Pharmacy Connection*, Fall 2014. Available at <a href="https://www.ocpinfo.com/library/practice-related/download/PhysicianAssistant.pdf">www.ocpinfo.com/library/practice-related/download/PhysicianAssistant.pdf</a>.
- See, for example, Advanced Care Paramedics, Special Project Palliative Care Medical Directive, March 20, 2021. Available at <a href="https://hsncpc.ca/wp-content/uploads/2022/02/ACP-Pall-Care-directive-treat-and-refer-20-3-2021-Version-2.1.pdf">https://hsncpc.ca/wp-content/uploads/2022/02/ACP-Pall-Care-directive-treat-and-refer-20-3-2021-Version-2.1.pdf</a>.
- While physician assistants are not typically among SCS staff, in some provinces (e.g. Alberta, Manitoba, New Brunswick) they are subject to provincial regulation with a scope of practice that varies slightly across the country and can include prescribing pursuant to a medical directive. See, for example, Ontario Hospital Association, *The Ontario Physician Assistant Initiative*, June 2009, available at <a href="https://www.oha.com/Legislative%20and%20Legal%20Issues%20Documents1/">https://www.oha.com/Legislative%20and%20Legal%20Issues%20Documents1/</a> Ontario%20Physician%20Assistant%20Initiative%202009.pdf.
- See, for example, British Columbia College of Nurses and Midwives, "G: Prescribing for Opioid Use Disorder and/or Pharmaceutical Alternatives for Safer Supply," Scope of Practice for Nurse Practitioners: Standards, Limits, and Conditions, last updated September 2023, available at <a href="https://www.bccnm.ca/NP/ScopePractice/part2/Pages/prescribing\_oat.aspx">www.bccnm.ca/NP/ScopePractice/part2/Pages/prescribing\_oat.aspx</a>, and College of Nurses of Ontario, "NPs and Prescribing Controlled Substances," last reviewed February 4, 2022, available at <a href="https://www.cno.org/en/trending-topics/nps-and-prescribing-controlled-substances/">www.cno.org/en/trending-topics/nps-and-prescribing-controlled-substances/</a>.
- 67 Government of Canada, Framework for Designating Additional Classes of Practitioners Under the New Classes of Practitioners Regulations, November 2012. Available at <a href="https://www.canada.ca/en/health-canada/services/health-concerns/controlled-substances-precursor-chemicals/policy-regulations/policy-documents/framework-designating-additional-classes-practitioners-under-new-classes-practitioners-regulations.html">https://www.canada.ca/en/health-canada/services/health-concerns/controlled-substances-precursor-chemicals/policy-regulations/policy-documents/framework-designating-additional-classes-practitioners-under-new-classes-practitioners-regulations.html</a>.
- Order of the Provincial Health Officer (Pursuant to section 13 of the Health Professions General Regulation, B.C. Reg 275/2008), Registered Nurse and Registered Psychiatric Nurse Public Health Pharmacotherapy, September 16, 2020. Though the specific COVID-19 context in which the order was issued has shifted, the risks sought to be addressed at the time of the order continue to escalate and the toxicity of the unregulated drug market is in and of itself enough to warrant similar orders. As the Order notes, "Unless rescinded earlier, this order will end on the date that I provide notice under section 59 (b) of the Public Health Act that the emergency related to the availability of highly toxic, illegally produced opioid fentanyl analogues and increase in people overdosing and dying associated with the use of these substances has passed."
- See British Columbia College of Nurses and Midwives, "BCCNM board approves new RN and RPN certified practice for opioid use disorder," September 23, 2023. Available at <a href="https://www.bccnm.ca/bccnm/Announcements/Pages/Announcement.">www.bccnm.ca/bccnm/Announcements/Pages/Announcement.</a> <a href="https://aspx?AnnouncementID=466">aspx?AnnouncementID=466</a>.
- <sup>70</sup> See, for example, Ontario's Regulated Health Professions Act, 1991.
- <sup>71</sup> Canadian Pharmacists Association, *Pharmacists' Scope of Practice in Canada*, revised October 2, 2023. Available at www.pharmacists.ca/advocacy/scope-of-practice/.
- The exemption expires September 30, 2026, or sooner if replaced or revoked.
- Canadian Pharmacists Association, National Pharmacist Survey on the Exemptions under the Controlled Drugs and Substances Act (CDSA), November 2021. Available at <a href="https://www.pharmacists.ca/cpha-ca/assets/File/cpha-on-the-issues/CDSA-Survey-Results-Web-Dec11.pdf">www.pharmacists.ca/cpha-ca/assets/File/cpha-on-the-issues/CDSA-Survey-Results-Web-Dec11.pdf</a>.
- See, for example, regulations made by the Ontario government in 2023 under the *Pharmacy Act* expanding the scope of practice for pharmacists and authorizing them to prescribe certain classes of drugs for 13 "minor ailments." See 0. Reg. 202/94: GENERAL under *Pharmacy Act*, 1991, S.O. 1991, c. 36.
- 75 See, for example, Nurses and Nurse Practitioners of British Columbia, RN Certified Practice Decision Support Tools & Competencies, March 2024, available at <a href="https://www.nnpbc.com/policy-and-professional-practice/rn-certified-pra

- Compassion clubs and buyers' clubs distribute criminalized, unregulated, or otherwise hard-to-access drugs to members to limit negative impacts of the unregulated market and may also provide social and other support to members. A co-operative approach to the club would be owned and operated by its members who share its benefits. See, for example, N. Rhodes, "Mapping buyer's clubs; what role do they play in achieving equitable access to medicines?" Global Public Health, 17(9), 1842–1853. <a href="https://doi.org/10.1080/17441692.2021.1959940">https://doi.org/10.1080/17441692.2021.1959940</a> and R. Starr, K. Murray, and M. Chaiton, "The Compassion Club: A New Proposal for Transformation of Tobacco Retail," Nicotine & tobacco research: official journal of the Society for Research on Nicotine and Tobacco vol. 25,12 (2023): 1822–1828. doi:10.1093/ntr/ntac295.
- <sup>77</sup> British Columbia Office of the Provincial Health Officer, 2023, supra note 13.
- <sup>78</sup> K. Larsen, "First ever paid prescription fentanyl program launches in Vancouver," *CBC* News, April 8, 2022, available at <a href="https://www.cbc.ca/news/canada/british-columbia/paid-prescription-fentanyl-vancouver-1.6412696">www.cbc.ca/news/canada/british-columbia/paid-prescription-fentanyl-vancouver-1.6412696</a>.
- G. Bardwell et al., *supra* note 10. See also CATIE, "MySafe safer opioid supply program using biometric dispensing machines," August 15, 2023. Available at <a href="https://www.catie.ca/programming-connection/mysafe-safer-opioid-supply-program-using-biometric-dispensing-machines">www.catie.ca/programming-connection/mysafe-safer-opioid-supply-program-using-biometric-dispensing-machines</a>.
- A. Weng, "The potential use of telemedicine to increase access to opioid agonist therapy in rural and remote communities," *BC Medical Journal*, vol. 62, No. 10, December 2020, pp. 377–379.
- British Columbia Office of the Provincial Health Officer, 2023, supra note 13.
- See Government of Canada, Interactive map: Canada's response to the opioid overdose crisis, last modified November 28, 2023. Available at <a href="https://health.canada.ca/en/health-canada/services/drugs-medication/opioids/responding-canada-opioid-crisis/map.html">https://health.canada.ca/en/health-canada/services/drugs-medication/opioids/responding-canada-opioid-crisis/map.html</a>. As Karen McDonald of Toronto's Drug Checking Service shared via email correspondence, the main barrier to offering drug checking services is related to limited funding available to provide this service and lack of guidance about drug checking technologies available; detailed drug checking processes are required by Health Canada and many SCS do not have resources to spend on drug checking.
- See, for example, G. Bardwell, J. Boyd, J. Arredondo, et al., "Trusting the source: The potential role of drug dealers in reducing drug-related harms via drug checking," *Drug Alcohol Depend*, 2019 May 1;198:1-6. doi: 10.1016/j. drugalcdep.2019.01.035.
- See Federal Actions on the Overdose Crisis, which states the federal government has "Authorized supportive services at sites including drug checking, peer assistance consumption and drug splitting and sharing." Government of Canada, Federal Actions on the Overdose Crisis, December 2023. Available at <a href="https://www.canada.ca/en/health-canada/services/opioids/federal-actions/overview.html">www.canada.ca/en/health-canada/services/opioids/federal-actions/overview.html</a>.
- J. Kalicum, E. Nyx, M.C. Kennedy, and T. Kerr 2024, supra note 22.
- Section 25.4 of the NCR provides: "a licensed dealer may sell or provide a narcotic to a person who is exempted under section 56 of the Act with respect to the possession of that narcotic."
- N. Maghsoudi, J. Bowles, and D. Werb, "Expanding access to diacetylmorphine and hydromorphone for people who use opioids in Canada," Canadian Journal of Public Health, vol. 111,4 (2020): 606-609. doi:10.17269/s41997-020-00315-4.
- Health Canada, Diacetylmorphine hydrochloride product monograph, 2022. Available at <a href="https://pdf.hres.ca/dpd\_pm/00064756.PDF">https://pdf.hres.ca/dpd\_pm/00064756.PDF</a>.
- S. Grochowski, "B.C. doctors upset their 'safe supply' of heroin going unprescribed during overdose crisis," *Vancouver Sun*, Dec 15, 2021. Available at <a href="https://vancouversun.com/news/b-c-doctors-upset-their-safe-supply-of-heroin-going-unprescribed-during-overdose-crisis">https://vancouversun.com/news/b-c-doctors-upset-their-safe-supply-of-heroin-going-unprescribed-during-overdose-crisis</a>. See also PAN, "Letter to Minister Dix regarding access to diacetylmorphine and Heroin-Assisted Treatment," February 24th, 2023. Available at <a href="https://paninbc.ca/2023/02/24/letter-to-minister-dix-regarding-access-to-diacetylmorphine-and-heroin-assisted-treatment/">https://paninbc.ca/2023/02/24/letter-to-minister-dix-regarding-access-to-diacetylmorphine-and-heroin-assisted-treatment/</a>.

- <sup>90</sup> An Open Letter calling for Public Drug Coverage of High Dose Injectable Hydromorphone for People Who Use Opioids in Ontario, 2019. Available at https://listhmonodb.wordpress.com/.
- See, for example, section 31(2)(c) of the NCR, restricting pharmacists from selling or otherwise providing diacetylmorphine unless they receive a written order or prescription from a physician or nurse practitioner. Section 25.2 of the NCR also indicates that a licensed dealer may only sell or provide to a physician, nurse practitioner, or dentist a diacetylmorphine.
- <sup>92</sup> See, for example, S. Klaire, C. Sutherland, T. Kerr, and M. C. Kennedy, supra note 10.
- Ministry of Mental Health and Addictions, Ministry of Health (B.C.), Access to Prescribed Safer Supply in British Columbia: Policy Direction, July 15, 2021. Available at <a href="https://www2.gov.bc.ca/assets/gov/overdose-awareness/prescribed\_safer\_supply\_in\_bc.pdf">https://www2.gov.bc.ca/assets/gov/overdose-awareness/prescribed\_safer\_supply\_in\_bc.pdf</a>.
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- Expert Task Force on Substance Use, Report 2: Recommendations on the federal government's drug policy as articulated in a draft Canadian Drugs and Substances Strategy (CDSS), July 11, 2021. Available at <a href="https://www.canada.ca/en/health-canada/corporate/about-health-canada/public-engagement/external-advisory-bodies/expert-task-force-substance-use/reports/report-2-2021.html">www.canada.ca/en/health-canada/ corporate/about-health-canada/public-engagement/external-advisory-bodies/expert-task-force-substance-use/reports/report-2-2021.html</a>.



