

INTRODUCTION

Supervised consumption services (SCS) consist of providing a safe, hygienic environment in which people can use drugs with sterile equipment under the supervision of trained staff or volunteers. SCS are part of a broader harm reduction approach to substance use, which promotes safety, health and dignity.

Many people who consume drugs are unable or unwilling to stop.² Like other harm reduction services (e.g. needle and syringe programs), SCS are a pragmatic, necessary and compassionate response to this reality. SCS offer a safe setting, sterile equipment and connections with health and social services without fear of arrest or harassment. These services attract and provide protection to some of the most marginalized people who use drugs whose social, physical and mental health-related needs are rarely met.3 In particular, SCS increase access to treatment and care while also reducing health risks associated with drug use, such as overdose death and the transmission of infectious diseases through the re-use of injection equipment for instance. SCS contribute to the safety and quality of life in local communities by reducing drug use in public places and the number of discarded needles or other materials.⁴ Despite clear evidence of their benefits, there are still concerns among the general public that SCS may encourage drug use or negatively affect public order. SCS continue to be highly politicized, and misconceptions about and prejudice against people who use drugs have created significant barriers to implementation of these services.

Today, more than 100 formal SCS exist in Australia, Denmark, Germany, Luxembourg, the Netherlands, Norway, Spain, France, Belgium and Switzerland, in addition to Canada. Efforts to implement SCS are also ongoing in the United States, Scotland, Ireland and Portugal. With 31 facilities in 25 cities, the Netherlands currently has the highest number of SCS operating in Europe. 7

Terminology clarification

For the purpose of this report, we use the term "supervised consumption services" (SCS) to designate services offering supervised consumption of drugs (usually pre-obtained illegal drugs) by trained volunteers and staff in a safe and hygienic environment.

Our definition of SCS is purposefully broad in order to encompass multiple forms of supervised consumption. In Canada, SCS are currently offered in "supervised consumption sites," which operate under an exemption issued by the federal Minister of Health for a "medical purpose" under section 56.1 of the Controlled Drugs and Substances Act (CDSA), and in temporary "overdose prevention sites" (OPS). OPS are essentially lower-threshold supervised consumption sites but the shift in terminology has proved crucial to the rapid rollout of these life-saving interventions in the context of the current overdose crisis. OPS have been approved unilaterally by provincial governments (British Columbia), or under a section 56 class exemption granted to provincial governments by the federal Minister of Health (Alberta and Ontario), or in some cases operate, or have operated, independently of formal provincial or federal approvals. Given the importance of having a wide range of different models available for supervised consumption in Canada, this report does not distinguish between supervised consumption sites and OPS except when necessary to clarify the history of SCS in Canada and different legal regimes for each service type.

A BRIEF OVERVIEW OF THE HISTORY OF SCS IN CANADA

As in many settings, implementation of SCS in Canada has been highly dependent on the political context and vulnerable to changes in government. If an SCS is operating with a federal exemption, staff and clients accessing the services are protected against criminal prosecution for drug possession under the CDSA. Starting in the 1990s, however, peer-led community groups opened and operated SCS without this authorization, and these groups have continued to fill gaps where necessary services are neither available nor authorized.8 In 2003, Insite, the first SCS known to operate with a formal CDSA exemption in Canada, finally opened in Vancouver, thanks to community efforts and cooperation at municipal, provincial and federal levels. Despite the remarkable benefits SCS offer to both people who use drugs and local communities, subsequent efforts to scale up these services across the country were sapped by persistent political opposition and legislative barriers. It took another thirteen years and another public health crisis before new SCS were authorized in Canada.

KEY MOMENTS IN SCS EXPANSION IN CANADA:

2002 — Located in Vancouver, British Columbia, the Dr. Peter Centre was the first healthcare facility to supervise injections in Canada. The Centre operates an HIV and AIDS day health program and a 24-hour nursing care residence for people living with HIV, especially for patients with multiple medical conditions who face significant social barriers to accessing care. For many years, the Dr. Peter Centre offered SCS without a formal federal exemption, but rather took the position that such activity fell within the accepted scope of practice for their staff nurses. They were supported in this view by an opinion stated from the Registered Nurses Association of British Columbia (RNABC) — now the Nurses and Nurse Practitioners of BC (NNPBC) — the professional association representing registered nurses and nurse practitioners in the province.9

2003 — The first SCS to operate with a formal exemption from the federal government — Insite — opened in 2003 in Vancouver's Downtown Eastside where the local health authority had declared a public health emergency in 1997 due to a dramatic increase of overdose-related deaths and infectious diseases. 10 The site was established first as a three-year pilot project under the condition that the program would be rigorously evaluated. Insite began as a stand-alone supervised consumption site where people could inject drugs under the supervision of nurses and health care staff and be referred to other harm reduction, treatment and social services. A detox and transitional housing program was subsequently opened in the same building, offering complementary health services.¹¹ Since its opening, more than 30 articles on Insite have been published in the world's leading peer-reviewed scientific and medical journals. Research clearly indicates that Insite has had many positive outcomes for people who use drugs and for the community as a whole.12

2006 — A new Conservative federal government that opposed harm reduction and SCS was elected in Canada. One year later, the government introduced the new National Anti-Drug Strategy and removed harm reduction as an official element of Canada's federal drug strategy.¹³

2008 — The federal Minister of Health indicated that he would not renew Insite's exemption. The Portland Hotel Society, the Vancouver Area Network of Drug Users (VANDU), and two of Insite's clients challenged this decision all the way to the Supreme Court of Canada (hereinafter the "case of Insite").¹⁴

2011 — The Supreme Court of Canada (SCC) unanimously ordered the federal Minister of Health to grant Insite the continued exemption. To deny this would, according to the Court, violate the rights to life, liberty and security of the person in a way that would be both "arbitrary" and "grossly disproportionate," forcing people who inject drugs to risk criminal prosecution in order to access an important health service. This violation of section 7 of the *Canadian Charter of Rights and Freedoms* could not be justified by the government. The SCC outlined factors to be considered by the Minister when exercising their statutory discretion in issuing or denying an exemption.

2015 — In response to the SCC decision, the federal government introduced the *Respect for Communities Act* (commonly known as Bill C-2), which mandated a highly burdensome application process for obtaining a ministerial exemption for SCS under a new section 56.1 of the CDSA. The legislation was adopted in June 2015 and proved to be a significant obstruction to SCS expansion in Canada. Until 2016, no new SCS were approved.

October 2015 — A new federal government that had expressed support for SCS was elected.¹⁸

2016 — In January, the Dr. Peter Centre received a formal exemption¹⁹ to provide SCS and in March 2016 Insite's exemption was renewed.²⁰ In December, the federal government restored harm reduction as a key pillar of Canada's drug strategy.²¹

2017 — The new government repealed the *Respect for Communities Act* and replaced it with Bill C-37 (*An Act to amend the CDSA*), which came into force in May 2017.²² Bill C-37 did not remove section 56.1 of the CDSA (which creates a specific exemption regime for supervised consumption sites for a medical purpose) but replaced previous onerous legislative requirements with simpler, streamlined requirements. The number of approved supervised consumption sites in Canada rose rapidly to 24 within the first five months the legislation was in effect.

2018 and on — As of January 2019, there were 28 SCS operating under a section 56.1 ministerial exemption in B.C., Alberta, Ontario and Quebec, two additional sites exempted but with an inspection pending, and 21 exemption applications being reviewed by Health Canada.²³ In addition to supervised consumption sites operating under section 56.1, OPS have been established in B.C. since late 2016, and more recently in Ontario and Alberta, originally without formal authorization. These sites represent a direct, grassroots response to the overdose crisis and have helped push for greater action at all levels of government. In 2018, both provincial and federal authorities took measures to authorize OPS under specific legal regimes. However, a change of government in Ontario in June 2018 has since put these efforts in jeopardy.

THE "SCALING-UP SCS IN CANADA" RESEARCH PROJECT

With 28 SCS currently operating under an exemption from the federal Ministry of Health, Canada is experiencing a remarkable shift in how SCS are implemented.²⁴ Current service availability, however, is insufficient. Increasing rates of overdose and the emergence of pop-up sites operating without official authorizations have demonstrated that more must be done to adequately scale up SCS across the country.

This research project and report provide an opportunity to review, record and assess the constantly evolving state of SCS in Canada and explore the impact of past and current laws and policies on the implementation of these services. The core objectives of this project are to:

- » Formulate a picture of SCS scale-up efforts in Canada before and after the most recent changes in legislation;
- » Outline facilitators and barriers faced by would-be and current SCS providers at the federal, provincial and municipal levels;
- » Provide recommendations to Canadian authorities to facilitate the scale-up of SCS in Canada with a focus on the federal government.

METHODS

Data for this report were drawn from available published literature as well as a series of 15 interviews with key informants, including researchers, SCS managers, exemption applicants, policymakers and people who use drugs. Interviews were conducted between March and June 2018 either in person or by phone and audio-recorded to ensure accuracy. Questions focused on people's experiences applying for and implementing SCS in communities across Canada, with particular attention to the impact of federal policy and legal requirements. A four-member advisory committee reviewed the work plan and provided input during the drafting of the report.

It is important to note that this report was drafted in the fall of 2018 and may not reflect all legal and policy changes after this point. There are unique challenges in describing an issue that is shifting and evolving quickly and as a result, the report cannot be fully comprehensive. The project also limited the focus of the interviews and report to five localities: Toronto, Montreal, Vancouver, Edmonton and Lethbridge.

PUBLIC HEALTH IMPERATIVE FOR SCS: THE OVERDOSE CRISIS IN NORTH AMERICA

North America is experiencing one of the most fatal public health crises in recent history. Drug overdose fatalities in the United States nearly tripled between 1999 and 2014,²⁵ with more than 70,000 overdose deaths in 2017 alone.²⁶ In Canada, there were more than 9,000 opioid-related deaths between January 2016 and June 2018.²⁷ An increasingly contaminated drug supply is at the core of the crisis: 72% of accidental overdose deaths in Canada in 2017 involved fentanyl or fentanyl analogues.²⁸ The overdose crisis has shed tragic light on service gaps for people who use drugs and deficiencies in Canada's punitive approach to drug policy.²⁹ There is no doubt it has played, and will continue to play, a significant role in the expansion of SCS in the country (as did the public health crises of the HIV and hepatitis C epidemics and open drug scenes in Europe in the 1980s, and the public health crisis in Vancouver's Downtown Eastside in the 90s).³⁰

CHANGES IN THE LEGAL LANDSCAPE

In Canada, unauthorized possession of a controlled substance is a crime under section 4 of the CDSA. Given that SCS offer an environment where people can consume pre-obtained illegal drugs, both clients and staff are at risk of prosecution for possession when accessing and/or working at SCS. Clients and staff may also be at risk of prosecution for trafficking under section 5 of the CDSA in relation to some activities that may take place at SCS, such as assisting someone with injection or drug-sharing.³¹

There are currently three options under the CDSA for providing exemptions from the application of the Act and thereby protecting SCS users and staff from criminal liability. These are discussed more completely later in the report, but briefly, these three options are:

- » SCS-specific ministerial exemption under section 56.1 of the CDSA.
- » General ministerial exemption under section 56 of the CDSA.
- » Regulations by Cabinet under section 55(1)(z) of the CDSA. The Cabinet may also make regulations for carrying out the purposes of section 56.1 (SCS-specific ministerial exemption) under section 55 (1.2) of the CDSA.

As of January 2019, Cabinet had not yet used its authority under section 55 to adopt regulations creating exemptions from the CDSA for SCS. However, the ministerial exemption regime (under each of sections 56 and 56.1) has proved central to establishing SCS in Canada. It has been used and shaped by the respective federal governments to either facilitate or impede the establishment of new SCS in Canada — including through legislative reforms in 2015 and 2017.

MINISTERIAL EXEMPTIONS PRIOR TO THE *RESPECT FOR COMMUNITIES ACT* IN 2015

Before the introduction of the *Respect for Communities Act* in 2015, the federal Minister of Health would grant exemptions for SCS under section 56 of the CDSA (of general application). Section 56 gave the Minister the power to grant an exemption from the application of the CSDA if, in their opinion, it was necessary for a *medical* or *scientific* purpose or if it was *otherwise in the public interest.* At the time, section 56 read as follows:

The Minister may, on such terms and conditions as the Minister deems necessary, exempt any person or class of persons or any controlled substance or precursor or any class thereof from the application of all or any of the provisions of this Act or the regulations if, in the opinion of the Minister, the exemption is necessary for a medical or scientific purpose or is otherwise in the public interest.³²

Section 56 was broad and did not impose any specific legal requirement to apply for an exemption. However, a 2002 interim guidance document released by Health Canada in anticipation of Insite's application imposed strict conditions for applications related SCS.³³ The guidance document described the process to be followed and information to be included including research protocols, information related to staff, floor plan of the proposed site, procedures and measures to minimize diversion of controlled substances and the risk to the health and security of staff and the local community, as well as letters of support from key partners in the community. According to the interim guidance, exemptions were to be granted "for a scientific purpose" in the context of a pilot research project.

Moreover, exemptions under section 56 were at the sole discretion of the federal Minister of Health and remain so today, leaving SCS highly vulnerable to changes in the political context. This became particularly problematic when the Conservative Party of Canada, which

at the time was publicly vocal against SCS (and harm reduction more broadly), came into power in 2006.³⁴ Respondents indicated that some service providers were too discouraged to apply for an exemption, knowing their application would likely be rejected. Others, such as the Dr. Peter Centre, nevertheless chose to apply for an exemption but felt pressured to prepare extremely comprehensive applications out of fear that the federal government would use any missing pieces to reject their application. And indeed, the federal government at the time took active measures to prevent SCS from operating in Canada, and no new sites received an exemption until a new government came into power in late 2015.

Operating SCS without a ministerial exemption

In the 1990s, in response to urgent need, including rising overdose deaths and HIV infections, peer-led groups and activists in Vancouver established SCS without seeking exemptions under the CDSA. These sites would often operate until the police shut them down, highlighting the need for legal protection for SCS.³⁵

In 2002, the Dr. Peter Centre started to offer supervised injection services after experiencing two overdoses on site. At the time, the Dr. Peter Centre did not seek an exemption from the federal Health Minister. Instead, the Centre received a nursing practice clarification from the Registered Nurses' Association of British Columbia (a professional association, not the legal regulatory body) taking the position that supervising injections fell within the scope of nursing practice and that it was part of the Centre nurses' ethical obligation to prevent harm to their patients.36 The Dr. Peter Centre provided this service for 18 months without an exemption (and without any police interference) until Vancouver Coastal Health invited the Centre to join its application, covering Insite's operation, for an exemption that was granted in 2003. For three years, the Dr. Peter Centre believed they were operating under an exemption. Later, they discovered that the federal minister at the time had never signed their part of the exemption and in 2006, the federal government refused to rectify this. Nonetheless, the Dr. Peter Center continued to provide its services until it received an exemption in 2016.

In its 2009 report, *l'Institut National de Santé Publique du Québec* indicated that Quebec could consider opening a site without a federal exemption.³⁷ The Institute stressed that they never had to apply for an exemption to implement needle and syringe programs and pointed to the example of the Dr. Peter

Centre. They also referred to the 2008 decision of the Supreme Court of British Columbia in the Insite case, ruling that section 4 of the CDSA (prohibiting possession of unauthorized controlled substances) was not applicable to Insite because it would deprive people with addictions from access to care, thus violating the *Canadian Charter of Rights and Freedom* (Charter).³⁸

The subsequent Supreme Court of Canada decision regarding Insite in 2011 was a significant victory, confirming that people who use drugs have a Charter right to not be criminalized when accessing the health service of supervised consumption at such a site. However, the SCC's ruling also entrenched the notion that an exemption from the federal Minister of Health, under section 56, is necessary for SCS to operate without clients and staff risking prosecution under the CDSA.³⁹

To our knowledge, there has so far been no attempt at the federal level to provide other forms of legal protection for SCS — for example, through the development of a regulatory framework under section 55 of the CDSA. In its 2018 guidance, Health Canada reiterates that a ministerial exemption is needed to operate a supervised consumption site for medical purposes.⁴⁰

THE SUPREME COURT OF CANADA 2011 DECISION IN THE CASE OF INSITE

In its 2011 decision, the SCC ruled that the Minister's refusal to grant Insite a new exemption in 2008 violated the Charter and ordered the federal Minister of Health to grant a new exemption. It recognized that "Insite saves lives" and "[i]ts benefits have been proven," without any "discernable negative impact on the public safety and health objectives of Canada. The SCC was clear: the Minister of Health must exercise his or her discretion to grant an exemption, in accordance with section 7 of the Charter, which guarantees the rights to life, liberty and security of the person. The government cannot deprive people of any of these rights except "in accordance with the principles of fundamental justice."

However, the SCC declined to rule that the underlying criminalization of possession (under section 4 of the CDSA) was unconstitutional because the CDSA provided the authority for the Minister and Cabinet to issue exemptions from criminal liability under sections

55 and 56 of the CDSA. According to the SCC, "the availability of exemptions acts as a safety valve that prevents the CDSA from applying where such application would be arbitrary, overbroad or grossly disproportionate in its effects."

For future exemptions under section 56, the SCC indicated that the Minister would have to strike the appropriate balance between both objectives of the CDSA — achieving public health and guaranteeing public safety — and "[w]here, as here, the evidence indicates that a supervised injection site will decrease the risk of death and disease, and there is little or no evidence that it will have a negative impact on public safety, the Minister should generally grant an exemption."

To prevent future decisions by the Minister from being arbitrary or creating grossly disproportionate harm to people by impeding their access to necessary health services, the Court also identified five factors to be considered by the Minister in making a decision about issuing a CDSA exemption:

- » the impact of such a facility on crime rates,
- » the local conditions indicating a need for such supervised injection site,
- » the regulatory structure in place to support the facility,
- » the resources available to support its maintenance,
- » and expressions of community support or opposition. 46

Importantly, the Supreme Court did *not* rule that these are preconditions that must all be addressed or satisfied before an application for an exemption could be reviewed or an exemption granted. The Court simply said that *if* there is evidence about these factors, then such evidence must be taken into consideration by the Minister. The Court also did not say that the evidence, if available, about any one of these factors is necessarily determinative. Not all five factors might be necessary or relevant — especially those related to community support and impact on crime rates, and some may pose particular challenges to the scale-up of SCS in Canada. ⁴⁷

THE 2015 RESPECT FOR COMMUNITIES ACT: A NEW, RESTRICTIVE SCHEME FOR MINISTERIAL EXEMPTIONS SPECIFICALLY FOR SUPERVISED CONSUMPTION SITES

In response to the SCC decision, the federal government enacted the so-called *Respect for Communities Act* in June 2015. The Act created an exceptional exemption regime under a new section 56.1 of the CDSA specifically designed for SCS. Because the Act prevented the use of section 56 in relation to controlled substances *obtained in a manner not authorized by the Act*, the federal government could only grant an exemption with respect to SCS (where people can consume pre-obtained illegal drugs), under the new section 56.1 for a "medical purpose." A similar provision prevented the federal Cabinet from adopting regulations under section 55 that would enable the operation of SCS.

The exemption regime established under section 56.1 was also much more restrictive and imposed an extremely burdensome exemption process. Under the new regime, the federal Minister of Health was not allowed to examine an application for exemption unless and until the applicant had submitted the 25 different pieces of information required by the law including:⁵⁰

- » Evidence of extensive consultations with "a broad range" of local community groups, and a report outlining steps to be taken to address "any relevant concerns" raised during those consultations;
- » Letters from various bodies including local authorities, provincial ministries, police forces, provincial licensing authorities for physicians and nurses etc. with their "opinion" on the proposed supervised consumption site;
- » A financial plan;
- Any available law enforcement research or statistics about crime or public nuisance near the proposed site, public consumption of drugs near the proposed site and in the municipality, drug-related litter near the site and in the municipality, as well as any "relevant information" on loitering that may be related to "certain activities" involving illegal drugs (activities that were not defined) and "minor offence rates" near the proposed site;

The name, title and resumé as well as police background checks for the proposed "responsible person in charge" (RPIC) of the site (i.e. the person responsible for ensuring any conditions attached to an exemption, if issued, are followed), the alternative responsible persons, and each one of the other proposed "key staff members" (i.e. the staff who will directly supervise the consumption of drugs at the site).⁵¹

Furthermore, and contrary to the spirit and letter of the SCC decision in the case of Insite, an exemption to operate a given SCS without risk of criminal prosecution could *only* be granted by the Minister in "exceptional circumstances," and only after the Minister had considered a number of principles set out in the Act.⁵² Several of these principles, such as the declarations that "organized crime profits from the use of illegal substances," were irrelevant to the operation of SCS and clearly intended by the drafters to provide statutory language that a government hostile to such services could invoke in court to defend its refusal if necessary.⁵³

Finally and for those who managed to provide all the excessive information required by the Act, there was no guarantee that the application would even be considered or that an exemption would be granted if all criteria were met, especially if a government opposed to SCS was in power. There was no set timeframe within which a Minister had to render a decision, and no obligation to provide any reasons for any decision.

A few sites in Montreal, Edmonton, Toronto and Vancouver had started to prepare exemption applications after the Supreme Court released its decision in the Insite case in 2011. Those efforts were still in progress when the federal government enacted its new, more onerous regime in 2015 via the *Respect for Communities Act*, and applicants subsequently sought to meet these new requirements. However, none of those sites received an exemption until early 2016, after a new federal government was elected in late 2015.

STREAMLINING SECTION 56.1: SPECIFIC MINISTERIAL EXEMPTION FOR A MEDICAL PURPOSE UNDER CURRENT LEGAL REGIME (AS OF 2017)

During the 2015 federal election campaign, the Liberal Party of Canada expressed support for harm reduction

and, in particular, the implementation of SCS as an integral part of a broader, evidence-based national drug strategy. ⁵⁴ The Liberal Party won a majority government in October 2015 and took office in November. In early 2016, both Insite and the Dr. Peter Centre were granted ministerial exemptions.

SCS supporters took this opportunity to renew advocacy aimed at changing the law to ensure easier, more widespread access to SCS. In particular, they urged the new government to repeal the *Respect for Communities Act*, which created significant barriers to SCS.⁵⁵

Pressured by community groups, health professionals and provincial authorities, the government finally introduced legislation in December 2016, which ultimately came into force in May 2017. The Act to amend the Controlled Drugs and Substances Act and to make related amendments to other Acts (commonly known as Bill C-37) maintained a particular regime in section 56.1 for an exemption issued specifically for a "medical purpose" for a "supervised consumption site", but it replaced previous onerous legislative requirements with fewer, simpler, streamlined requirements. The new law also restored the authority of the health minister to issue an exemption under the broader section 56 and the power of the federal Cabinet to issue regulations under section 55 that could be used to exempt SCS clients and operators from the risk of criminal prosecution (see alternative avenues below).56

Section 56.1 and Health Canada's current requirements: a brief overview

Under the current section 56.1 of the CDSA legal regime, an application for an exemption shall include:

- » information regarding the intended public health benefits of the site, and
- » information, if any, related to:
 - the impact of the site on crime rates;
 - the local conditions indicating a need for the site;
 - the administrative structure in place to support the site;
 - the resources available to support the maintenance of the site; and
 - expressions of community support or opposition.⁵⁷

These legal requirements mirror the five factors articulated by the SCC in the *Insite* decision. In keeping with that decision, the Act says that information about these factors is only legally required *if it is available*.

However, in practice, Health Canada continues to require a wealth of information and materials that correspond more or less to all five factors before the Minister will decide on an exemption. Such requirements are no longer prescribed by the law but are included in detailed guidance developed by Health Canada. (At the time Bill C-37 was being debated in Parliament, community and health groups such as the Canadian HIV/AIDS Legal Network, Pivot Legal Society and the Canadian Medical Association submitted amendments to avoid precisely this situation where the law is interpreted as requiring information on all five factors described in the SCC's Insite decision in 2011. However, those particular amendments were not adopted.)⁵⁸

Because the law does not prescribe these detailed requirements, practice can evolve, and indeed guidelines from Health Canada have changed since the new legislation came into force. The latest guidelines were posted to Health Canada's website in November 2018. Contrary to previous practice, Health Canada is now more public and transparent about the application process and what it requires from applicants. It has also removed or streamlined some of its requirements. For example, now it is only the "responsible person in charge" of a site who is subject to a criminal record check. And in the updated November 2018 guidelines, Health Canada removed the requirement that an applicant must submit a letter from the provincial or territorial health minister as part of the application. Recent practice also shows a greater openness to new services being offered at SCS, such as drug checking, supervised inhalation or peer-assisted injection.

Despite welcome changes that have removed some barriers, some requirements still being imposed in practice by Health Canada continue to be problematic for applicants and providers, as described in subsequent sections of this report.

Section 56.1 and Procedural Matters

In addition to streamlining requirements for an application, Bill C-37 introduced some other important changes:

- » The current legislation no longer states that exemptions will only be granted in "exceptional circumstances."
- » The Minister is no longer required to wait for all information to be submitted by an applicant before reviewing the exemption.
- » While it does not require the Minister to render a decision on a completed application within a fixed period of time, the current law does provides some greater transparency and accountability by requiring the Minister to provide their decision about an exemption publicly in writing and, in the case of a refusal, to include the reasons for that refusal.⁵⁹

However, contrary to what community and health groups had called for in their submissions to Parliament, the current legislation does not include a specific provision enabling provincial or territorial authorities to grant exemptions from the CDSA if needed to address a risk to public health or public safety. Exemptions are still granted at the sole discretion of the federal Ministry of Health.

ALTERNATIVE AVENUES TO GRANT EXEMPTION UNDER CURRENT LEGAL REGIME

Section 56: General ministerial exemption

As described above, Bill C-37 restored the possibility for the federal government to grant an exemption under section 56 in relation to controlled substances obtained illegally if in the "public interest" or necessary for a "scientific purpose." If the exemption is granted to allow activities to take place at a "supervised consumption site" for a "medical purpose," however, the Minister must follow the requirements set out in section 56.1.61

The federal government used this flexibility to respond to the current overdose crisis by issuing class exemptions under section 56 to provinces for temporary "overdose prevention sites" on the basis that this was "in the public interest." In approving OPS, the federal government recognized the need to go beyond section 56.1 and use other legal tools to expand access to services of various kinds that involve supervising the consumption of controlled substances. (See below for more information on OPS.)

Section 55: Regulations adopted by Cabinet

Ministerial exemptions under sections 56 and 56.1 are not the only avenues for the federal government to grant exemptions to SCS. The federal government can also use its regulatory powers under section 55 of the CDSA.

In particular, section 55(1)(z) of the CDSA provides broad powers to the "Governor in Council" (i.e. the federal Cabinet) to "exemp[t], on any terms and conditions that are specified in the regulations, any person or class of persons [...] from the application of all or any of the provisions of this Act or the regulations" [emphasis added]. Section 55, along with section 56, was identified by the SCC in the Insite decision as "a safety valve that prevents the CDSA from applying where such application would be arbitrary, overbroad or grossly disproportionate in its effects."62 Nothing in section 55 prevents the Cabinet from using its power to adopt regulations that grant exemptions in relation to SCS especially if exemptions are granted in the public interest rather than for a medical purpose as provided by section 56.1 of the CDSA.

A special regime for temporary Overdose Prevention Sites

OPS are temporary, low-threshold SCS designed primarily to prevent overdoses. Like supervised consumption sites, OPS provide a safe space where people are able to consume drugs under the supervision of trained volunteers and/or staff. Though both models provide SCS, OPS tend to be lower budget, more flexible in design, serve even more marginalized populations, and often offer fewer ancillary services, such as counselling or HIV testing, than supervised consumption sites. Beyond legal subtleties, however, the distinction between OPS and supervised consumption sites is not necessary or meaningful. OPS are simply low-threshold designs that fall along a continuum of diverse SCS service models. The current legal regime regarding supervised consumption sites, however, has forced stakeholders to create a distinction between the two terms in order to implement vital health services in a time-sensitive manner.

OPS have functioned both to save lives and to put pressure on political leaders to act more urgently to ensure greater access to SCS. The first OPS opened in Vancouver in late 2016 without a federal exemption or approval from any level of government; other "non-authorized" sites later emerged in Toronto and Ottawa and operated for several months without a federal CDSA exemption or provincial (or municipal)

government support.⁶³ Subsequently, on December 9, 2016, the B.C. Minister of Health enacted a ministerial order to support the implementation of these sites across that province — again, without seeking a federal ministerial exemption (for services being characterized as "overdose prevention sites" rather than "supervised consumption sites"). The order was issued the province's *Health Emergency Services Act* and *Health Authorities Act*, in the context of a public health emergency declared in April that year.⁶⁴ Since then, more than 20 OPS have opened in B.C.⁶⁵

In December 2017, Health Canada announced that it would authorize emergency "overdose prevention sites" for those provinces and territories that request them. 66 Current class exemptions for OPS were granted in "the public interest" to provinces under section 56.67 Characterizing these sites as OPS allowed organizations to bypass the burdensome application process required to secure an exemption for a supervised consumption site under section 56.1 of the CDSA.

Ontario was the first province to be issued a section 56 class exemption for OPS, and the provincial Ministry of Health and Long-Term Care (MOHLTC) published a set of criteria in January 2018 to assist organizations in applying to the province for authorization and funding to operate OPS.⁶⁸ However, at the time this report was completed, those original criteria are no longer applicable, following a change in approach by the new provincial government elected in June 2018 (see below). Alberta also received a class exemption and has one OPS currently operating in Red Deer, but no application guidelines have been released to date.⁶⁹

Before the Ontario government changed its approach in late 2018, the application procedure under the class exemption was not radically different from Health Canada's requirements for SCS, although the process was more streamlined and tended to be more rapid. To receive provincial funding and to enter into a legal agreement with the MOHLTC or a local health authority (known as a Local Health Integration Network), Ontario applicants had to demonstrate some minimum requirements. These included: being an incorporated healthcare or community-based organization or partnering with one; having a letter of permission from the land/ property owner (if the applicant did not own the premises); having space to operate SCS with minimal or no capital start-up costs; meeting provincial and municipal safety requirements; and having a minimum of two trained staff and one health professional available either on site or on call. In addition to Ontario's minimum requirements, OPS had to comply with Health Canada's terms and conditions related to

data collection and the prevention of activities not authorized under the exemption that could amount to "trafficking" of controlled substances. The OPS application form prior to the late 2018 changes was short and much of it took the form of yes-or-no checkboxes. OPS applicants had to provide evidence demonstrating local need for such a service, as well as a criminal record check for the designated person in charge. Contrary to SCS applications, however, OPS applications were not required to conduct community consultations or provide detailed information regarding policies and procedures in place at the site.

As in B.C., the first OPS in Ontario was a makeshift service, operating out of tents in Moss Park in downtown Toronto, which opened without any federal CDSA exemption in August 2017. It operated for more than ten months on a completely volunteer basis, with no government funding. The site later applied for and received provincial authorization and support, thereby becoming covered by the class exemption issued to Ontario. With funding and this legal protection in place, the service moved from the public park to a permanent location in early July 2018. Leigh Chapman, an organizer of the site, explained that the organization had never intended to run long-term in a municipal park on crowdfunded resources and volunteer labour; the organization applied for provincial support to legitimize the operation and to ensure that the service was sustainable. Despite the OPS exemption process then being more streamlined and flexible, respondents indicated that the provincial requirements still imposed requirements that limited the ability of the services to adapt to the needs of individual communities. For example, inhalation services were not permitted despite evidence that these services were well used at the Moss Park OPS as well as at a pop-up OPS in Ottawa that opened soon after the Toronto site, both of which provided services without an exemption.⁷¹ Funding was also limited to three to six months (compared to the already short one-year SCS exemptions); the time-limited nature of OPS exemptions appeared particularly short-sighted and problematic in the midst of a crisis that shows no signs of abating.

As described by informants, OPS were originally set up by community members to provide an emergency solution in the face of an overdose emergency that was being exasperated by government inaction. This low-barrier model not only fills this gap, but also accommodates a particularly marginalized demographic who are not captured in more clinical settings and for whom the OPS model is most appropriate. A permanent supportive housing facility, for example, may only have a few clients, but should be able to allow staff to monitor these

clients on the premise. The OPS model should also be made available for organizations that work with people who use drugs but may not have the capacity to expand to formalized supervised consumption sites. Informants maintained that the small-scale nature of this service does not justify any burdensome authorization process and should be permitted to operate indefinitely if there is a need.

The future of OPS in Canada is unclear. By the end of September 2018, eight OPS were operating in Ontario under the class exemption with provincial funding, but as noted above, a change in provincial government has put this progress in jeopardy. In early August 2018, the Ontario government announced a "review of the evidence" regarding SCS.72 The government imposed an indefinite moratorium on provincial support for new OPS pending this review. It also "paused" some already-approved sites that were on the verge of opening, 73 forcing volunteers to — once again — set up tents in parks to provide urgently needed life-saving services and advocacy actions. 74 In late October 2018, the Ontario Minister of Health announced that funding would remain available for a maximum of 21 sites offering SCS in the province, all of which would need to conform to a new model of "Consumption and Treatment Services." All existing SCS and OPS were required to reapply to the province for funding under new burdensome criteria that were released in November 2018 and included limits to the locality of SCS and challenging capacity and infrastructure requirements.75 The new Consumption and Treatment Services model effectively terminates the low-threshold, flexible OPS model and removes mechanisms put in place through a class exemption by the current federal and former provincial governments to facilitate the scale-up of SCS. OPS that had been operating with legal protection under the short-term "class exemption," issued by the federal government to cover Ontario-approved OPS, had already felt pressured to seek longer-term, individual exemptions directly from the federal health minister as "supervised consumption sites." Under the Consumption and Treatment Services guidelines issued in late 2018, service providers are now obliged to obtain a federal exemption under section 56.1 of the CDSA as a precondition for provincial funding.⁷⁶ Unfortunately, the high administrative burden of applying for a CDSA section 56.1 exemption may mean this is not feasible for smaller organizations with limited capacity, and some of the associated restrictions on the services offered will prevent the site from maintaining their low-threshold nature.

EXPANDING ACCESS TO SCS:REMAINING FACILITATORS AND BARRIERS

In an effort to explore the effects of past and current laws and policies on SCS implementation in Canada, key informants were interviewed about their experiences of applying for exemption and implementing SCS in their communities. The following section outlines the key facilitators and barriers — as identified by these informants — that shape the expansion of these services. Particular focus was placed on strengths and limitations of the federal exemption process.

FACILITATORS

Following the change in government in November 2015 and the enactment of Bill C-37 in May 2017, Health Canada's approach to SCS has shifted significantly. Communication between Health Canada and applicants has improved tremendously, with government staff responding promptly to inquiries and maintaining engagement throughout the application process. The expansion of SCS has also been facilitated by collaboration, knowledge exchange and partnerships between sites, and depending on local context, by the support of elected officials, law enforcement authorities and regulated health professionals. Finally, community activists, particularly people with lived experience of using drugs, have pushed the agenda forward across the country, demanding that elected officials respond more urgently to the ongoing overdose crisis.

Shift in Health Canada's approach to SCS

Between 2006 and 2015, the federal government strongly and explicitly opposed harm reduction, prompting many organizations across the country to shelve their planned SCS projects. Respondents described a "climate of distrust" between service providers and Health Canada during this time. No information was available about the administration's policy on or requirements for SCS exemptions until the *Respect for*

Communities Act was passed in 2015. As a result, the few organizations that nevertheless decided to apply for an exemption were operating in the dark and felt pressured to prepare extremely comprehensive applications out of fear that they would have to go to court to challenge a refusal. Montreal's application for instance, was 350 pages in total, according to one of the respondents. Some said they would even refrain from discussing details of their project out of concern that any leak about their application might be used against them by Health Canada.

In late 2015, with the election of a new federal government that was explicitly supportive of harm reduction including SCS, informants noted a striking change in Health Canada's responsiveness. Health Canada staff began reaching out to applicants to reopen discussions about expanding SCS. Lines of communication between Health Canada and applicants have continued to open since then, with staff responding promptly to inquiries and maintaining engagement throughout the application process.

With Bill C-37 coming into force in May 2017, there was an influx of applications for section 56.1 exemptions. As Health Canada staff became more knowledgeable about SCS and their comfort reviewing applications increased, the turnaround time for applications gradually shortened. While the 2017 amendments streamlined legal requirements to some extent, the biggest change seemed to be in how Health Canada handled applications, with greater engagement with applicants, increased familiarity with the process, and responsiveness to new models. Respondents felt that Health Canada's overall approach to SCS is starting to move towards a more flexible, health-centered model.

The exemption process has also become increasingly transparent, with explicit application requirements and guidance documents now published on Health

Canada's website. Application approvals and the status of open applications are also made public online, in stark contrast to the previous opacity. Though Health Canada is hesitant about publishing draft protocols for applicants out of concern about imposing only one acceptable model, the current application form — updated in November 2018 — provides applicants with the option of sharing policies and procedures, which can prove helpful to other would-be SCS applicants.⁷⁷

Health Canada's openness to novel SCS

Health Canada has also indicated some willingness to support novel SCS, such as supervised inhalation services where people can smoke crack and other illegal drugs under staff supervision, as well as hospital-based SCS for in-patient access. This is important, given that all respondents called for new services and a more flexible approach to SCS. Though supervised inhalation services are increasingly being offered in European SCS,78 the first and only federally exempted supervised inhalation service in Canada didn't open until March 2018 at ARCHES in Lethbridge, Alberta. Organizers of the SCS at ARCHES described the application process as fairly simple, with frequent communication with Health Canada about their proposed service model, and a reasonably fast turnaround. The organization submitted their application in July 2017 and received approval in October 2017. They described Health Canada as operating with a more open approach of asking the applicant to "demonstrate to us why the service should operate in this way," rather than top-down guidance about what the service should look like. As long as ARCHES could prove that their proposal was in line with federal, provincial and municipal legislation in relation to health and safety, the federal Minister of Health saw no reason not to grant the exemption. Other respondents explained that it remains unclear what standards SCS would have to meet to include inhalation in their services, given that occupational health and safety legislation or other legislation restricting smoking in various locations may vary from one province to another. Of note, Ontario's new Consumption and Treatment Services model adopted in late 2018 does not include inhalation services.⁷⁹

Health Canada's openness to authorizing supervised inhalation services marks a clear divergence from previous

unwillingness to pursue alternative service models. Canada's first authorized SCS, Insite, has provided supervised injection services since 2003 and applied several times to expand their services to accommodate inhalation, facing rejection each time.80 Several supervised inhalation services have operated and continue to operate without federal exemption. For example, the Vancouver Area Network of Drug Users (VANDU) operated a peer-run service between 2011 and 2013 without any CDSA exemption that included supervising inhalation of substances on site. Despite evidence from this site demonstrating high demand for such facilities and the potential for this approach to improve the health and safety of people who inhale drugs, local health authorities ordered VANDU to close the service because it was operating without an official federal exemption.81 More recently, supervised inhalation services were provided without exemption at OPS in Ottawa and Toronto⁸² and continue to operate at an OPS in Vancouver.83

Another new SCS model has recently been implemented at the Royal Alexandra Hospital in Edmonton, Alberta. While the Dr. Peter Centre has provided SCS in a licensed nursing care facility for people living with HIV for more than 16 years, the Royal Alexandra Hospital is the first acute care hospital to offer SCS to in-patients in North America, and provides another example of Health Canada's flexibility to support novel approaches to SCS. Along with other hospital leaders, Dr. Kathryn Dong, director of the Inner-City Health and Wellness program at the Royal Alexandra Hospital, argued that providing SCS to in-patients was a necessary part of the spectrum of care for people who use drugs. Clients ought to receive at least the same level of evidence-based care while in hospital as they would in the community. Having to leave the hospital or hide to use drugs places patients at heightened risk of overdose and other harms. Dr. Dong maintained that Health Canada was very supportive through the application process for this novel service.

Stakeholder Support and Partnerships

Respondents identified the ability to network with service providers from other sites across Canada as a key facilitator in scaling up SCS. The Canadian Drug Policy Coalition (CDPC) and the Canadian HIV/AIDS Legal

Network co-hosted a knowledge-exchange working group on SCS as a way to build connections and share information, as well as to discuss collective advocacy strategies in light of an evolving legal environment. In January 2017, CDPC and the Legal Network co-organized a national community consultation in Vancouver where current and potential SCS applicants could share experiences and concerns and learn from each other. Learning about different models of operation and cooperation with provincial and local health authorities was eye-opening for some of the respondents. The Dr. Peter Centre is now offering a formalized knowledge exchange program funded by the Public Health Agency of Canada (PHAC) to facilitate networking between sites and to support the establishment and implementation of SCS across Canada. The program involves capacity and skills building training for front-line organizations as well as facilitation of knowledge dissemination and exchange among organizations, policymakers, health care professionals and knowledge networks across the country.84

Other forms of support include direct collaboration between sites. For example, Toronto sites worked closely with the Dr. Peter Centre and Insite to develop policies and procedures for their SCS. The Dr. Peter Centre has also developed a guidance document to assist applicants with community consultation and engagement and to share their experiences with other SCS providers. Respondents suggested further expanding collaboration between sites and developing a more extensive shared database of policies, documents and practical information, such as what furniture and equipment would be required to establish a SCS. Easily accessible resources and templates would be particularly helpful for smaller organizations with limited capacity.

Preparing joint applications between organizations within cities can, depending on context, also help reduce the administrative burden of undertaking intensive application components, such as community consultation and gathering evidence of local need. Montreal, Toronto and Edmonton have used this method to share the workload with some success. The Royal Alexandra Hospital in Edmonton, for example, was able to be a partner on the Access to Medically Supervised Injection Services Edmonton (AMSISE) application prepared jointly with Boyle McCauley Health Centre, Boyle Street Community Services and George Spady

Society, which saved them time and resources when preparing their own application. Parkdale Queen West Community Health Centre in Toronto also worked with two other services in the city — South Riverdale Community Health Centre and Toronto Public Health's program "The Works" — in developing their applications. Working with a program like The Works, with direct connections to city council, facilitated engagement with councillors and key stakeholders.

Canadian sites have also turned to international models in order to learn about innovative approaches to SCS. A group of stakeholders from Quebec, including members of community organizations, representatives of the Montreal Public Health Agency and the Quebec Ministry of Health, attended the 2008 International Harm Reduction Conference in Barcelona. The delegation visited different sites in that city, including a mobile site. Inspired by their visit, they decided to open multiple sites in Montreal. Montreal has since opened a set of four services — three integrated sites and one mobile site — to increase their reach and accessibility in the city.⁸⁶

In addition to collaboration between organizations — within cities, across Canada, and internationally respondents advised that early and widespread partnerships with local municipal leaders and law enforcement officials were helpful in easing both the exemption application process and the implementation of SCS. Maxine Davis, former Executive Director of the Dr. Peter Centre, noted that coordinating a meeting with the Vancouver Police Department (VPD) as soon as the Centre publicly announced that they would be providing SCS was critical to their continued positive relationship and communication. In Montreal, a respondent said having police support was particularly helpful when consulting with local communities. Informants acknowledged that the success of exemption applications remains largely determined by these partnerships; lack of support from these stakeholders is often one of the most significant barriers to moving ahead with projects.

Finally, support from regulatory bodies, such as provincial nursing associations, has proved important in expanding SCS. Specifically, the Dr. Peter Centre was the first health care setting in North America to provide SCS by integrating it into its licensed care residence and

day health program. It did so after receiving an opinion from the Registered Nurses Association of BC indicating that supervision of injections, for the purposes of preventing illness and promoting health, was within the scope of registered nursing practice.87 Very soon thereafter, Dr. Peter Centre obtained the same scope of practice clarification from the Registered Psychiatric Nurses Association of BC (RPNABC).88 In addition, the Dr. Peter Centre obtained a legal opinion that it could be at risk if it refused to permit nurses to practice according to their regulatory body's practice clarification.89 Health Canada never questioned the Centre's decision to provide the service without an exemption, despite the Centre making its decision public in 2002. Moving forward, Davis suggests that re-framing the provision of SCS as an integral part of nursing practice, rather than as an exceptional service, could facilitate the acceptability and expansion of these services across Canada.

Community involvement

Much of the success in advancing harm reduction across Canada has been and continues to be the result of efforts by people who use drugs, community organizations and advocates. Starting in the 1990s, peer-led groups opened and operated SCS without authorization, and since then, they have filled gaps where necessary services are neither available nor authorized.90 Community members began to open OPS in late 2016 to bring essential services to their communities. Many of these sites were operated uniquely by volunteers and without authorization or funding from any level of government. As more and more cities adopted this model, from Vancouver in B.C. to Toronto and Ottawa in Ontario, SCS become more acceptable to the general public. OPS also put pressure on political leaders to respond more urgently to the overdose crisis, pushing both the federal and provincial governments to facilitate the authorization and fund temporary OPS. This is a clear example of how community activism can shape public policy. People who use drugs have also played a critical role in guiding the implementation of SCS in their cities, by way of participation in community consultations, working groups and feasibility studies. Peers and activists continue to raise alarms when services are not adequate and push to expand life-saving harm reduction services across the country.

ONGOING BARRIERS

The expansion of SCS in Canada continues to be limited by a legislative regime that is subject to the political ideology of the federal government of the day and treats SCS as exceptional rather than as health vital services. The politicized nature of SCS in Canada and lack of consistent approach across provinces, territories and municipalities also make these services highly context-dependent.

Despite important legal reforms and policy changes, respondents maintained that the exemption application process is still overly burdensome and that many of the criteria and requirements in the law or policies are problematic or irrelevant. Respondents urged Health Canada to take greater leadership in permitting and supporting diverse and innovative models of SCS. In particular, they called for a wider range of activities and services to be allowed where needed. Better support is also needed from all levels of government to facilitate involvement of people who use drugs in the design and delivery of SCS.

An Exceptional Regime

A fundamental barrier to the expansion of SCS in Canada is the exceptionality of the legislative regime related to SCS. The implementation of these vital health services continues to take place within a system where exemptions from possible criminal prosecution need to be obtained from the federal government, often with excessive contingencies and bureaucratic barriers. Given that exemptions are granted solely at the discretion of the federal Minister of Health, the process is vulnerable to changes in political leadership and party leanings. The experience of recent years has demonstrated how sensitive the exemption process is to prevailing political ideology.

Respondents stressed that decisions about health services should be made based on need rather than political ideology, and that organizations seeking to provide supervision of drug consumption as a harm reduction measure should not be required to pass a series of unnecessary bureaucratic hurdles before opening. The roll-out of SCS continues to be slow, in stark contrast to public health responses to influenza outbreaks, for example, where treatment services are

made available within days. Health Canada, however, continues to be constrained by the use of section 56.1 exemptions (issued for a "medical purpose") as the principal avenue for providing protection to SCS clients and providers from potential prosecution. Respondents recommended moving away from an outdated, problematic system requiring a specific federal exemption and towards larger-scale policy shifts that would better support the expansion of harm reduction services.

Inconsistency across provinces, territories and municipalities

Implementation of SCS in Canada is contingent not only on the federal government's approach to exemptions, but also on the willingness of provincial, territorial and municipal authorities to support the services. For example, provincial authorities are traditionally in charge of funding harm reduction services, including SCS, meaning that service providers must navigate between different levels of government to be able to operate SCS. Disparities in approaches between provinces and municipalities can make this particularly challenging in some jurisdictions.

In British Columbia, provincial authorities have consistently led the expansion of harm reduction services while would-be providers in other provinces have experienced little movement from their governments, structural barriers or even explicit obstruction to the implementation of SCS. Ontario's recent announcement of new funding requirements for SCS and intention to cap the total number of sites in the province to 21 is a clear example of this.⁹² In Quebec, current provincial guidelines on SCS date from 2013. They were written based on Montreal's experience at that time and have yet to be adapted to reflect the evolution of Health Canada's approach to exemptions and public health needs. These guidelines include myriad criteria to be met by SCS applicants and impose significant involvement of the local public health agency, even where the project is to be led and implemented by community organizations.93 Other harm reduction programs in the province are not required to fulfill such conditions to operate. According to some respondents, while such an approach may have been justified at the time the guidelines were developed, it can pose unnecessary challenges for applicants, especially where visions for SCS might differ between public

health agencies and community organizations, or where public health agencies might be slow to take action on this specific issue.

Respondents explained that in some communities the most significant barriers are faced not at the federal or provincial level, but rather at the municipal level. In Red Deer, Alberta, for example, the province is seeking to fund SCS in the community, in response to high rates of overdose deaths and public drug use. Municipal land use bylaws, however, only permit SCS to be established as mobile sites, and these bylaws have been used by opponents to restrict implementation in the city.⁹⁴ Organizations in Ottawa, Ontario, have also faced consistent and public opposition to SCS from their mayor, Chief of Police and other key stakeholders, which has delayed and limited any expansion of services in the city and forced concerned community members to operate OPS without exemption and despite opposition, in order to save lives.95

A burdensome application process

FIVE SPECIFIC CRITERIA

The federal exemption process continues to be exceedingly time- and resource-intensive. Under section 56.1 of the CDSA regime, applicants must provide information regarding the intended public health benefits of a future SCS and, *if any*, information related to the five criteria outlined by the Supreme Court of Canada. Key informants discussed the relevance of and challenges posed by each of these criteria.

1) The impact of the site on crime rates

Informants stressed that information about the expected impact of potential SCS on crime rates is not relevant when assessing an application for exemption. This is consistent with the position of the Canadian Nurses Association, the Canadian Medical Association and legal organizations who have called for the removal of this requirement in the law. Prior to May 2018 when Health Canada released its new guidance document, applicants were expected to include, *if any*, statistics related to: crime and public nuisance; public drug consumption; inappropriately discarded drug-related litter; law enforcement; trends in loitering or trafficking of controlled substances. Informants explained that

gathering this data can be a barrier for organizations given that accessing records tends to be difficult and time consuming; often the information is out of date or incomplete. Estimating the impact a facility may have on crime is also difficult to quantify before the site is established. The most recent iteration of Health Canada's application guidance document, however, shows signs of moving away from weighting this criterion as heavily in evaluating exemption applications. Instead of making crime statistics a core application requirement, "local crime rates" is simply offered as an example of "factors that may impact public health and safety" to support consideration of the "local conditions" of a proposed site. "99"

Informants stated that requiring crime statistics reinforces a pervasive misconception that SCS will bring increased crime and other negative impacts to the community, despite a lack of evidence to support this. 100 Paradoxically, respondents explained that this requirement has also given the public a false expectation that SCS should reduce crime, and some sites have become scapegoats for public disorder reported in areas surrounding SCS. While evidence from existing SCS has demonstrated neutral or positive effects on rates of drug-related crime in the surrounding areas, 101 expecting or requiring these health services to reduce rates of crime is no more logical or justifiable than having the same expectation for any health clinic or a hospital, particularly given that drug-related law enforcement issues are deeply rooted in intersecting factors such as drug prohibition and poverty. While SCS can contribute to the safety and quality of life of community members by reducing the impact of open drug use and by reducing discarded drug-use paraphernalia, the fundamental goal of SCS remains to save lives and minimize harm among people who use drugs. Any positive public order impacts are simply positive consequences and should be treated as such.

2) The local conditions indicating a need for the site

The majority of informants indicated that providing evidence of local need is a reasonable requirement for exemption applicants unless it requires providing an excessive amount of information. The Canadian Nurses Association went further in recommending that this be the sole criterion to be considered. 102 Respondents

explained that under the previous regime legislated in the Respect for Communities Act (Bill C-2), there was an expectation that applicants must provide detailed information regarding drug consumption patterns in the community, rates of infectious disease, overdose statistics, coroners' reports, and any public health emergencies in the proposed site area. 103 The 2017 amendments simplified the requirements, and the updated 2018 Health Canada policy provides even fewer specifications, focusing on target client demographics, rates of drug-related overdoses and deaths, as well as any intended health impacts of the site.¹⁰⁴ Respondents agreed that only minimal information should be required to indicate local need; for example, presence of a homeless population and a well-used needle and syringe program could be sufficient evidence to grant an exemption. Collecting extensive information about local conditions can pose an unsurmountable barrier for small organizations or those in communities where data is not accessible.

3) The administrative structure in place to support the site

Though this criterion tended to be interpreted differently between respondents, most agreed that the level of information — particularly detailed policies and procedures - required by Health Canada is still excessive. The current application guidelines request a physical site plan and detailed operating procedures including: responsibilities of staff members; client "flow" through the facility; disposal procedures for any illegal substances left behind; site security; and record keeping and reporting protocols for unidentified substances left behind.¹⁰⁵ Respondents took issue with the fact that these requirements centered heavily on public safety considerations, such as drug trafficking and theft, rather than the safety of those accessing the services. Some also pointed to the challenges in providing such detailed information, regarding staff members or site plan for example, before funding is secured and guaranteed at the provincial level.

In addition to policies and procedures, one responsible person in charge (RPIC) must be named in the application and both a resumé and criminal record check must be provided to Health Canada. Under the previous regime of the *Respect for Communities Act*, however, a

criminal record check was legally required for the RPIC as well as any staff supervising consumption. ¹⁰⁶ Sandhia Vadlamudy, the former executive director of CACTUS Montréal, explained that it was a "big relief" when Bill C-37 passed in 2017 and removed the requirement for a criminal record check for all key staff. The previous legislation had been problematic for their organization because requiring criminal record checks for a wider range of staff posed a barrier to including peers in the operation of the site, including access to the supervised consumption room. Given the expertise that peers can bring as harm reduction workers, they must be central to the implementation of SCS, and the legislation should better reflect the value peers have in the design and delivery of these services.

Furthermore, Health Canada requires all supervised consumption sites to maintain records of the training completed by staff members and logbooks tracking the entry and exit of all clients and visitors to the site. 107 In addition, sites can be required to collect and report data regarding the estimated impact of the services on the neighbourhood on an ongoing basis as well as general demographics of the clients served.¹⁰⁸ Informants felt that some reporting requirements presented a barrier because gathering demographic details from clients at SCS can feel invasive. Given that drug use is still criminalized, people tend to be wary of providing personal information out of fear that it may be leaked to the police. As such, any record-keeping and data collection can affect how accessible the service feels for clients. Some informants explained that they used an anonymous code system to track people and that they try to fill out the logbook as discreetly as possible in order to minimize discomfort for their clients.

4) The resources available to support the maintenance of the site

Informants agreed that funding is necessary to operate SCS and to ensure sustainability, but that having funding confirmed should not be a precondition for obtaining a federal CDSA exemption. Health Canada requires a financial plan that "demonstrates the feasibility and sustainability of the site," including but not limited to financial statements or audits, confirmed funding sources and budget proposals. ¹⁰⁹ This requirement, however, has caused significant delays in

some communities where would-be service providers are in a "Catch-22" situation where the province will not fund a site until an exemption is secured, but Health Canada requires evidence of provincial funding before authorizing the site. Informants from Montreal explained that securing funding posed one of the most significant barriers to opening their services. Despite receiving a conditional exemption from the federal government, the Montreal sites were unable to move forward and send structural plans to Health Canada until provincial funding was confirmed. A restructuring of provincial budget and health services in Quebec created uncertainty about funding, and negotiations between federal and provincial governments caused unnecessary delays in opening the services. Similar concerns exist in Ontario with the new Consumption and Treatment Service model, where only providers who have received a federal exemption to establish "a supervised consumption site" can apply for provincial funding.110

5) Expressions of community support or opposition

Informants strongly agreed that expressions of community support or opposition are not relevant to the Minister's decision to approve or refuse an exemption application. Whether a health service is provided in a community should not depend on public opinion. Given that no other health service is required to submit a community consultation report, this criterion reinforces the notion that SCS are exceptional, that their value is a matter of debate, and that they exist outside the continuum of care for at-risk populations. ¹¹¹

Under the previous regime of the *Respect for Communities Act*, applicants for a federal exemption were required to submit reports outlining extensive consultation with a broad range of stakeholders and professional licensing authorities, as well as letters of opinion from the provincial ministers of health and of public or community safety, local government, head of the local police force and the lead public health professional of the province.¹¹² The 2017 amendments eliminated these requirements as a matter of law. The 2018 guidelines suggest that Health Canada is adopting a more relaxed and flexible interpretation of what community consultation can look like for potential sites. As of November 2018, the letter of opinion from the provincial

or territorial Minister of Health required in the previous guidelines is no longer mandatory.¹¹³ The required community consultation report must outline the results of any activities undertaken to engage with the community, as well as all feedback and comments received, and proposed measures to address any concerns raised. Methods of consultation, however, are not prescribed. 114 Pivot Legal Society notes that section 56.1 does not legally require applicants to gather expressions of support or opposition from the community. The language is permissive, and submission of expressions of community support or opposition is prefaced by the words "if any." 115 It is unclear, however, how Health Canada interprets this criterion. Given the hostile environment toward harm reduction under the previous federal government, most respondents explained that their organizations conducted extremely thorough community engagement as an extra precaution should litigation prove necessary to challenge the minister's decision to deny an exemption. Undergoing such a resource- and time-intensive process has proven to be a particular barrier for smaller, grassroots organizations, which may have limited capacity but are well-positioned to provide SCS in their communities and to respond rapidly to the current overdose crisis.

Informants explained that the act of consulting the community is also problematic because it can be used to perpetuate stigma related to drug use and may, in some circumstances, promote a false belief that the opinions of neighbours and local business associations can determine if, where, and in what form health care interventions are made available for people who use drugs. 116 Dr. Elaine Hyshka, assistant professor at the University of Alberta, pointed to Edmonton's experience implementing SCS outside a hospital setting. She explained that services could have opened quietly within existing community-based organizations that were already serving local people who use drugs. Instead the organizations were required to broadly consult businesses and residents in three surrounding neighbourhoods. The consultation process provided an avenue for some community members and elected officials to advance unsubstantiated fears about people who use drugs, and gave the perception that consultation meant that members of the public had full authority to determine whether SCS could be provided in the city, and to specify permissible locations. Since the opening of

the SCS, the Chinatown and Area Business Association in Edmonton has gone further to file a federal court application seeking judicial review of the Minister's decision to grant the exemptions. The applicants are arguing that they had a right to formal standing in the Minister's decision-making process.¹¹⁷

In contrast, the SCS located within the Royal Alexandra Hospital in Edmonton faced minimal opposition. Dr. Kathryn Dong, director of the Inner-City Health and Wellness program at the hospital, believes this may be due to the public feeling more at ease with the services being provided within an established medical facility, such as a hospital. This is comparable to the experiences of Maxine Davis at the Dr. Peter Centre in Vancouver. This site opened quietly and has faced little to no opposition in its 16 years of operation. Both informants explained that there is a "softening effect" and the public tends to be more accepting of SCS if it is integrated within an existing health service and simply adding to the spectrum of care.

Overall, informants insisted that community consultation should not be a formal requirement for exemption. Instead, it should be left up to individual organizations to assess the context and determine the most appropriate method of gathering input from potential clients and to educate local community members and business groups about the service. Most SCS applicants are already providing harm reduction services within their community and have pre-existing relationships with their neighbours and local community members. As such, individual organizations are better positioned to negotiate with their community on their own terms. Informants stressed that community approval should never be a determining factor in whether a site is opened.

A LONG AND RESOURCE-INTENSIVE PROCESS

Informants maintained that the current regime continues to be too onerous, not flexible enough, and incapable of supporting appropriate and timely responses to public health emergencies, such as the current overdose crisis. The way in which community members have sought work-around solutions by opening OPS without official authorization demonstrates that despite the progress made, the current regime does not adequately

support communities' needs. Many of the informants interviewed for this report obtained exemptions under the current regime (which came into force in May 2017 with Bill C-37) but had prepared their application in the years prior (i.e. with reference to the much more onerous requirements of the preceding Respect for Communities Act). As such, their applications were more comprehensive than what is expected under the current regime, including numerous letters of opinion from stakeholders. It took some sites in Edmonton six years to prepare their exemption applications and try to fulfill all of the requirements outlined in the former Respect for Communities Act. Dr. Hyshka explained that some organizations took money out of their limited budgets to hire dedicated staff and devoted a huge amount of time to prepare the comprehensive applications.

Despite the 2017 amendments streamlining the requirements for an exemption application, several informants, including recent applicants, felt that it simply "squished 25 criteria into five" and was not notably different in practice from the previous regime. They urged that the exemption process should be further streamlined to reduce the administrative burden of applying and to ensure that these services are implemented widely and rapidly where and when they are needed most.

Informants highlighted that many grassroots and less well-resourced organizations (including those that are peer-led) are well positioned to provide SCS but do not have the financial and human resources necessary to go through the laborious application process. Potential and current SCS providers are often already at the frontlines of the opioid crisis and stretching limited funds to save lives within their communities. It is neither reasonable nor realistic to expect these applicants to have the resources, time and support to gather the documentation necessary for the application.¹¹⁸ Not surprisingly, Health Canada has yet to receive applications from sites in smaller, remote communities. Informants urged Health Canada to find better ways to support smaller organizations and make it easier for them to apply for exemptions.

Several informants called on Health Canada to allow submission of joint applications from locations that are geographically close as a way to share the administrative burden. Sites in cities such as Edmonton and Toronto worked closely to conduct community consultations, gather letters of opinion, and to prepare other application material; however, they were required to submit individual, site-specific applications for exemptions. Montreal was an exception: ultimately Health Canada accepted one application covering four different services (three fixed, one mobile), but only after intense negotiations that led to further delay. However, this flexibility has not been consistent. In Edmonton, for example, service providers from three community organizations wanted to apply as one program that would have three separate but geographically close locations, rather than three site-based programs, to create a network where clients could transition seamlessly between sites. This was of particular importance given the close proximity between the three SCS: they are located within a few blocks and tend to serve many of the same clients. Having to prepare site-specific exemptions required additional resources and added an unnecessary layer of complication. Similarly, the Moss Park OPS in Toronto tried to apply for an exemption by way of the South Riverdale Community Health Centre, but Health Canada was firm about not allowing satellite site exemptions and indicated no flexibility in easing this restriction.

BARRIERS FACED AFTER AN EXEMPTION IS GRANTED

Organizations offering SCS face barriers that extend beyond the application process. Before opening, all organizations must pass an inspection from Health Canada. Current SCS providers explained that they received no guidance from Health Canada about how they should prepare or what to expect from the inspection. Instead, they were assisted by other sites that had already been inspected and were willing to share their experiences. For example, the policies and protocols provided to the inspectors had to be signed and approved by the management team, and the safe designed to hold any illegal substances left behind by service users was required to be bolted shut. Inspections also tend to be quite long; one respondent recalled that two inspectors visited their site for approximately three hours.

Even after their sites opened, respondents reported that the paperwork required by Health Canada continued to be extensive. All policies and protocols submitted as part of the application quickly became mandated as conditions of the exemption, despite being developed when the service delivery model was conceptual. Any changes — even simple things like deactivating a door that isn't working properly — must be approved by Health Canada through a request for amendment. This burdensome paperwork can be particularly challenging for SCS providers who are not the direct recipients of the exemption for their site. CACTUS in Montreal, for example, cannot negotiate amendments to protocols or conditions or operation directly with Health Canada but must go through the Centre intégré universitaire de santé et de services sociaux du Centre-Sud-de-l'Île-de-Montréal (the recipient of the exemption) and negotiate at the regional level. While this can have some advantages, including better coordination of services across the region, it also means additional time and consultation are required to adapt services and that community organizations have less flexibility to implement their own approach.

The discretionary nature of exemptions has also allowed for differences in terms and conditions that individual SCS must meet. In Edmonton, for example, Health Canada issued exemptions to three community-based organizations with added conditions that all exemption letters be made publicly available online, and that each site submit a public report outlining the impact of the SCS on the neighbourhood within 90 days of opening.¹¹⁹ These 90-day reports are particularly stressful for organizations at a time when they should be focused on implementing their programs. In addition, it is unreasonable to expect that a site could demonstrate an impact — positive or negative — in only 90 days. Accessing the necessary data, such as law enforcement statistics, is often difficult and time consuming, and preparing these reports requires additional human resources that may not be available.

Barriers to innovative approaches and diversity of models

While Health Canada has recently demonstrated openness to some novel SCS models, applicants have asked for more guidance and more flexibility from the federal government to increase the diversity of allowed services and activities. Respondents from ARCHES explained than the main barrier to the implementation of inhalation services wasn't Health Canada's lack of openness to their proposal, but rather the creation of brand-new policies and protocols for a service that had yet to be authorized as well as designing and building

a new ventilation system for the site. Furthermore, scientific evidence of health benefits associated with health services is weighed heavily by Health Canada in the decision-making process. Despite the availability of supervised inhalation services in Europe, there has been minimal literature gathered from these sites, which makes it challenging to provide evidence of their effectiveness to Health Canada. 120

Health Canada continues to be resistant, however, to allowing assisted injection or drug sharing and splitting at SCS despite many respondents highlighting the need for such services. Failure to authorize assisted injection — either by peers, staff or nurses — bars particularly vulnerable populations of people who use drugs from accessing services, including women who are more likely to seek assistance injecting from an intimate partner and are less likely to know how to inject, as well as individuals with physical limitations. 121 A number of existing SCS in Canada have requested the expansion of services to include assisted injection, including South Riverdale Community Health Centre (SRCHC) in Toronto, Ontario. Health Canada advised them to remove assisted injection from their initial exemption application to expedite approval. Soon after opening, they resubmitted for an amended exemption to include assisted injection. SRCHC submitted updated policies and protocols for Health Canada to review but they did not hear back for months. Health Canada has yet to articulate clearly why they have been hesitant to support such services.

More recently, Health Canada finally agreed to undertake a short pilot program of peer-to-peer assisted injection at four SCS across Canada between June and December 2018, including SRCHC. ¹²² However, Health Canada refused to expand the pilot to more sites, despite advocacy from community groups and from SCS who were not selected for the pilot and who were not given the opportunity to apply for selection. In December 2018, Health Canada decided to extend its pilot project until the end of 2019 for those sites originally included, as well as to permit existing SCS or sites with an application under review to apply for inclusion in a one-year peer assistance pilot. ¹²³

In contrast, OPS in Ontario were permitted to offer peer-to-peer assisted injection under the section 56 class exemption.¹²⁴ SCS providers have expressed frustration over the fact that these temporary sites can provide services that supervised consumption sites operating under a federal exemption cannot. Of note, assisted injection by a nurse or another staff member has not yet been authorized in Canada even though the Registered Nurses' Association of Ontario has stated doing so may reduce or eliminate injections in dangerous environments (such as injecting in local alleys).¹²⁵

Drug sharing and splitting is another element that several respondents said should be authorized at SCS. Failure to allow this on the premise can discourage clients from accessing services, thereby exposing them to risk of arrest or police harassment. Many people purchase drugs collectively with the intention of sharing them. ¹²⁶ Similarly, drugs in pill form often have to be prepared in solution before they can be divided, making it impossible to split in advance. ¹²⁷ Providing this service brings illegal activity inside, which serves to both protect vulnerable clients and achieve community goals of moving drug preparation activities off of the street.

Respondents also stressed the need for a greater range of medical options to be available to address the critical issue of unsafe drug supply that is contributing to a high toll of overdose deaths in Canada. Dr. Mark Tyndall, executive director of the BC Centre for Disease Control, explains that appropriate public health responses to a poisoning epidemic must include provision of safer alternatives for people at risk. Making a regulated supply of pharmaceutical-grade opioids available would help to replace the illegal, unregulated street drug supply. This could take the form of a program, such as the Providence Crosstown Clinic in Vancouver, where patients can access injectable heroin or hydromorphone to be used under medical supervision. Heroin-assisted treatment (HAT) programs have been available in Switzerland, Denmark, Germany, Luxembourg, the Netherlands and the United Kingdom for many years. 128

In Canada, the North American Opiate Medication Initiative (NAOMI) ran from 2005 to 2008 to evaluate the effectiveness and feasibility of implementing HAT.¹²⁹ Despite positive findings, the federal government at the time refused to extend the initiative or set up a permanent HAT clinic.¹³⁰ Since then, another study has been undertaken — the Study to Assess Longer-term Opioid Maintenance Effectiveness (SALOME) — to compare the effectiveness of HAT and hydromorphone

therapy.¹³¹ Participants from this study continue to access HAT at the Providence Crosstown Clinic in Vancouver, the only medical facility to offer HAT in North America.¹³²

In 2018, Health Canada amended regulations for opioid substitution treatments and paved the way for the expansion of methadone and HAT.¹³³ A type of injectable opioid agonist therapy (iOAT), supervised injectable hydromorphone programs have been implemented more recently in Ottawa¹³⁴ and in 2017, the Alberta provincial government agreed to develop pilot projects in Edmonton and Calgary to allow patients to inject hydromorphone under the supervision of medical professionals.¹³⁵ According to Dr. Tyndall, however, such program models, while necessary, are limited in their scalability. These limits are due to the high cost of hydromorphone and diacetylmorphine, the logistical barriers of setting up clinics to provide the drugs and medical supports, and that this model requires people to give up the freedom to use drugs when and how they want. Clients of these programs need to attend a medical clinic up to three times per day, 136 a commitment that most people are not willing or able to make. Other models such as the distribution of hydromorphone pills at medical clinics, pharmacies, SCS or supportive housing units remain largely untested but have the potential to be more easily scalable and thereby reach a larger number of people who use drugs. 137

Respondents were unanimous: there is a strong need for a continuum of SCS to be made available in Canada, from peer-run low-threshold services to comprehensive health services offering primary care, mental health care, treatment and/or social services. 138 SCS should be made available in multiple forms and in multiple places to adapt to clients' needs, including in mobile sites, housing facilities, harm reduction organizations, drop-in centres, shelters, stand-alone sites or hospitals.¹³⁹ In particular, some informants emphasized the need for greater accommodation of and support for peer-led, non-medicalized SCS in addition to more traditional supervised consumption sites where health care workers can play important roles. Jean-François Mary, from l'Association Québécoise pour la promotion de la santé des personnes utilisatrices de drogues, explains that low-threshold models are needed for those who are not comfortable accessing institutionalized structures.

Respondents from Montreal described some recent tensions between community organizations and public health agencies in their approach to SCS. Given the political context at the time that they were preparing their applications (i.e. under the previous federal government), community organizations agreed to shift leadership for their SCS applications to the local public health agency to enhance credibility, gain greater support at the local level, and increase their chances of being granted an exemption. While agreed upon and strategic at the time, this delegation of ownership became problematic later by complicating the governance of the site and by making it more difficult for community organizations to maintain their traditional low-threshold approach. This has left some peers and harm reduction workers feeling removed from their own initiative and that their expertise is being devalued. Similarly, Pivot Legal Society explained that many applicants felt that the federal exemption process gives the impression that Health Canada does not trust or recognize the work that people who use drugs have been doing successfully for decades. Peers and frontline workers have consistently led efforts to save lives during crises, and they should not be required to seek an exemption to continue the work they are already doing. 140 Canada needs a framework that supports the implementation of diverse SCS models, including those that are less medicalized and those that rely on and build capacity among people who use drugs.

Health Canada needs not only to relax its approach to SCS and be less prescriptive when providing exemptions, but also to play a greater leadership role in directly supporting and encouraging provincial authorities to support the implementation of diverse SCS models. Ontario's recent announcement of a singular Consumption and Treatment Service model restricts the implementation of diverse service models. While important progress has been made in Canada to expand SCS, this is yet another reminder that more must be done to ensure that all Canadians have the evidence-based care that they need.

CONCLUSIONS

Over the past two years, Canada has experienced a remarkable shift in the scaling up of SCS across the country, in large part because of a public health emergency with more than 4,000 overdose-related deaths in 2017¹⁴¹ and more than 2,000 deaths in the first half of 2018. This tragic situation has shed light on the consequences of Canada's harmful approach to drug policy, which has focused on prohibition and consistently downplayed — or even ignored — the benefits of harm reduction for many years. While efforts were made in some provinces to support harm reduction services, federal authorities explicitly took measures to prevent implementation of SCS in Canada between 2006 and 2015. Expansion of SCS has been led by the dedicated efforts of people who use drugs, service providers, health professionals and their supporters who have advocated at many levels (including in courts) to push for these life-saving services. More recently, these efforts have been paralleled by increased political will — especially at the federal level — pressured by the ongoing overdose crisis and the emergence of unauthorized SCS in Vancouver, Toronto and Ottawa.

The election of a new federal government in late 2015 marked a turning point in the scaling up of SCS in Canada. The federal government restored harm reduction as a key pillar of Canada's drug strategy in 2016, and in 2017, removed some of the legislative barriers to SCS that had been imposed by the previous government. Measures were taken to increase transparency and to streamline the process of applying for a SCS exemption. All respondents described better lines of communication with Health Canada; greater responsiveness; improved collaboration; faster turnaround for applications; and some openness to novel SCS designs, including supervised inhalation.

While efforts have been made to facilitate the expansion of SCS across the country, the fact remains that service providers cannot confidently and sustainably offer SCS without a specific federal exemption protecting staff and clients from criminal prosecution under the CDSA. Such an exceptional regime for an evidence-based health service constitutes a significant barrier to their rapid implementation and is a great source of vulnerability. The history of SCS in Canada demonstrates that relying on the discretion of the federal Minister of Health to obtain an exemption makes SCS highly vulnerable to the political context (even if the Supreme Court of Canada has set some parameters to limit the exercise of ministerial discretion). 143 The current approach to SCS is limited by providing exemptions only on a case-bycase basis. This approach also perpetuates the politicization of a health issue by leaving the decision to open sites offering SCS in the hands of the government. The current legal regime also gives the federal government significant power to control, restrict and oversee the implementation and operation of SCS, which can limit access to diverse and innovative models.

Our report identifies a number of priorities, focusing on the federal government's role and responsibilities, for improving Canada's approach to SCS in order to facilitate the expansion of these vital health services. Measures need to be taken to normalize and integrate SCS seamlessly into a comprehensive set of services for people who use drugs.

As a fundamental start, we propose a legal framework in which decisions about authorizing SCS are no longer at the discretion of the federal government and the conditions for opening SCS are eased. Recognizing differences in local contexts, with provincial and municipal authorities also sometimes presenting significant obstacles, we recommend a legal framework wherein a specific exemption would no longer be required to provide SCS if a certain number of minimal conditions are met. Ultimately, ending the blanket criminal prohibition on drug possession would facilitate the operation of life-saving SCS, but other measures could be taken immediately, within the current legislative framework, to facilitate the rapid scale-up of SCS.

Such further legal measures are essential, but not sufficient. Other concrete measures, including increased funding, should also be taken by all levels of government to support community organizations and health care providers in establishing a wide variety of services adapted to the needs of people who use drugs. The federal government must take a leadership role and work with provinces to provide greater access to life-saving, health-promoting SCS across the country.

RECOMMENDATIONS TO THE FEDERAL GOVERNMENT

1. DECRIMINALIZATION

The federal government should decriminalize activities related to personal drug use.

Drug prohibition does not protect either public health or public safety. In particular, the criminalization of possession for personal use puts people who use drugs at increased risk of harm, including by impeding their access to much-needed services and emergency care in the event of an overdose. More generally, criminalization perpetuates stigma, discrimination and the over-incarceration of people who use drugs.¹⁴⁴ Successive measures of criminal prohibition targeting various substances have also had a displacement effect, contributing to the increasing toxicity of the illegal drug market in Canada and the ongoing overdose crisis. Decriminalization would effectively end SCS exceptionalism as there would be no need for an exemption from criminal prosecution to protect SCS clients and staff. It would allow these services to open and operate in a similar fashion to other harm reduction services and help remove SCS decision-making from the political realm. Calls for decriminalization of possession are mounting in Canada, including among health professionals who have been calling for a public health approach to problematic drug use.145

2. CLASS EXEMPTION FOR SCS CLIENTS AND PROVIDERS

In the interim, before necessary decriminalization, the federal government should grant a class exemption protecting clients and staff, including volunteers, from prosecution for drug possession or for activities (such as drug sharing or assisted injection) that may amount to "trafficking" when accessing or providing SCS that meet minimum required conditions.

As outlined above, under section 56 of the CDSA and within the current legal framework, the federal Minister of Health could grant a class exemption, *in the public interest*, under certain conditions. Alternatively, under section 55, the federal Cabinet could adopt a regulation granting such an exemption from the CDSA under certain conditions. A further alternative would be for Parliament to amend the CDSA to create a standing exemption in the statute itself for SCS clients and staff under certain conditions.

A class exemption that automatically provides protection against prosecution to clients and staff of SCS, for any service meeting the defined conditions, would remove a significant administrative burden from SCS operators who would no longer have to apply for caseby-case exemptions from Health Canada. Such an approach is particularly important in the context of an ongoing public health emergency requiring a rapid response and for small harm reduction organizations with limited capacity. Moreover, it would be entirely consistent with the federal government's recognition that SCS are life-saving services that improve health, are cost-effective, do not increase drug use or crime, and are an entry point to treatment and social services for people who wish to stop or reduce their use of substances — as demonstrated by research conducted both in Canada and internationally.146

Whether it takes the form of a ministerial exemption, a Cabinet regulation or a statutory provision in the CDSA itself, the class exemption would have to be broad enough to offer flexibility for the implementation of a continuum of SCS models across the country, from peer-run, low-threshold services to comprehensive health services. The wording of the exemption would set out certain minimum conditions to protect the safety and wellbeing of clients, staff and the surrounding community. It is important to underscore that these minimum conditions for supervised consumption would be developed *for the purpose of defining when the criminal law does not apply*, and would not replace

best practices that may guide the implementation of different models of SCS of different scale.

Minimum conditions would be designed in consultation with service providers and people who use drugs, following experiences in other countries and within Canada including with OPS. They would focus on structural aspects of services related to personnel, procedures and protocols, equipment and health and safety requirements. Minimal conditions should not be excessive or onerous, as that would maintain or recreate barriers to the scale-up of much-needed services. Based on the OPS experience in Canada, minimum conditions for being covered by the class exemption from CDSA prosecution might include the following:

- » A reasonable minimum number of people with training in administering naloxone and CPR on site at all times as well as a "designated person" responsible for overseeing all operations of the SCS, including guaranteeing that minimum standards, procedures and protocols are respected, and for liaising with the local community.
- » Availability of appropriate equipment to ensure the immediate provision of evidence-based emergency interventions in the event of an overdose (e.g. naloxone, administration of oxygen) and to provide SCS, including harm reduction supplies such as sterile needles, syringes and other safer drug use equipment, as well as basic equipment for the safe disposal of used equipment.
- Basic health and safety protocols and procedures related to: the roles and responsibilities of staff; response in the event of an overdose; disposal of used drug equipment and substances left behind; and preventing any activity that amounts to "trafficking" of substances (other than as may be permitted by the terms of the class exemption, such as the sharing of limited quantities of a substance between service users).
- » Satisfying reasonable provincial and municipal requirements of general application (e.g. to meet health and safety requirements such as fire safety regulations).
- » A notification to Health Canada within five days of beginning to offer services in a given venue.

3. A STREAMLINED PROCESS FOR SCS EXEMPTION APPLICATIONS

If the federal government insists on unnecessarily maintaining a case-by-case SCS exemption process, it should take measures to further streamline the current application requirements and process.

Changes in Health Canada's policies and practices or through regulations¹⁴⁷ should be made to address the following:

- » Additional pathways are necessary to allow for expedited exemptions to be issued either by provincial/territorial or local health authorities, or by the federal minister simply on the basis of such a request from such authorities.
- » Health Canada should not demand more information from applicants than is legally required by CDSA section 56.1 or impose additional hurdles for prospective service providers. Decisions about the implementation of health services should be based on evidence of need and the potential for benefit in addressing that need. In particular:
 - Community consultation should not be required to provide an exemption. Instead, it should be left up to organizations to determine appropriate methods and time to engage with local community. The purpose of such engagement is to facilitate effective operation of the site; it is not something on which potential criminal liability of site users or staff should depend.
 - Securing funding should not be a precondition for federal exemption. It should be feasible to secure an exemption that removes any legal uncertainty about the operation of the service, before securing the funding for operations. In fact, federal funds should be made available to support SCS including in provinces where local governments are reluctant to fund these life-saving services.

- o Organizations should be permitted to submit joint applications and to open satellite sites without having to apply for a new exemption. This would ease the administrative burden associated with exemption applications and facilitate coordination of service implementation within municipalities.
- » To better accommodate the needs of individual communities, greater flexibility is needed to encourage and authorize a wide range of service models and an ability to adapt to changing contexts. Services should be expanded where needed to accommodate not only supervised injection, oral and intranasal consumption, but also inhalation, assisted injection, drug checking, drug sharing, and interventions to address the critical issue of the unsafe drug supply leading to fatal overdoses (e.g. prescription of controlled substances).
- » Exemptions should be granted for more than one year so that communities are not required to repeatedly undergo a burdensome reporting and approval process.

4. OTHER MEASURES THE FEDERAL GOVERNMENT SHOULD ADOPT TO SUPPORT SCS EXPANSION

As noted above, federal funds should be made available to support SCS, including in provinces and territories where authorities are reluctant to fund these life-saving services.

The federal government should work with provincial, territorial and municipal governments to ensure they commit to facilitate the scale-up of SCS where needed, including through immediate and sustained operational funding for SCS.

Greater support should be made available to service providers, especially grassroots, peer-led organizations who are well positioned to provide SCS but may not have the financial or human resources necessary to apply for an exemption or implement SCS meeting the minimum criteria. For instance, community organizations may need support to undertake renovation or build consumption rooms that respond to safety requirements.

The federal government should convene dialogue between law enforcement, health care professionals, social workers, people who use drugs and community organizations to increase understanding and acceptability of SCS across the country.

RECOMMENDATIONS TO PROVINCIAL, TERRITORIAL AND MUNICIPAL AUTHORITIES:

Implementation of SCS in Canada is contingent not only on the federal government's approach to exemptions from potential criminal liability under the CDSA, but also on the willingness of provincial, territorial, and municipal authorities to support the services including through funding and by not imposing unnecessary regulation. Efforts must thus be made at and by all levels of government to scale up SCS across the country.

- » Provincial and territorial authorities should provide immediate and sustained operational funding for SCS in their province or territory.
- » Provincial and territorial authorities should not impose conditions for SCS implementation that are not required for other health services. In particular, provincial and territorial authorities should not create exceptional hurdles for service providers to receive funding to provide a wide range of supervised consumption services. Provincial guidance related to SCS should be amended accordingly.
- » Municipal authorities should not impede the establishment of SCS through the enactment of by-laws.

APPENDIX

EXAMPLES FROM EUROPE

SCS have been operating in Europe for 30 years. The first SCS opened in Switzerland,

Germany and the Netherlands in the 1980s and early 1990s in response to emerging HIV and hepatitis C epidemics, increasing open drug scenes and overdose-related deaths. 148 Other European countries have more recently revised their legislation to authorize SCS, and a range of legal regimes exists across the continent. While organizations offering SCS are often required to obtain a specific exemption or licence from a governmental authority at the national or provincial level, SCS in Switzerland, Spain and the Netherlands are not currently subjected to any specific approval process.

No specific regime:

The first SCS in Switzerland opened in Berne in 1986. 149 Since then, SCS have been recognized and accepted in Switzerland as part of a public health approach to drugs and are not subjected to any specific legal regime that would distinguish them from other harm reduction measures. As described by Diane Steber Buechli from the Federal Office of Public Health, there is no need to obtain an exemption from the criminal law or a specific authorization from the federal authorities to operate SCS in Switzerland. The Federal Act on Narcotics and Psychotropic Substance declares harm reduction as one of the four pillars of Switzerland's policy on drugs; these consist of prevention, therapy and reintegration, harm reduction and survival support, control and law enforcement.¹⁵⁰ The Swiss federal law also specifically states that cantons (member states of the Swiss Confederation) "shall introduce harm reduction and survival support measures" "[i]n order to prevent or reduce health-related and social harm among persons with disorders associated with addiction."151 Each canton is therefore responsible for the implementation of SCS in its region if it so decides. There is no specific approval process but the decision to open a site will depend on a local political decision that includes considerations of local needs and agreed priorities for funding.¹⁵² Currently, Switzerland has 12 facilities offering SCS in eight different cities offering SCS in Switzerland. 153 While the

Federal Office of Public Health has no jurisdiction to over funding or implementing SCS at a local level, they play an important role in creating spaces for dialogue between various stakeholders that help increase understanding of drug-related issues and acceptability of harm reduction measures including SCS in particular across the country.¹⁵⁴

Spain is another country where the establishment of SCS is not currently subject to a specific approval process. Drug consumption or possession of small amounts has always been free of criminal penalties in Spain although consumption or minor personal possession in public spaces can lead to severe administrative sanctions. Regional and local governments are responsible for the development of services related to prevention and treatment in relation to drug use. This has allowed some sub-national "autonomous communities" (especially Catalonia and the Basque Country) to push for innovative drug policies and implement a variety of harm reduction interventions, including SCS. There are currently 13 SCS in seven cities in Spain and SCS have the express support of the central government.

The Netherlands opened its first SCS in Amsterdam in the 1970s, and to date there is no specific legal framework allowing SCS or providing a strong legal guarantee against prosecution. Some prosecutorial guidelines of the Prosecutors General's Office from 1996 indicate that the possession of drugs in drug consumption rooms is tolerated provided the facilities met the requirements set out by the police, the mayor and the public prosecutor. There are currently 31 SCS operating in 25 cities in the Netherlands.

A specific regime requiring designation or authorization by national authorities

In France, SCS have also been officially recognized as an element of harm reduction policy in public health since legislation was passed in 2016. ¹⁶⁰ In contrast with Switzerland, a specific legal regime that applies to SCS has been outlined as part of a six-year SCS implementation pilot project. The law requires SCS to be designated by the Ministry of Health after consultation with regional public health and municipal authorities. While the law provides some minimal conditions to

be respected by SCS, the Ministry of Health is responsible for defining the conditions of operation through regulations. ¹⁶¹ Current regulations impose strict and detailed conditions for operation. ¹⁶² Under the 2016 legislation, staff and clients of designated SCS are expressly protected from prosecutions related to illegal drug use, possession or facilitation. ¹⁶³ Only two sites are currently operating in France: one in Paris ¹⁶⁴ and one in Strasbourg. ¹⁶⁵

In Ireland, as in Canada, SCS operators can now apply to the Ministry of Health "for a licence to operate a supervised injecting facility in respect of certain premises."166 Relevant criteria for granting a licence notably include the suitability of the premises, the experience and expertise of the applicant, the establishment of appropriate protocols and the availability of information on people who inject drugs, overdoses or deaths to suggest local need.¹⁶⁷ The Misuse of Drugs (Supervised Injecting Facilities) Act 2017 (published May 16, 2017) specifically provides that client and staff of authorized SCS are not subject to criminal provisions related to illegal drug use and possession.¹⁶⁸ There are no SCS currently operating in Ireland. One site was scheduled to open in Dublin, but is facing barriers at the local level. The Dublin City Council has requested additional information before it agrees to grant planning permission for the facility. The site may not be able to open its doors until after 2019.169

Similarly, the law in Luxembourg was amended in 2001 to protect client and staff accessing facilities specifically authorized by the Ministry of Health.¹⁷⁰ There is only one SCS currently operating in Luxembourg.¹⁷¹

In Portugal, where drug possession is decriminalized but still constitutes an administrative offense, harm reduction services, including SCS, are regulated by decree (which sets out a number of conditions). 172 Regulations enacted in 2001 state that SCS must be implemented by municipal councils or at the initiative of private bodies working on drug addiction, but that authorization for SCS are granted by the Portuguese Institute on Drug and Drug Addiction after consultation with the relevant municipal council (unless the municipal council initiated the project). In 2012, the autonomous Institute was merged with the country's National Health Service. 173 Any entity that proposes to create and maintain harm reduction programs, including SCS, must now request authorization from the General Directorate for Intervention on Addictive Behaviours

and Dependencies (SICAD).¹⁷⁴ SICAD is attached to the Ministry of Health and supports the national drug strategy's implementation.¹⁷⁵ According to APDES, an NGO in Portugal, barriers to implementation of SCS are at the municipal level because SCS eventually depend on the good will of municipalities.¹⁷⁶ Currently, efforts to open SCS in Portugal are ongoing. Lisbon recently announced the opening of three sites that should be operating by early 2019.¹⁷⁷

A specific regime requiring a licence from provincial, state or regional authorities

In Germany, SCS have been operating since the 1990s, although it was not until 2000 that the German Narcotic Drugs Act was amended to provide a legal basis for the establishment of SCS in the country. While SCS are legal in Germany, any person who wishes to operate a SCS must obtain "a licence of the competent highest Land [i.e. state-level] authority."178 A licence can only be issued where the Land's government has enacted a specific ordinance to regulate SCS. The Narcotic Drugs Acts lays out ten minimum standards for SCS that must be included in ordinance. 179 In a 2011 report, the Deutsche AIDS-Hilfe observed that "[a]fter 10 years of practice [...] the passed legal ordinance and the requirements of supervisory authorities (municipal agencies, police and state prosecutors) have had a rather restrictive effect on conceptual considerations and room to maneuver."180 Furthermore, they observed that several states had not enacted the required ordinances to authorize SCS given political or ideological opposition. As noted by Deutsche AIDS-Hilfe, the current regime makes "the establishment of drug consumption rooms [...] dependant of the political will of the respective state government." Local health interests cannot be realized without support at the state level. 181 As of today, there are 24 SCS operating in 15 cities in Germany. 182 In 2014, Germany was known to have the strictest admission criteria for accessing SCS in Europe. 183

A feasibility study conducted in Belgium has identified three legal avenues to authorize SCS in that country. Suggested avenues include explicit exception to criminal provisions that put staff or clients at risk of prosecution through law reform¹⁸⁴ or by means of a royal decree.¹⁸⁵ While such measures have yet to be taken, a new facility opened its doors in September 2018 and enforcement authorities declared they would not take proactive action to close the site.¹⁸⁶

- SCS are also known as "supervised injection sites," "drug consumption rooms" or "medically supervised injection centres," depending on the jurisdiction and scope of services offered.
- ² Harm Reduction International, What is harm reduction? A position statement, 2019.
- D. Hedrich, European report on drug consumption rooms, European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), 2004.
- 4 C. Potier et al., "Supervised injection services: What has been demonstrated? A systematic literature review," Drug Alcohol Depend. 145C (2014): pp. 48-68; European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), Perspective on drugs. Drug consumption rooms: an overview of provision and evidence, 2018.
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- 6 EMCDDA 2018, supra note 4; Drug Policy Alliance, Supervised Consumption Services, March 2017.
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- ²⁹ M. Tyndall, "An emergency response to the opioid overdose crisis in Canada: a regulated opioid distribution program," *Canadian Medical Association Journal* 190(2) (2018), E35-E36.
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- In the "Insite" decision, the Supreme Court of Canada explicitly stated that clients and staff could be at risk of prosecution under section 4 of the CDSA:
 "...without a s. 56 exemption, s. 4(1) applies to the staff of Insite because, by operating the premises opening the doors and welcoming prohibited drugs inside the staff responsible for the centre may be 'in possession' of drugs brought in by clients. They have knowledge of the presence of drugs, and consent to their presence in the facility over which they have control." See *Canada (Attorney General) v. PHS Community Services Society, supra note 10 at para 89. According to the SCC, neither the clients nor the staff of Insite, could be said to be involved in trafficking simply for possessing, or tolerating the possession of, controlled substances on the premises. In particular, the court indicated that clients "[did] do not obtain their drugs at the facility, and [were] not permitted to engage in activities that could be construed as trafficking while they are on the premises" (at para 95). This might be different in SCS authorizing assisted injection or drug-sharing between clients.
- The full text of section 56 currently reads as follows: "56 (1) The Minister may, on any terms and conditions that the Minister considers necessary, exempt from the application of all or any of the provisions of this Act or the regulations any person or class of persons or any controlled substance or precursor or any class of either of them if, in the opinion of the Minister, the exemption is necessary for a medical or scientific purpose or is otherwise in the public interest.

 (2) The Minister is not authorized under subsection (1) to grant an exemption for a medical purpose that would allow activities in relation to a controlled substance or precursor that is obtained in a manner not authorized under this Act to take place at a supervised consumption site." See Controlled Drugs and Substances Act, S.C. 1996, c. 19, s. 56 at https://laws-lois.justice.gc.ca/eng/acts/C-38.8/index.html.
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- ⁵⁰ Section 56.1(3) of the CDSA (Version of section 56.1 from 2015-06-30 to 2017-05-17).
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- 57 Controlled Drugs and Substances Act, S.C. 1996, c. 19, s. 56.1 (2).
- Se Canadian HIV/AIDS Legal Network, Saving Lives, Protecting Health: Strengthening Bill C-37 to expand and expedite access to supervised consumption sites, Submission to the House of Commons Standing Committee on Health, February 6, 2017; PIVOT, Brief to the Standing Committee on Health on Bill C-37: An Act to amend the Controlled Drugs and Substances Act and to make related amendments to other Act, February 6, 2017; Canadian Medical Association, CMA Submission to the study of Bill C-37 An Act to amend the Controlled Drugs and Substances Act and to make related amendments to other Acts, Submission to the Senate Standing Committee on Legal and Constitutional Affairs, April 6 2017; Canadian Nurses Association, Bill C-37: an act to amend the controlled drugs and substances Act and to make related amendments to other acts, Brief for the Standing Committee on Legal and Constitutional Affairs, March 2017.
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- ⁶⁰ Canadian HIV/AIDS Legal Network, supra note 58; PIVOT, supra note 58; Canadian Medical Association, supra note 58; Canadian Nurses Association, supra note 58.
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- 168 Ibid, section 10.
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- ¹⁷⁶ Ximene Rego, APDES, "Portuguese Harm Reduction Under Scrutiny," Drug Reporter, September 3, 2018; "Drogues: lancement de salles de consommation à moindre risque (SCMR) à Lisbonne (Portugal)," Coalition Plus, January 14, 2018.
- $^{\scriptscriptstyle{177}}$ European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) 2018, supra note 4.
- Section 10a 1), Act to regulate the traffic in narcotics (Narcotics Act) 1981. Available at www.emcdda.europa.eu/topics/law/drug-law-texts?pluginMethod=eldd. showlegaltextdetail&id=677&clang=en&T=2.
- 179 Ibid, section 10a(2): "The Land governments are authorized to lay down, by means of an ordinance, the prerequisites for the issue of a licence pursuant to subsection 1. The provisions shall regulate, in particular, the following minimum standards for the security and control of the use of narcotic drugs in drug consumption rooms:
 - 1. Appropriate equipment of the premises that are to serve as drug consumption rooms;
 - 2. Arrangements to ensure the immediate provision of medical emergency care;
 - 3. Medical counselling and assistance for the purpose of reducing the risks involved in the use of the narcotic drugs brought by drug-addicted persons;
 - 4. Placement in follow-up and abstinence-oriented counselling and therapy services;
 - 5. Measures to prevent criminal offences under this Act from being committed in drug consumption rooms, other than the possession of narcotic drugs pursuant to section 29 subsection 1 sentence 1 number 3 for personal use in small quantities;
 - Required forms of co-operation with the local authorities responsible for public order and safety to prevent, as far as possible, any criminal offences from being committed in the immediate surroundings of drug consumption rooms;
 - 7. A precise definition of the group of persons entitled to use drug consumption rooms, especially with regard to their age, the kind of narcotic drugs they may bring with them and the consumption patterns that are tolerated; obvious first-time or occasional users are to be excluded from using these rooms;
 - 8. Documentation and evaluation of the work done in the drug consumption rooms;
 - Permanent presence of a sufficient number of personally reliable staff whose professional training qualifies them to comply with the requirements specified in numbers 1 to 7;
 - 10 Appointment of a competent person who shall be responsible for compliance with the requirements specified in numbers 1 to 9, the obligations imposed by the authority issuing the licence and the orders issued by the monitoring authority (responsible person) and who is able to permanently meet the obligations incumbent on him."
- Deutsche AIDS-Hilfe, Drug Consumption Rooms in Germany. A Situational Assessment by the AK Konsumraum, 2011, p. 9.
- 181 Ibid, p. 10.
- $^{\mbox{\tiny 182}}$ European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) 2018, supra note 4.
- European Harm Reduction Network, Drug consumption rooms in Europe Models, best practice and challenges, 2014.
- ¹⁸⁴ In combination with secondary legislation, where a royal decree would provide the conditions and modalities applicable in order to allow for the exception provided in the basic primary legislation. See F. V. Laenen, supra note 158, p. 87.
- This option would be to modify the reach of the law prohibiting facilitation through a royal decree in order to provide a sufficient degree of protection from prosecution under the law. SCS responding to specific preconditions and modalities provided in the royal decree could be recognised as a specific harm reduction measure aimed at promoting the health of the users, thus justifying an exception to the application of the offence of facilitation under current legislation. F. V. Laenen, supra note 158, pp. 87-88.
- 186 "Première en Belgique: une salle de consommation de drogue ouvre ce mercredi à Liège," RTBF, September 5, 2018.

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Canadian HIV/AIDS Legal Network

1240 Bay Street, Suite 600 Toronto, ON M6R 2A7

Telephone: +1 416-595-1666 Fax: +1 416-595-0094

Email: info@aidslaw.ca

www.aidslaw.ca



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Réseau juridique canadien VIH/sida

1240 Bay Street | Suite 600 | Toronto, Ontario, Canada | M5R 2A7 Telephone: +1 416-595-1666 | Fax: +1 416-595-0094 | Email: info@aidslaw.ca | www.aidslaw.ca