Access to Prescribed Safer Supply in British Columbia: Policy Direction

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Ministry of Mental Health and Addictions
Ministry of Health
Land Acknowledgment

The Ministry of Health and the Ministry of Mental Health and Addictions would like to respectfully acknowledge that the land on which we primarily work is the unceded territory of the Lekwungen speaking people, also known as the Songhees and Esquimalt First Nations and the Coast Salish people as well as Métis Chartered Communities, Inuit and Urban Indigenous peoples.
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Executive Summary

It has been over five years since British Columbia’s Provincial Health Officer declared a public health emergency due to rising rates of illicit drug toxicity deaths. This rise in deaths continues to be driven by the adulteration of street drugs with highly toxic illicit fentanyl. Since 2016, a range of health sector programs and services have been implemented to reduce drug toxicity events, injuries and deaths. Despite these efforts, people continue to die in unprecedented numbers due to a toxic drug supply. In fact, 2020 saw the highest number of deaths ever recorded in one year and record high numbers of deaths and injuries have continued through the first part of 2021. We also know that the illicit drug supply has become increasingly toxic; the BC Coroners Service reports that 86% of deaths in the last year are linked to fentanyl and 14% of cases show evidence of extreme fentanyl concentrations.\(^1\)

In 2019, First Nations people in B.C. died due to drug poisonings at 3.9 times the rate of non-Indigenous people and in 2020, this increased to 5.3 times. While males represent almost 80% of all deaths, First Nations women, in particular, experience a higher risk from the toxic drug emergency, representing 32.2% of First Nations deaths in 2020, as compared to non-Indigenous women (16.6% of non-Indigenous deaths).\(^2\)

The escalating number of drug toxicity deaths, increasing toxicity of the illicit drug supply and deepening inequities demonstrates a need to explore new and innovative ideas to stop the loss of life and stem the tide of grief and pain that comes in the wake of these deaths.

This policy is a step in that direction. It is an enabling document that supports the provision of pharmaceutical grade alternatives to illicit drugs to people who are at risk of drug toxicity events and death. The goals of this policy are to reduce drug-related harms, including toxicity injuries and deaths, enhance connections to health and social supports, and improve overall health and wellness for people receiving these medications.

This policy directive is a shared responsibility of the Ministry of Mental Health and Addictions and the Ministry of Health. It is part of a commitment by government to establish prescribed alternatives to toxic drugs as one tool in a *comprehensive package of essential health sector interventions* that guide the response to the overdose public health emergency. This package includes take-home naloxone, overdose prevention services, acute overdose risk case management, and treatment and recovery, including low barrier access to the full spectrum of treatment services such as opioid agonist treatment (OAT).\(^3\) The combined impact of these services averted close to 6,000 drug toxicity death events between 2015 and 2019.\(^4\)

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This document contains the fundamental components required for regional health authorities (including contracted service providers, and other programs such as the federally funded SAFER initiatives\textsuperscript{5}) to provide prescribed safer supply. This document also describes the key policy directives including the following:

- This policy is intended to support individuals with opioid use disorder (OUD) or other substance use disorders (SUD) or individuals actively using illicit substance use who are at high risk of illicit drug toxicity death or other drug related harms due to the toxic drug supply, to access prescribed safer supply.
- Health authorities must support uptake of this policy through the development of programmatic or other clinical settings that can provide prescribed safer supply. Programs and services must be supported by provincially or regionally developed medication protocols.
- Clients will not be required to engage in Opioid Agonist Treatment (OAT) or other treatment modalities if they do not want to or are not ready.
- Prescribed safer supply and the pharmacy services related to providing these prescription drugs will be covered through Pharmacare.
- Services should be delivered in the context of the guiding principles and service delivery attributes identified in this policy.
- Safer supply prescribers and programs must become part of the provincial evaluation.

This policy is recognized as a significant shift for the health system and a change in the established clinical practices of health professionals. As providing prescribed safer supply, such as fentanyl products, as a harm reduction measure is an emerging practice, there is currently limited evidence upon which to base the development of provincial clinical guidance to support this form of prescribing. While prescribing is encouraged, given the limited evidence base and concerns about patient safety, it is recognized that prescribing will occur at the discretion of clinicians.

Because of the need to continue to establish an evidence base to support this initiative, prescribed safer supply will be initially implemented primarily in a phased approach beginning with health authority funded programs and services as well as the federally funded SAFER programs. These programs are ideal settings for testing and refining the use of these medications as they provide health authority oversight, team-based care and access to other health services and supports. Given the lack of clinical guidance to support this type of prescribing, programs are required to develop clinical protocols to support the use of selected medications. These protocols may be developed at either the regional or provincial level and are meant to support programs to trial the use of these medications to determine effectiveness and safety. A process for scaling regional protocols to a provincial level is currently in development.

Evaluation and monitoring are critical to both understanding the impacts of the policy on reducing overdose deaths and events, and for the future development of clinical guidance that could support wider implementation. Prescribed safer supply programs will contribute to an evidence-gathering process to determine the effectiveness of this approach, assess its impacts on client and public safety, inform the development of provincial guidance, and support policy refinements and service quality improvement. Evaluation findings will also help inform the development of future phases of this project.

\textsuperscript{5} Funded by the Substance Use and Addictions Program at Health Canada. See: https://www.canada.ca/en/health-canada/services/substance-use/canadian-drugs-substances-strategy/funding/substance-use-addictions-program.html#a5
This policy represents an opportunity to provide people who use drugs with safer alternatives to the toxic drug supply, and to better understand the role of pharmaceutical grade medications as part of a comprehensive package for responding to the drug toxicity public health emergency.

During the consultations for the development of this policy, feedback revealed significant reservations about the approach outlined in this document including concerns that substances like opioids are potentially dangerous and must be treated with care and with clear evidence and guidance to support prescribing. Health system partners have told us that prescribing a safer supply for primarily harm reduction purposes is not typically part of the training or orientation for most prescribers.

We acknowledge these concerns and while there is not yet enough peer-reviewed scientific evidence to develop guidance, we are requiring that any prescribers who are working with medications like fentanyl products do so as part of health authority funded services (and federally funded SAFER programs) and adhere to locally or regionally developed medication protocols.

It is also acknowledged that this policy includes some components and limitations that do not feature in the safer supply programs and models envisioned by a range of stakeholders. Some partners have told us that prescriber-based models implemented in program settings are not nimble enough to respond to this crisis nor to the needs of people who use drugs. We recognize that we have been unable to address all concerns, but we also recognize that we must start somewhere. This document is that starting point, and steers towards a public health approach to substance use in B.C. while balancing the perspectives of diverse stakeholders who share a common goal – reducing harm and saving lives in a public health emergency that currently takes the lives of five to six people in our province every day.
Commitment to Reconciliation

The Province of British Columbia is committed to a lasting reconciliation with Indigenous peoples.

The United Declaration on the Rights of Indigenous Peoples (‘the UN Declaration’) constitutes “the minimum standards for the survival, dignity and well-being” of Indigenous peoples and affirms the right of Indigenous peoples to self-determination and the right to autonomy and self-government. The provincial government passed the Declaration on the Rights of Indigenous Peoples Act (‘the Declaration Act’) in November 2019 to implement the UN Declaration, which the Truth and Reconciliation Commission of Canada confirms as the framework for reconciliation.

The Ministry of Mental Health and Addictions contributes to the implementation of the UN Declaration by establishing partnerships with Indigenous peoples that support Indigenous self-determination; strengthen the cultural safety and humility of the mental health and substance use system of care, and advance a distinctions-based approach that best serves the diversity of First Nations, Métis, Inuit, and urban and away-from-home Indigenous peoples in B.C. The Ministry of Mental Health and Addictions also collaborates with Indigenous partners to include Indigenous perspectives into the planning, design and implementation of new initiatives and the overall alignment of provincial policy and programs with the Declaration Act.

Indigenous peoples and communities in B.C. have been disproportionately impacted by the public health emergency related to drug toxicity deaths. As outlined in the In Plain Sight⁶ report, Indigenous people often experience unique additional barriers when accessing health care, including systemic racism, inequity in service access, and, if services are available, a lack of culturally safe and appropriate care. These barriers—combined with other systemic factors related to the historic and ongoing impacts of colonialism in B.C. —continue to shape the health and social inequities faced by Indigenous communities in the province, and related poorer health outcomes for Indigenous peoples.

Government is committed to reconciliation, addressing anti-Indigenous racism in the B.C. health system, and reducing the health and social inequities that have led to Indigenous peoples being disproportionately impacted by drug toxicity deaths. Government will meet these commitments by partnering with First Nations, Métis and Inuit communities and organizations to develop culturally safe programs, including by supporting Indigenous efforts to strengthen cultural identity, connections and approaches and improve Indigenous wellness, recognizing that a distinctions-based approach is needed to ensure the unique rights, interests and needs of Indigenous peoples are represented and implemented.

Intended Audience

The intended audience for this policy includes health authorities, physicians, pharmacists, nurses, other allied health professionals, medical, nursing and pharmacy students, and people accessing the unregulated drug market for their drug supply.

Background

On April 14, 2016, B.C.’s Provincial Health Officer declared a public health emergency under the Public Health Act following an unprecedented increase in drug toxicity events and deaths. The increase in drug toxicity-related harms was associated with fentanyl adulteration of the unregulated drug supply, which was becoming increasingly unpredictable and highly toxic—a trend that has continued since this time. The public health emergency related to drug toxicity deaths is ongoing in B.C. and entered its fifth year in April 2021. Illicit drug toxicity remains the leading cause of unnatural death in B.C. surpassing homicides, suicides, and motor vehicle collisions combined. At the population level, B.C.’s life expectancy at birth for males has declined as a direct consequence of the drug toxicity crisis.

While B.C. experienced a significant decline in illicit drug toxicity death rates in 2019 (984 compared to 1,549 in 2018), drug toxicity events remained high in this same period. The downward trend in deaths was dramatically reversed in 2020, with the province experiencing a record high of 1,728 drug toxicity deaths that year—a 74% increase over 2019. This surge has continued into 2021, and as of May 31, 2021, there have been 851 illicit drug toxicity deaths—almost six drug toxicity deaths per day. Paramedic attended drug toxicity events have also climbed in 2020 and again in 2021, reaching an all-time high of 1,867 in April 2021.

The primary driver for this rise in deaths is the increasingly toxic drug supply. Among the drug types identified in completed B.C. Coroners Service illicit drug toxicity death investigations, the presence of fentanyl has increased from 5% in 2012 to 86% in 2020. The proportion of completed drug toxicity death investigations

Drug Toxicity Deaths Among First Nations People in B.C.

First Nations people in B.C. are disproportionately impacted by the drug toxicity crisis. While First Nations people make up 3.3% of the B.C. population, in 2020, 14.7% of all people who died due to the toxic drug supply in the province were First Nations people, up from 11.8% in 2019. In total, 254 First Nations people in B.C. died due to toxic drugs in 2020, compared to 116 in 2019. This was a 119% increase in toxic drug deaths among First Nations people in B.C. between 2020 and 2019. In 2020, First Nations women experienced toxic drug death rates 9.9 times higher than non-First Nations women. This means that last year, First Nations people in B.C. died due to toxic drugs at 5.3 times the rate of other B.C. residents.

Why is this happening?

First Nations people are disproportionately represented in toxic drug deaths because of:

- insufficient access to culturally safe mental health and addiction treatment
- systemic racism being a barrier to accessing health care
- intergenerational trauma caused by colonial laws, policies and practices


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7 Ibid. Note: 2021 B.C. Coroners data will change as further toxicology results are received.
that identified the presence of methamphetamine also increased, from 14% in 2012 to 43% in 2020, and the proportion of completed investigations that identified opioids other than fentanyl and cocaine have steadily declined from 2012 to 2020; however, cocaine was still detected in 46% of drug toxicity deaths in 2020.11

In addition to high mortality rates, the drug toxicity crisis is leading to additional drug-related health and social impacts. These harms include the devastating impacts of grief and loss on family, friends and community. The continued number of deaths also has negative impacts on the mental health of front-line workers and health professionals who see the impacts of illicit drug toxicity deaths and events daily. As well, anoxic brain injuries resulting from non-fatal illicit drug toxicity events, have contributed to morbidity and mortality, reduced individual quality of life, and resulted in significant costs to the health care system.12 The total health costs of opioid use in B.C. are estimated to exceed $90 million annually and the economic costs of lost productivity associated with opioid use are close to $1 billion annually.13

To respond to the public health emergency, the Province has implemented a comprehensive package of essential health sector interventions and strategies to reduce drug toxicity deaths and drug-related harms.14 This package includes increasing access to naloxone; expanding overdose prevention services (including prescribed safer supply); increasing proactive follow-up support for people at high risk of drug toxicity events and deaths; expanding access to evidence-informed OUD treatments like opioid agonist treatment (OAT); and providing other comprehensive

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13 Canadian Substance Use Costs and Harms, 2017. Available at: https://csuch.ca/
treatment and recovery services. The combined impact of these services averted close to 6,000 drug toxicity death events between 2015 and 2019.\textsuperscript{15}

As of 2020, it is estimated that over 100,000 people in B.C. have OUD, but only 76,791 people in B.C. have been diagnosed with OUD.\textsuperscript{16} This does not include individuals who are using opioids intermittently and do not meet the criteria for OUD. Oral OAT (primarily methadone, Suboxone and Kadian) is an evidence-based approach to OUD—and remains a critical tool for addressing the drug toxicity public health emergency.\textsuperscript{17}

Injectable opioid agonist treatment (IOAT - hydromorphone and diacetylmorphine) has also proven to be effective for those who prefer to inject or who have not found oral OAT beneficial. Switzerland has used supervised prescription diacetylmorphine (also known as heroin-assisted treatment – HAT) as a standard drug treatment since 1999. The prescription of diacetylmorphine has been demonstrated to be effective and cost-effective in Europe and Canada (specifically in Vancouver and Montreal).\textsuperscript{18}

Other program models provide lower barrier more flexible models and medications such as hydromorphone tablets.\textsuperscript{19} A recent qualitative study of these flexible programs in Vancouver, B.C., found that clients reported positive outcomes such as increased stabilization with access to a reliable source of opioids, although program barriers such as hours of operation and structural barriers such as poverty and lack of housing need to be addressed.\textsuperscript{20}

However, known limitations of OAT—including engagement and treatment retention for oral medications, and the high intensity regime of injectable OAT, which requires multiple trips to a clinic per day—can present barriers for some patients.\textsuperscript{21} This is indicated in OAT engagement rates; approximately 24,000 people in B.C. have recently been on any form of OAT, and only 10,292 individuals are retained in treatment for over 12 months.\textsuperscript{22} In addition, current evidence for the effectiveness of OAT was generated before the advent of fentanyl in the illicit drug supply. Emerging evidence also suggests that some individuals seek out fentanyl in


the drug supply because of tolerance to other opioids and/or preference for fentanyl.\textsuperscript{23} Compounding the limitations of these approaches is the reality that many people using the toxic drug supply do so intermittently and would not necessarily meet the criteria for OUD.

Despite these limitations, optimizing OAT and providing additional support with psychosocial treatment interventions as an evidence-based addiction treatment—including increasing OUD screening and diagnosis rates, providing more lower barrier access to OAT, and increasing OAT provider—capacity continue to be an important component of the comprehensive package of health sector interventions.

With respect to stimulants, drug checking services across B.C. continue to detect the unexpected presence of fentanyl in stimulant samples such as methamphetamine and cocaine, suggesting that individuals who use stimulants could benefit from separation from the toxic drug supply.\textsuperscript{24} In the published literature, available evidence is concentrated on the use of psychostimulants and other pharmacotherapies for the treatment of stimulant use disorder. As this research is focused on treatment, with the primary goal of increased abstinence and reduction in use, outcomes may not align with patient goals when stimulants are prescribed in a harm reduction setting. While further research is warranted to determine the use of psychostimulants for the treatment of stimulant use disorders, initial research may help inform the direction of future research and initiatives for pharmaceutical-grade stimulants.

## Purpose and Rationale

Given the limitations noted above, combined with the realities of current toxic drug markets and highly potent street fentanyl, there is an urgent need to make available other pharmaceutical grade medications to support individuals to disengage from the toxic drug supply.

This document outlines B.C.’s prescribed safer supply policy, which enables individuals to receive a range of medications through prescription to reduce the risk of drug toxicity poisonings and death due to reliance on the illicit drug supply. This policy fulfills a commitment to developing a prescribed safer supply policy – also known as pharmaceutical alternatives – outlined in the Ministry of Mental Health and Addictions’ \textit{Pathway to Hope: a Roadmap for making mental health and addictions care better for people in British Columbia}\textsuperscript{25} and is reiterated in the Minister of Mental Health and Addictions 2020 \texttt{mandate} letter.\textsuperscript{26} Calls for prescribed safer supply have also been made by a range of institutions, organizations and health system leaders, including the First Nations Health Authority, the Canadian Association of Chiefs of Police, the Federal Government of Canada, the Chief Coroner of B.C., and the B.C. Provincial Health Officer.

This policy builds on B.C.’s experience with of a range of treatment and harm reduction options for the use of toxic street drugs including established oral, injectable, and tablet injectable opioid agonist treatment, to rapidly-developed flexible approaches including the \textit{Risk Mitigation in the Context of Dual Public Health}

Emergencies: Interim Clinical Guidance. This guidance, published in March 2020 by the B.C. Centre on Substance Use, is based on a recognition that extraordinary measures are needed to support people who use drugs to manage withdrawal symptoms in situations where people need to isolate or quarantine and to prevent the community spread of COVID-19 among a structurally vulnerable, often immune-compromised population. (Please see Appendix 6 for more information on initial descriptive findings from an evaluation of this measure).

This policy is intended as an enabling document to provide health authorities, programs and clinicians, researchers, regulatory colleges, professional associations, Indigenous partners, and people with lived and living experience with information on government’s broad policy orientation to prescribed safer supply. The key policy components are described in this document, including client eligibility criteria for medication coverage. The appendices outline service delivery attributes, provide more information on harm reduction, clinical resources and provincial evaluation and monitoring activities.

During the development of this policy, extensive consultations were held with health system partners and stakeholders. These consultations revealed significant reservations about the approach outlined in this document. Feedback highlighted concerns that substances like opioids are potentially dangerous and must be treated with care and with clear evidence and guidance to support prescribing. Health system partners have told us that prescribing a safer supply for primarily harm reduction purposes is not typically part of the training or orientation for most prescribers. We acknowledge these concerns and while there is not yet enough peer-reviewed scientific evidence to develop guidance, we are requiring that any prescribers who are working with medications like fentanyl products do so as part of health authority funded services (and federally funded SAFER programs) and adhere to locally or regionally developed medication protocols. As described in Appendix 4, we have also developed a path forward for turning regionally developed protocols into provincial level documents as expertise grows in this area. And we have also developed a robust approach to evaluation and monitoring that is meant to track the intended and unintended outcomes of prescribed safer supply.

Other partners have told us that prescriber-based models implemented in program settings are not nimble enough to respond to this crisis nor to the needs of people who use drugs. As noted in the executive summary, providing safer supply to people at risk of overdose—without the involvement of a prescriber—would require federal regulatory action under the Controlled Drugs and Substances Act. For this reason, the province is rolling out a prescriber-based model for safer supply. We also acknowledge that this approach has its limitations but is a beginning step that will help to meet some people’s needs while gathering the evidence needed to move forward.

The Province will continue to explore all potential options for the provision of safer supply.

This policy is intended to be a living document and will be updated as prescribing practices develop and balance of outcomes becomes clearer. As enabling policy, this document does not include clinical guidance or protocols.

More information on clinical supports can be found in Appendix 4.

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Development

This document was developed in partnership with the Ministry of Mental Health and Addictions and the Ministry of Health. The 2020 clinical guidance document, *Risk Mitigation in the Context of Dual Public Health Emergencies*, provided key input to this document. This policy directive was also informed by existing research literature on safer supply initiatives, early research findings from the Canadian Institute of Health Research funded evaluation of the Risk Mitigation Guidance, and extensive consultations with key stakeholders, and experts including Office of the Provincial Health Officer, Indigenous partners and organizations, people with lived and living experience, addiction medicine physicians and other clinicians, and regulatory colleges and professional associations.

Goals and Objectives

The goal of prescribed safer supply is to provide a public-health oriented, health system-level harm reduction intervention to separate people from the toxic drug supply by providing access to pharmaceutical grade alternatives. The objectives of this initiative include the following:

- Significantly decrease the use of illicit drugs and reduce illicit drug toxicity injuries and deaths.
- Improve equitable access to prescribed safer supply and link people to other health services and social supports.
- Ensure that prescribed safer supply is provided in a culturally safe manner that meets the needs of Indigenous peoples.
- Deliver services in a manner that respects the dignity and human rights of individuals who use drugs.
- Mitigate, as much as possible, the potential harms of prescribed safer supply for individuals and communities.

Policy Directives

Prescribed safer supply services will be delivered primarily in a phased approach, focused initially in health authority operated/funded programs and services (See Appendix 1). These services can also be provided in federally funded programs such as SAFER and other community-based initiatives delivered in programmatic settings with health authority oversight (programs directly operated or funded by health authorities).

Prescribers include physicians and nurse practitioners. Prescribers operating independently of health authorities can currently only prescribe safer supply according to publicly available clinical guidance from the B.C. Centre on Substance Use (See Appendix 4).

While there is limited clinical evidence for prescribed safer supply, government is supporting this approach because of the urgency of the drug toxicity public health emergency. This initiative will be accompanied by an evaluation plan that will gather evidence to determine if this approach meets its goals and assess the feasibility of developing provincial level clinical guidance to support broader uptake. Safer supply prescribers

must become part of the provincial evaluation and monitoring process as outlined in Appendix 5. (See Appendix 5 for more information on the approach to evaluation and monitoring).

Health authorities must support uptake of this policy through the development of programmatic or other clinical settings that can provide prescribed safer supply. These settings should enhance patient access and engagement related to prescribed safer supply. Settings may include a range of programs including injectable opioid agonist treatment (iOAT), tablet injectable opioid agonist treatment (TiOAT) clinics and services, overdose prevention services/supervised consumption services (OPS/SCS), health authority operated or funded health clinics and virtual care support programs (More details about service delivery are included in Appendix 1 including a more fulsome description of the phased implementation approach). To support prescribed safer supply and where provincial protocols do not exist, health authorities will be required to develop protocols, clinical workflows and other resources as needed, to support prescribing and meet clinical practice needs.

Clients will not be required to engage in OAT or other treatment modalities if they don’t want to, or are not ready. While many people who are prescribed these medications may also receive opioid agonist treatment (OAT), or have personal goals related to stabilization on OAT, it is critical to note that entering OAT or other treatment services is not a prerequisite for access to prescribed safer supply, nor should OAT be discontinued if individuals are provided with prescribed safer supply medications. Where other services align with client goals, prescribed safer supply programs can serve as entry points to the health system and other substance use services, including other harm reduction and treatment and recovery-oriented services. Services should be offered in as low-barrier and flexible a manner as possible. Services must also be delivered in the context of the guiding principles identified below and with reference to the service delivery framework outlined in Appendix 1.

Personnel working in a range of health care settings should support individuals to access prescribed safer supply programs. These health care settings could include overdose prevention and supervised consumption services, rapid access clinics, virtual care, emergency departments, hospital, and community pharmacies, Community Health Centres (CHCs), Urgent and Primary Care Centres (UPCCs), or First Nation-led Primary Care Centres.

Eligibility

People who use substances can be prescribed a range of pharmaceutical grade alternatives to the toxic drug supply. This policy is intended to support individuals with OUD or other substance use disorders (SUD) or individuals who are actively using illicit substances and are at risk of illicit drug toxicity death or other drug related harms due to the toxic drug supply. This may include individuals who use illicit substances on an intermittent basis and do not meet the criteria for a substance use disorder, but who are procuring and using illicit drugs and who are at risk of illicit drug toxicity death.

Screening for eligibility should be aligned with current regional or provincial guidance on assessment related to substance use. Substance use treatment, or other health and social services should be offered where appropriate and when aligned with client goals. While prescribing based on the criteria above is encouraged, it is ultimately up to each clinician to determine whether they will prescribe at all.
Medications

Initial implementation of this policy will focus on ensuring access to a priority list of opioid medications. A process for supporting the use of stimulants beyond those already prescribed according to existing guidance will be developed at a later date. More information on the phased approach to implementation is available in Appendix 1.

Medication Coverage

Prescribed safer supply medications and the pharmacy services related to providing these prescription drugs will be covered through Pharmacare. Prescribed safer supply medications and the pharmacy services related to providing these prescription drugs will be covered through Pharmacare for eligible B.C. residents according to the general coverage policies and plan(s) that apply to PharmaCare patients. Some medications must be accessed through Special Authority and a description of procedures for accessing coverage is included in Appendix 3.

Guiding Principles

Implementation and provision of prescribed safer supply should be based on the following guiding principles and aim to integrate the service delivery attributes as outlined in Appendix 1. These principles have been adapted from the guiding principles in Pathway to Hope: A Roadmap for Mental Health and Addictions Care Better for people in British Columbia, as well as at the principles set out by B.C.’s Provincial Health Officer for safer supply programs. Other input includes Health Canada’s Substance Use and Addictions Program, the Harm Reduction Services program at the BC Centre for Disease Control (BCCDC), and from a range of other relevant sources including an ethical analysis of prescribed safer supply conducted by Dr. Eike Kluge.

Harm Reduction Oriented

Harm reduction refers to policies, programs and practices that aim to minimize negative health, social and legal impacts associated with drug use, drug policies and drug laws. Harm reduction is grounded in justice and human rights – it focuses on positive change and on working with people without judgement, coercion, discrimination or requiring that they stop using drugs as a precondition of support.

Informed by Lived and Living Experience

Engaging people with lived and living experience of drug use in the design, delivery, evaluation and staffing of programs and services is a core principle of harm reduction and a best practice for harm reduction programs. Involvement of people with lived and living experience in the design and delivery of prescribed safer supply is highly recommended.

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30 Please see: Health Canada (2019). Substance Use and Addictions Program – Call for proposals -guidelines for applicants – July 2019. The program principles outlined in this call for proposals were key inputs to the development of the BC Prescribed Safer Supply policy.

31 Kluge, Eike. (2020). Alternatives to the toxic drug supply: an ethical analysis. Available upon request to oerc@gov.bc.ca


**Health Equity**

Health equity exists when all people can experience optimal health and well-being regardless of race, ethnicity, religion, gender/sex, age, socioeconomic status, ability, sexual orientation, or other social factors and systems. The pursuit of health equity seeks to reduce the excess burden of ill health among socially and economically disadvantaged populations.\(^{34}\)

Achieving equity requires addressing systemic barriers associated with these social and economic factors.\(^{35}\) As much as resources and system capacity allow, programs and services must ensure equitable access including for those living in rural and remote areas. Where appropriate, access to and reach of prescribed safer supply programs can be supported by virtual care, mobile care, and outreach.

**Cultural Safety and Humility**

Services and supports must be culturally safe, provided with humility, and be free from stigma and discrimination. Culturally safe care is based on respect and recognizes and strives to combat the systemic racism inherent in the health care system. Cultural humility involves developing and maintaining respectful relationships based on mutual trust by reflecting on personal and systemic biases. Cultural safety and humility can contribute to the creation of environments free of racism and discrimination, where people feel safe seeking out and receiving health care.\(^{36}\)

**Gender Based Analysis+ Lens**

There is clear evidence that intersecting biological, social, economic and cultural factors shape people’s experiences of substance use (e.g., sex, gender, age, race, ethnicity, indigeneity, ability, rurality, socioeconomic status, values, attitudes, perceptions, behaviours). These factors can also shape how services respond to people’s needs in terms of access and barriers. Data, both quantitative and qualitative, used to inform planning for this initiative should be disaggregated by factors such as sex and gender at all levels. This

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can help inform better design, delivery, and implementation of services targeted to meet the specific needs of unique populations.37

**Focus on Patient and Public Safety**

Programs and services must ensure there is sufficient monitoring for adverse events and unintended consequences, and the system must act quickly to reduce these harms.

Public health actions should always consider risks as well as benefits. Prescribed safer supply as a public health measure is an emergent and innovative prescribing practice, and the precautionary principle outlines that, when developing novel public health approaches with limited supporting evidence, both foreseeable and unintended negative consequences are inherent risks. To account for the precautionary principle, prescribed safer supply initiatives should balance the need to reduce harms caused by the toxic drug supply with other potential risks to client and public safety.

**Informed Consent**

While prescribers can provide guidance on an individual’s health status in alignment with individualized health goals, patients have a legal and ethical right to autonomous decision making, and to limit the extent of the relationship with a health care provider based on their self-identified needs (the doctrine of informed consent38). Informed consent means that individuals receive the necessary information, have the capacity to understand the information and are able to make decisions free of coercion. Access to prescribed safer supply should be based on informed consent, and programs should use a valid informed consent process, which includes documentation in the patients’ medication record. Individuals should also provide informed consent for participation in evaluation activities. Representation agreements or substitute decision makers should be consulted when patients are unable to make decisions. Programs may also want to consider including patient agreements in the informed consent process. These agreements describe the rights and responsibilities of patients, time commitments, any rules of the program and the roles and responsibilities of program/team members. See Appendix 1 for more information.

**Evaluation and Monitoring**

Evaluation is a critical part of this initiative; it will be fundamental to determining the impacts of this policy and the clinical practices it enables, and to identify, understand, and prevent or mitigate any potential risks or harms to individual clients, as well as at a population level. The implementation of prescribed safer supply will be accompanied by an evaluation and monitoring plan that will assess both anticipated and unanticipated individual and population health impacts.

The Ministries of Health and Mental Health and Addictions, in collaboration with the Office of the Provincial Health Officer and key research and health system partners, will ensure ongoing monitoring and evaluation of access to prescribed safer supply including tracking (a) intended and unintended impacts (benefits and harms), (b) impact on health outcomes, and, (c) challenges and benefits of implementation including consideration for the suitability of programs as well as their effectiveness at increasing client access and


program reach. Information generated by evaluation and monitoring will enable both prescribers and the health system to act quickly to reduce any adverse unintended consequences or harms and also provide feedback to decision-makers to support quality improvement efforts, including identifying administrative or other barriers to implementation and suggestions for improving service delivery.

Programs and services offering prescribed safer supply will be sites for generating evidence about the use of these medications, for both clients and the community at large.

Health authority programs and services delivering prescribed safer supply will be required to participate in this evaluation process and will be asked to collect data according to the evaluation and monitoring framework. (Please see Appendix 5 for more information about the monitoring and evaluation framework).
Appendices
Appendix 1: Service Delivery Framework

Overview

This Service Delivery Framework will assist Health Authorities (HAs) and other service delivery partners in implementing and designing prescribed safer supply in established and new programmatic settings. This document outlines attributes to support flexible, accessible operational program structures that should ideally, and where possible, be situated within a range of substance use and other services.

This Service Delivery Framework will be updated regularly to reflect changes in evidence, practice, policy, and service delivery models. As the implementation of prescribed safer supply occurs it is anticipated that additional service delivery models and considerations will emerge and be added to this document.

As this initiative is further developed, activities such as training and professional development, knowledge exchange, support tools and other resources will be developed to support implementation.

Phased Approach to Implementation

The prescribed safer supply policy will be implemented in B.C. in a phased approach as described below:

<table>
<thead>
<tr>
<th>Phase One</th>
<th>Phase Two</th>
</tr>
</thead>
<tbody>
<tr>
<td>The first phase will focus on supporting existing health authority and Health Canada funded programs and services (e.g. injectable opioid agonist iOAT, TiOAT, SAFER, health clinics, etc.) to offer opioids as alternatives to the toxic drug supply. This phase will also focus on expanding the access and reach of prescribed safer supply through new and/or expanded program-based settings with health authority oversight.</td>
<td>Based on evidence generated in Phase One, the second phase will focus on assessing the feasibility of developing provincial clinical guidance to support broader access through a range of settings and individual prescribers and consider the inclusion of additional medications.</td>
</tr>
</tbody>
</table>

Implementation is currently focused on Phase One as described above.

While this Framework sets broad provincial direction and considerations for service delivery attributes, local flexibility is anticipated in the implementation of prescribed safer supply to integrate, innovate, and build on existing service delivery models (Phase 1).

Provincial clinical guidance (Phase 2) is out of the scope for this document, but it is anticipated that protocols generated during the implementation of regional prescribed safer supply programs will enable and inform any future provincial guidance (see Appendix 4 for more information).

Programs and services offering prescribed safer supply should ensure that the availability of these services is communicated widely.
Implementation of prescribed safer supply in programmatic settings should be based on the guiding principles described in the main body of this document and aim to integrate the service delivery attributes outlined below (additional details on clinical supports are included in Appendix 4).

**Service Delivery Attributes**

The following is a list of service delivery attributes that can inform the design of programs and the development of program policies and processes.

**Patient and Peer Engagement**

Health authorities should include the voices of people with lived and living experience (PWLLE) in the planning and implementation of prescribed safer supply programs and services. It is particularly important to ensure that PWLLE have opportunities to contribute to and review program details and requirements such as client/provider agreements and protocols for discharging clients because of suspected diversion/displacement of substances.

**Regional Expertise and Protocols**

Prescribed safer supply programs will be supported by regionally developed clinical protocols, although these will be linked and aligned as closely as possible for consistency of evaluation. It is expected that these regional protocols will be informed by local expertise, and that they will in turn support and inform the development of overarching provincial clinical protocols. Please see Appendix 4 for more information.

**Monitoring and Evaluation**

Robust provincial and regional monitoring and evaluation of prescribed safer supply programs, prescribing and service delivery models will support client safety, generate evidence regarding the efficacy of prescribed safer supply, and support ongoing service quality improvements. Regional monitoring and evaluation activities will be linked to the overarching provincial prescribed safer supply monitoring and evaluation process. Patients should be informed of ongoing evaluation and provide consent for their participation in evaluation activities. Please see Appendix 5 for more information.

**Multiple Access Points**

A range of health services—including overdose prevention and supervised consumption services, outreach workers, mental health and substance use teams, rapid access clinics, virtual care, emergency departments, hospital, and community pharmacies, Community Health Centres (CHCs), Urgent and Primary Care Centres (UPCCs), Patient Medical Homes (PMHs), and First Nations-led Primary Care Centres—may serve as access points for clients to be linked to prescribers of safer supply. Local service planning considerations may help to identify which settings are most suitable for particular contexts or client populations.

**Connection to Other Health and Social Services**

Pharmaceutical alternative programs should serve as a low-barrier access points to the health system and provide close linkages to other health services.

Where possible, clients should also be offered access to the full range of substance use services, including comprehensive primary care and psychosocial supports, such as counselling, OAT and other substance use treatment and recovery services, harm reduction services, mental health supports, culturally-safe care (including spiritual and cultural connections), and referral to services addressing social determinants of
health. Pharmaceutical alternative programs should also support connection to Indigenous land-based healing, traditional practices and cultural supports.

Health care practitioners should ensure clients are aware of the range of available substance use treatment services and continuously assess clients for readiness to access additional programs for substance use disorders. Movement between services should be seamless and client-centered, with service navigation strategies in place to help people transition between services and supports as needed. Referral to other services must be guided by the wishes and needs of clients.

Programs and services should ensure continuity of care, including developing protocols and ensuring regular follow-up, in the case of hospitalization or incarceration, and potential transitions in treatment as client health and socio-economic circumstances evolve. Considerations should be given to developing clinical protocols to support transitions from acute to/from community and from mental health and substance use bed-based care to/from community services, where appropriate.

**Interdisciplinary Team-Based Care**

Where possible services should be delivered in a team-based, integrated manner. This could include physicians, nurse practitioners, registered nurses, registered psychiatric nurses, licensed practical nurses, peer navigators and Indigenous peer navigators, social workers, outreach workers and community support workers, Elders and Traditional Healers, specialists, pharmacists and other health care professionals as appropriate.

Given the range of settings in which prescribed safer supply could be provided, it will not always be possible for prescribers to work in team-based settings. In these cases, programs providing prescribed safer supply should be familiar with additional community resources and supports that address health and harm reduction needs and well as the social determinants of health in these settings, but additional client and community safety precautions may be warranted.

**Lower-Threshold Programs**

As with other harm reduction services, where possible, prescribed safer supply should be delivered in as low threshold (or low barrier) a manner as possible to encourage access and engagement. Programs should be tailored to meet the needs of the client. Low threshold services can be defined as services where: people who use drugs are the key target population; abstinence is not required; and barriers to access (e.g. limited hours of operation) are reduced as much as possible.  

**Embedded Harm Reduction**

Upon receiving prescriptions for prescribed safer supply medications, clients should be provided with harm reduction information, education, and supplies suitable to their intended route of administration, such as filters, alcohol swabs, sterile syringes, sterile smoking supplies, and information on how to use them safely. Peer support workers could be involved in this important service. More information is available in Appendix 2.

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Informed Consent and Patient Agreements

As described in the principles section of this document, the patient should provide informed consent before being prescribed any medication. Programs may also want to consider including components of patient agreements in the informed consent process. These agreements should be used in a way that supports both patient-centred care and joint decision-making, describe the rights and responsibilities of patients, time commitments, any rules of the program and the roles and responsibilities of program/team members.⁴⁰

Rural and Remote Considerations

There are unique barriers to both accessing and providing substance use care in rural and remote areas. Rural and remote communities may have limited health services (e.g. clinics or pharmacies), requiring patients to travel to neighbouring communities to access substance use care. Recruiting and retaining adequate health and human resources in rural settings is often challenging. This has implications for policies, programs or services that may require increased or new health and human resources. Additionally, rural residents tend to have comparatively poorer health outcomes and socioeconomic status compared to their urban counterparts. A strong sense of place also characterizes rural B.C., and positive attributes associated with rural settings include fulsomely developed generalist care models. The nature of rural service delivery requires partnerships across multiple sectors, innovation and creativity to meet the needs of communities and individuals.⁴¹

One strategy to mitigate potential health care access issues is the use of virtual care/telemedicine, which enables family physicians, nurse practitioners, addiction specialists and pharmacists to consult with patients from a distance; however, telemedicine supports may be limited in some communities, with unique access and limited reach. Other strategies include mobile outreach services linked to service hubs; adaptation in prescribing and dispensing practices; and medication and formulation changes or referral to online psychosocial supports.

For effective rural and remote service delivery, it will be important to work closely with available community organizations and substance use outreach teams, including local First Nations health services, that can assist with engaging and retaining clients, supporting seamless transitions between services, and providing wrap-around care. Other service providers can also assist with providing access to overdose prevention services (including episodic services), harm reduction supplies, supporting delivery of medication and facilitating access to other supports and services, depending on capacity.


Appendix 2: Prescribed Safer Supply and Harm Reduction

Harm reduction is a set of principles, practices and approaches to care that aims to minimize negative health, social, and legal impacts associated with substance use, and is an integral component of the substance use system of care. Harm reduction is grounded in evidence, justice, and human rights, and respecting, and representing the rights of people to self-determination and equitable access to the services and supports that protect their health.42

In relation to substance use care, harm reduction is a pragmatic response that focuses on keeping people safe and minimizing death, disease and injury while recognizing that a person may continue to use substances. Harm reduction-oriented services do not require a person to stop using substances as a precondition of care and support, and respect human rights and dignity by adhering to basic ethical principles.43 This is a person-centered approach which recognizes that, for people who use substances, access to health care services is often undermined by and defined by experiences of discrimination and stigma—harm reduction seeks to address negative health outcomes related to substance use, engage people who use drugs in the health system, and reduce stigma by delivering care with respect, and without judgement.

In the context of a toxic drug supply and an ongoing public health emergency related to drug toxicity, prescribed safer supply is a harm reduction-oriented public health intervention, and part of a larger set of substance use services aimed at reducing overdose events and deaths. It acknowledges the extreme risk of harm related to accessing the toxic drug supply, and represents a health promotion approach for people who use drugs by providing access to a regulated, safer supply of controlled medications, and facilitates low-barrier access to the health system and a broader range of health supports and services.

Harm Reduction in British Columbia: Overdose Prevention, Naloxone and Prescribed Safer Supply

The Province of British Columbia is committed to providing access to harm reduction services and programs, including supervised consumption, overdose prevention, and sterile supply distribution, as key components of the substance use system of care.

The province also aims to ensure harm reduction principles extend to community engagement and service delivery that can be applied in any community, health, or social services setting.

Harm reduction is often viewed as a set of specific, distinct services and programs, including supervised consumption sites and sterile supply distribution. However, harm reduction approaches, activities and principles can also be applied to and embedded in multiple settings, including those focused on treatment of substance use disorders. For example, opioid agonist treatment prescribers can provide individuals with information on harm reduction including avoiding using illicit drug alone, carrying take-home naloxone kits and using overdose prevention services.44

42 Adapted from BCCDC. (Forthcoming) Updated B.C. Harm Reduction Strategies and Services Policy
43 Ibid.
Indigenous peoples have also expanded on conventional conceptions of harm reduction by recognizing that connections with community, culture and the land also serve as harm reduction strategies for Indigenous people who use substances. The First Nations Health Authority describes Indigenous Harm Reduction as a process of integrating cultural knowledge and values into the strategies and services associated with the work of harm reduction. Indigenous knowledge systems are strongly connected to spirituality, holism, and the natural environment.

The FNHA vision for harm reduction includes:

- Meeting individuals, families and communities where they are at and working alongside them as they travel along their health and wellness journeys
- Promoting a First Nations, strengths-based, people-centred, destigmatizing harm reduction approach based on dignity, self-determination, empathy, love, compassion, lateral kindness, culture and traditions and relationships
- Facilitating, promoting and sustaining the availability of culturally safe and trauma- and violence-informed harm reduction strategies, practices and services, in the context of a continuum of mental health and wellness programs and services; and
- Recognizing the self-determination of individuals, communities and Nations by supporting them to develop or access the harm reduction strategies, practices and services that work for them.

Pharmaceutical grade alternatives to illicit drugs are provided as part of the public health overdose emergency response and are supported by an ethical analysis and framework based on four basic ethical principles (principles of autonomy; equality; beneficence; and non-maleficence). This ethical analysis articulates how prescribed safer supply can be safely and effectively delivered within a public health and harm reduction-oriented approach to substance use care.

For prescribed safer supply programs to be ethically defensible, it is important that harm reduction approaches are embedded in programs providing prescribed safer supply medications. Also, while a primary goal of this policy is to reduce peoples’ reliance on the toxic drug supply, it is recognized that clients receiving prescribed safer supply may continue to use illicit drugs. This means that prescribed safer supply programs and prescribers should provide access, information and education related to Take-Home Naloxone, harm reduction supplies, advice for safer drug use, drug checking services, overdose prevention/supervised consumption sites, and other relevant harm reduction services and programs.

**Harm Reduction Supports**

**Take Home Naloxone**

Naloxone is a medication that can be used to reverse the effects of an opioid overdose. Take-Home Naloxone is associated with significant decreases in mortality in individuals who use illicit opioids and should be

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48 Kluge, E. (2020). Alternatives to the Toxic Drug Supply: An Ethical Analysis. Available upon request to oerc@gov.bc.ca
considered a standard of care for all individuals who use opioids. The BC Centre for Disease Control Take Home Naloxone (THN) program provides THN kits at no cost to the individual. More information can be found at BC Centre for Disease Control’s program, Toward the Heart. The First Nations Health Authority also provides nasal spray naloxone to First Nations people, organizations and communities.

**Overdose Prevention/Supervised Consumption Services**
Overdose prevention services (OPS) and supervised consumption sites (SCS) provide places to use drugs witnessed by a person trained to respond should an overdose occur, including peers and other health professionals.

**Harm Reduction Supplies**
The BC Centre for Disease Control manages the B.C. harm reduction supplies program. Sites authorized by regional health authorities can order and distribute sterile syringes, pipes, filters, and other supplies for safer substance use. More information can be found at Toward the Heart.

**Drug Checking**
Drug checking services perform chemical analysis of a sample substance’s composition. Drug checking is useful for identifying some unknown components of an illicit or unidentified drug, including the presence of adulterants and contaminants, including fentanyl. If illicit drug use is ongoing, health care providers should recommend that clients access drug checking services if available. (Drug checking services in B.C. vary by regional health authority).

**LifeGuard App**
LifeGuard is a mobile app designed as an overdose prevention service for people who use drugs alone and that can be used to prevent drug toxicity deaths. The LifeGuard app is based on a timed response function. A person activates the app when they intend to use drugs, which begins a timer. After 50 seconds, an alarm will sound, which the person can stop by using the app. If the person has not stopped the alarm within 75 seconds, the app automatically connects to emergency services, indicating a potential drug toxicity event.49

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Appendix 3: Medications and Coverage

Medications

A range of pharmaceutical grade substances have been approved for public funding as PharmaCare covered medications. Available medications will vary by setting based on clinical and operational factors (e.g. fentanyl patches, fentanyl buccal tablets, injectable hydromorphone, and tablet hydromorphone and others as determined by programs). Individual programs will choose which medications they will provide. All medications must be supported by a clinical protocol or by existing guidance. Although initial implementation will focus on opioids, a range of stimulants have also been approved for coverage. A process for supporting the use of stimulants, beyond those medications already prescribed according to existing guidance, will be developed at a later date.

Medication Coverage

Pharmaceutical alternative medications will be covered either as regular PharmaCare benefits or as Limited Coverage drugs available via the Special Authority process.

Limited Coverage Criteria

Limited coverage drugs are medications not generally considered to be the standard first treatment of choice or are medications for which more cost-effective alternatives exist. When circumstances warrant, PharmaCare will provide access to limited coverage drugs for patients who meet established criteria. To receive coverage, a prescriber, on behalf of their patient, must submit a Special Authority request to the Ministry of Health. Specific criteria for Limited Coverage of individual pharmaceutical alternative medications is available through the Special Authority Drug list (e.g. Fentanyl Patches).

Plan G Coverage

Registration for PharmaCare Plan G must be initiated by a prescriber using the Psychiatric Medication Coverage: Application for Pharmacare Plan G (PDF) form. Plan G coverage cannot be provided retroactively. If a client requires coverage under Plan G, this must be in place before a prescription is filled.

50 See: British Columbia. Special Authority. Available at: https://www2.gov.bc.ca/gov/content/health/practitioner-professional-resources/pharmacare/prescribers/special-authority#_Special_Authority_drug
Appendix 4: Considerations for Development of Clinical Support Resources and Protocols

The provision of prescribed safer supply is an emerging practice that builds on evidence and expertise generated by B.C.’s experience with oral, injectable, and tablet injectable opioid agonist treatment, as well as already existing safer supply prescribing and the Risk Mitigation in the Context of Dual Public Health Emergencies: Interim Clinical Guidance. To support prescribed safer supply and where provincial protocols do not exist, health authorities will be required to develop and/or endorse protocols, and develop clinical workflows and other resources as needed, to support prescribing and enable local solutions to meet clinical practice needs.

Individuals can access a range of medications through prescribers working in health authority-led and/or funded programs (and the federally funded safer supply programs), supported by medication-specific protocols and clinical expertise. These programmatic settings must provide clinical supervision and must be linked to both provincial and regional evaluation and monitoring. Regional prescribing will contribute to an evidence-gathering process to inform the development of provincial protocols, as well as ongoing policy refinements and service quality improvement (See Appendix 5: Evaluation and Monitoring).

Provincial Supports for Regional Protocol Development

Health authorities are supported by the Province to develop regional protocols. As outlined in Appendix 1, the Ministry of Mental Health and Addictions and the Ministry of Health endorse a phased approach to implementation with an initial focus on adding medications to existing or new programs and services funded or run by health authorities (and federally funded safer supply programs).

Significant clinical expertise and innovative practice exists in B.C. that can be leveraged for the development of regional protocols. The BC Centre on Substance Use will be leading the development of provincial protocols and guidance and may also provide expert advice to support the development of regional protocols.

Health authorities can leverage established processes for developing protocols. Best practice documents for guidance development may also help inform approaches to protocol development. 51,52,53

Health authority protocol development processes will be further supported by provincial mechanisms (e.g. working groups, community of practice forums, linkage to the provincial evaluation) that promote information sharing, adaptation of locally developed protocols, connection to clinical experts, and lessons learned.

Considerations for Regional Protocols

Although there is a recognized need to tailor protocols to meet specific program needs and community resources, health authorities should consider the following in any medication-specific protocols developed to support this work.

- Inclusion of principles of care, commitments to cultural safety and engaging people with lived and living experience in protocols development (refer to Guiding Principles in the main body of this document and to the Service Delivery Attributes outlined in Appendix 1)
- Eligibility criteria
- Screening and initial assessment including ongoing assessment intervals and indicators to determine benefits and potential adverse outcomes
- Enrollment procedures and consent to participating in evaluation
- Process to obtain and document informed consent (including patient agreements or equivalent mechanisms to establish a joint understanding of risks, safety, concerns, expectations and processes.)
- Medication initiation, titration, and transition to other medications or treatments
- Guidance for assessing benefit and harm
- Considerations and criteria for when observed dosing is recommended
- Tapering or transitioning if patient is not taking or benefiting from use of prescribed safer supply medication
- Patient-centered procedures and processes to prevent displacement (i.e. the receipt and use of medications by individuals who were not prescribed them) for when displacement is suspected or confirmed.
  - Clients should not be automatically asked to leave a program if displacement is suspected or confirmed, rather medication options, dosage, harm reduction education, and treatment agreements should be reviewed and discussed with patients
- Documentation procedures including chart notation and processes for how information is entered into PharmaNet
- Considerations for pharmacy communication
- Considerations for linkage and alignment to the provincial evaluation
- Supporting documents including:
  - Policies for medication administration, dispensation and documentation
  - Policies related to medication security and storage if medications are kept on site
  - Pathways for connection and/or transition to additional supports and care (e.g. primary care, referrals to psychosocial supports, etc.)
  - Clinical support tools (e.g. algorithms, decision support tools, medication guides, patient agreements, and patient information sheets)
  - Documents that support clinical workflows for describing roles and responsibilities of prescribers, nurses, peer workers, and other members of the team, as well as emergency response pathways
Prescribing Independently of Programmatic Settings

While health authority-led programmatic settings will be offering a wider range of novel medications, such as fentanyl products, prescribing of other medications, such as oral opioids, under the Risk Mitigation in the Context of Dual Public Health Emergencies: Interim Clinical Guidance, is encouraged and supported to continue where clinically appropriate. In addition, prescribers operating independently of health authorities may prescribe pharmaceutical alternatives to the illicit drug supply, outside of the context of COVID-19 according to the BC Centre on Substance Use resources that support the provision of medications to reduce harms associated with illicit opioid use. These resources include the BCCSU’s soon to be released Opioid Use Disorder Practice Update and the Stimulant Use Disorder Practice Update. Independent prescribers who would like to offer medications not described in the BCCSU resources, are encouraged to connect with their regional health authorities to explore opportunities to connect to program settings.

Safer supply prescribers and programs must become part of the provincial evaluation. For independent prescribers operating outside of health authority-led programmatic settings, this will occur through two avenues:

1. All safer supply prescribing will be captured in the health administrative data from PharmaNet.
   - Dispensation of prescribed safer supply to individuals at pharmacies or clinic settings will be recorded in PharmaNet, which will be used to support provincial evaluation and monitoring efforts.
   - Prescribers must indicate on the prescription that the drug is prescribed safer supply, so that pharmacists or other practitioners are able to provide appropriate and informed care and record the prescription in different information systems. More information will be forthcoming on how to correctly record prescriptions in appropriate data systems.

2. As the provincial evaluation is initiated, prescribers will be invited to engage in additional types of evaluation as appropriate (refer to Appendix 5).

Clinical Resources

The following clinical resources and consensus guiding documents are available for clinicians supporting people who use drugs. Many protocol development initiatives are underway in the province and this section will be updated as new resources are developed:

- BCCSU Resources:
  - The BCCSU provides a variety of up-to-date and evidence-based and evidence-informed guidance documents, clinical guidelines, practice updates, practice support tools and bulletins. Refer to [https://www.bccsu.ca/opioid-use-disorder/](https://www.bccsu.ca/opioid-use-disorder/) for documents that may be relevant for the provision of OUD care and the provision of medications to reduce harms associated with illicit opioid use.
  - The BCCSU 24/7 Addiction Medicine Clinician Support Line is available to support physicians, nurse practitioners, nurses, and pharmacists who are engaged in prescribed safer supply. Refer to [https://www.bccsu.ca/24-7/](https://www.bccsu.ca/24-7/) (778-945-7619).

- Harm reduction resources can be found in Appendix 2, and on the BC Centre for Disease Control website: [http://www.bccdc.ca/health-professionals/clinical-resources/harm-reduction](http://www.bccdc.ca/health-professionals/clinical-resources/harm-reduction).
• The federally funded Victoria SAFER Initiative run by AVI Health & Community Services has produced a practice bulletin to provide practical guidance to inform planning, development and implementation of safer supply programs. This bulletin can be obtained by contacting AVI or through this site: https://www.colabbc.ca/s/bulletin-safer.pdf


Development of Provincial Protocols and Guidance

It is anticipated that the regional medication-specific protocols developed, evaluated, and refined during Phase 1 implementation of the prescribed safer supply policy will inform the development of provincial medication-specific protocols and provincial clinical guidance.

A core function of the BCCSU is to develop and disseminate provincial evidence-based clinical practice guidelines and protocols focused on substance use disorders, health system interventions, and key populations. The BCCSU will lead the development of provincial protocols and guidance according to internationally-recognized guidance development processes.
Appendix 5: Evaluation and Monitoring Framework

Prescribed safer supply will be subject to both evaluation and monitoring data collection activities. Monitoring activities include the systematic collection, analysis and dissemination of near real-time data to describe service utilization and assess certain outcomes. Monitoring will be a continuous process to provide information and feedback to programs and other stakeholders for policy and program improvement, and to assess policy impacts and effects. Data from monitoring activities will also be used to inform the evaluation. These activities will be undertaken by the BCCDC and will be facilitated by the Centre’s access to real-time health system data. A detailed monitoring plan will be developed with BCCDC.

Evaluation will draw on the data and information generated by monitoring activities, as well as primary data collection activities, to assess and analyze policy outcomes and effects, determine the extent to which prescribed safer supply is achieving its stated goals and objectives, and the extent to which results can be attributed to this policy/intervention. Evaluators will be sought through an RFP process and will be expected to work closely with BCCDC personnel. One of the first deliverables for the evaluators will be a detailed evaluation plan for review by the Monitoring and Evaluation Project Advisory Group. Evaluators will be expected to work closely with people who use drugs, clinicians and other service providers, and regional and provincial policy makers to ensure that the evaluation will meet their needs.

Purpose and Scope of Monitoring and Evaluation

The evaluation will focus on Phase One of implementation as described in Appendix 1. The purposes of monitoring and evaluation are to:

1. Determine the effectiveness of prescribed safer supply in meeting its objectives
2. Inform program and policy adjustments, improvements, and refinements
3. Identify barriers and facilitators to program access and uptake
4. Identify and assess potential unintended consequences of prescribed safer supply policy
5. Reinforce an evidence-based and data-driven response to the illicit drug toxicity crisis

This framework supports consistent data collection by both health authorities and third-party evaluation experts and researchers and enables monitoring and evaluation activities at both the provincial and regional levels. At the provincial level, monitoring activities will use administrative data coupled with advanced analytics to describe and analyze health service utilization and population-level outcomes.

Evaluation activities at the provincial level will focus on building an overall picture of the impacts of this policy by pulling together monitoring data with primary data collection to better understand specific program implementation and individual clinical outcomes. Provincial monitoring and evaluation activities will also support consistent approaches to regional health authority driven evaluation and quality improvement work drawing on the analysis of anonymized patient specific records.

Both monitoring and evaluation will be guided by a common set of provincial measures and indicators to ensure the reliable capture and measurement of outputs and outcomes. Monitoring and evaluation activities are intended to capture both program-level and provincial-level outputs, impacts and outcomes across the following dimensions over the course of short (1-12 months), medium (1-3 years), and longer (3+ years) time periods: service utilization, program outputs, clinical outcomes, population-level impacts and outcomes, and
mapping implementation to assess and capture key success factors, barriers and facilitators, as well as unintended consequences.

The evaluation must also include data collection strategies to identify and measure potential/observed positive or negative unintended outcomes, including for example: community impacts (e.g., changes in drug-related crime), changes in local drug economies/markets, patient safety, displacement/sharing, increase in prescribed safer supply medications available/being sold in communities, changes in OUD diagnoses, or impact on existing harm reduction strategies such as OAT uptake and retention.

Displacement or sharing of medications is of particular interest, and the successful evaluation applicant will be required to outline specific strategies to capture both multiple perspectives (clients, prescribers, others) on displacement/sharing of prescribed medications and the complexity of reasons for sharing/displacement (e.g., the intersection of diversion with structural vulnerability, reasons for displacement/sharing, involvement of organized crime).

More details about possible approaches to evaluation and monitoring are contained in the full evaluation and monitoring framework available by request to oerc@gov.bc.ca.
Appendix 6: Evaluation of the Risk Mitigation in the Context of Dual Public Health Emergencies

In 2020, a group of researchers in B.C. was awarded a Canadian Institutes of Health Research grant to conduct a mixed methods evaluation of risk mitigation (RMG) measures to address the dual public health crises of COVID-19 and overdose. This project is led by investigators from the BC Centre for Disease Control (BCCDC) (Dr. Amanda Slaunwhite), Simon Fraser University (SFU) (Dr. Bohdan Nosyk, Dr. Natt Hongdilokkul), and Canadian Institute for Substance Use Research (CISUR) at University of Victoria (UVIC) (Dr. Bernie Pauly, Dr. Karen Urbanoski). This project uses mixed methods (qualitative and quantitative) to provide a comprehensive assessment of the impact of the RMG on overdose and COVID-19 transmission (primary outcomes) and other secondary outcomes, among people at risk of overdose.

Initial evaluations of the implementation of the RMG have revealed several key lessons. While the full findings from this evaluation are still forthcoming, descriptive administrative data using PharmaNet and other Ministry of Health data available through the B.C. COVID-19 Cohort (BCC19C), estimates that 6,498 people were dispensed RMG prescriptions from March 27, 2020 to February 28, 2021. Opioid medications were dispensed to 3,771 persons (58.0%), stimulant medications were dispensed to 1,220 persons (18.8%), alcohol withdrawal management medications were dispensed to 1,431 (22.0%) persons and benzodiazepines were dispensed to 784 persons (12.1%). Overall, there were 179,349 unique medication dispensations, more than 70% of which were for opioids, and approximately 20% of which were for stimulants.

Preliminary data from the B.C. COVID-19 Cohort indicates that, of 6,498 persons who were dispensed RMG medications from March 27, 2020 to February 28, 2021, 82 persons died during that period. Of the persons who died, 33 (40%) received opioids only, 9 (11%) received stimulants or stimulants and opioids, 6 (7%) received alcohol withdrawal medications and another RMG medication (unspecified), and the rest (34; 42%) received only alcohol withdrawal medications or only benzodiazepines. Of the 82 persons who died, 7 had an active dispensation on the day they died (n=4 opioids; n=3 alcohol withdrawal management medications).

The cause of death for a high proportion of deaths (n=37; 45%) is not specified due to the lag in Vital Statistics data. Of those deaths where cause is specified (n=45; 55%), none were due to illicit drug toxicity death. Among persons who received RMG prescriptions that were not active on the day they died, the average length between prescription end date and death was 41 days for stimulant medications, 56 days for opioid medications, 86 days for benzodiazepine medications and 72 days for alcohol withdrawal management medications.

In addition, a mortality rate for persons who received RMG prescribing was 13.2 deaths per 1,000 person years. This rate includes individuals prescribed a variety of classes of medications (opioids, stimulants, benzodiazepines, and alcohol withdrawal medications). Other findings from the ongoing evaluation include the fact that 94.3% of all Risk Mitigation prescriptions were daily dispensed.

More recent data (up to February 28, 2021) found that 68% of persons dispensed prescription opioids through RMG prescribing had been dispensed OAT in the 30 days prior to first Risk Mitigation dispensation, almost 2% received their first OAT dispensation on the same day as their first RM dispensation, and almost 15% had OAT dispensated within 7 days of receiving their first RM dispensation.

Further findings from this evaluation will be forthcoming.