

Recommendations

Engrossed Substitute Senate Bill 5187; Section 215(124)(d); Chapter 475; Laws of 2023

December 1, 2024

Executive summary

This document summarizes the final report on the recommendations provided by Health Management Associates (HMA) to the Washington State Health Care Authority (HCA) regarding the establishment of the safe supply work group and their recommendations, as outlined in Engrossed Substitute Senate Bill (ESSB) 5187 (2023). The creation of this work group was in alignment with recommendations in the substance use recovery services plan, which was enacted through Engrossed Senate Bill 5476 (2021). This report aims to present the final recommendations set forth by this workgroup.

ESSB 5187; Section 215(124); granted authorization to allocate \$300,000 from the opioid abatement settlement account as a state appropriation. This allocation, specifically designated for establishing a statewide safe supply work group, supported HCA's efforts in this area as part of recommendations from the Substance Use Recovery Services Advisory Committee. HCA contracted with HMA to facilitate the workgroup, develop a report capturing the workgroup's final recommendations, and provide ongoing status updates to HCA.

The work group's primary objective was to conduct a thorough analysis and assessment of the current state of the opioid use epidemic, including an examination of the factors contributing to the crisis, an evaluation of existing treatment options, and an exploration of potential solutions. The workgroup aimed to provide comprehensive findings and evidence-based recommendations to address the opioid epidemic in a timely manner, through the means of a safer supply treatment model. The final report, which includes detailed data analysis and policy recommendations, is attached.

Work group background

The work group was created to evaluate potential safe supply models and recommend integrating a safe supply framework into Washington State. This framework aims to provide a regulated and tested supply of controlled substances to individuals at risk of drug overdose. The work group represents several areas of expertise and interest in implementing a safer supply model, such as individuals in recovery from substance use disorder, treatment professionals, insurance payors, public health experts, and representatives addressing the specific needs of rural communities. All statewide Safe Supply Work Group members are appointed by the governor's office, as per ESSB 5187; Section 215(124).

The work group, comprised of 12 members, conducted 11 meetings from March to September. Throughout the process, multiple virtual meetings were held to discuss and refine our recommendations. These meetings featured presentations and group discussions and facilitated consensus building. All other interactions were conducted virtually except for one in-person meeting to review the final recommendations.

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Committee recommendation framework

This work group is tasked with an evaluation that shall include, but is not limited to, the following:

- Examining the concept of "safe supply," defined as a legal and regulated supply of mind or bodyaltering substances that traditionally only have been accessible through illicit markets.
- Examining whether there is evidence that a proposed "safe supply" would have an impact on fatal or nonfatal overdose, drug diversion, or associated health and community impacts.
- Examining whether there is evidence that a proposed "safe supply" would be accompanied by increased risks to individuals, the community, or other entities or jurisdictions.
- Examining historical evidence regarding the overprescribing of opioids.
- Examining whether there is evidence that a proposed "safe supply" would be accompanied by any other benefits or consequences.

Final recommendations:

The following are the final recommendations of the work group, which are further described and detailed in the attached report developed by HMA:

- Recommendation 1: Remove barriers to the implementation of a randomized clinical trial of safer supply for people with opioid use disorder in Washington.
- Recommendation 2: Propose state legislation establishing a scalable, safer supply pilot program.
- Recommendation 3: Enhance and expand existing harm reduction and substance use disorder treatment services statewide.

Conclusion

The work group's primary objective was to conduct a comprehensive assessment of the current state of the opioid epidemic and recommend a safe supply model to provide a regulated, tested supply of controlled substances to individuals at risk of drug overdose. They extensively studied safe supply models and proposed a process for developing and integrating a safe supply model into Washington State. While the work group has not proposed a specific framework for the state to adopt, they have provided recommendations that will:

- Serve to provide evidence of the efficacy and viability of safe supply (recommendation 1),
- Establish a pilot program to verify efficacy prior to statewide expansion (recommendation 2), and
- Strengthen the impact of existing harm reduction and SUD treatment services (recommendation 3).

The final report from HMA is attached. The Health Care Authority acknowledges the hard work and dedicated effort the workgroup put into their recommendations.

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Washington State Safe Supply Workgroup

Final Report

December 1, 2024

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A NOTE ON TERMINOLOGY

The term "safer supply" will be used in this report instead of "safe supply" to acknowledge that the use of drugs always comes with risk that cannot be completely mitigated. "Safer" recognizes that a drug of known quality, composition, and potency is less risky than drugs purchased on the street through an unregulated market. The definition of safer supply can be found on page 8.



ACKNOWLEDGEMENTS

Health Management Associates (HMA) would like to thank the Washington State Health Care Authority for its leadership and partnership throughout this process, and representatives from the Washington State Department of Health, Office of Infectious Disease and Health and Safe Communities, who took time to attend workgroup meetings and share information.

This would not have been possible without the commitment, inquisitiveness, and compassion of the Washington Safe Supply Workgroup:

- Mike French
- Laura Healy
- Tania Hernandez, DO
- Malia Lewis, MSW
- Robert James Leyden
- Devin Majkut, MSW, SUDPT
- Robert Nelson
- Addie Palayew, PhD
- Melissa Saiz, MJ
- Tanikka Watford

Dr. Paxton Bach, Dr. Geoff Bardwell, Dr. Caleb Banta-Green, Dr. Addie Palayew, and Dr. Marlene Haines contributed to the Workgroup process as guest speakers at meetings. Their efforts to implement and expand safer supply throughout Canada and beyond significantly informed this process and those efforts are greatly appreciated.

HMA would also like to thank WA SPEAKS and those who came to the meeting to share their lived experience. WA SPEAKS provided stipends to the three participants who shared their stories during Workgroup meetings. The perspectives of people who would be eligible for a safer supply program are invaluable to its successful planning, implementation, and evaluation.

HMA acknowledges and honors the many lives lost in Washington to overdose and thanks the harm reduction advocates who made the Workgroup and this report a reality.



Let's Bring Safer Supply to Washington.

After examining the evidence base, associated health benefits, and potential community impact, the Washington Safe Supply Workgroup concluded that people who use drugs deserve more treatment options and that the benefits of a safer supply program outweigh the risks.



EXECUTIVE SUMMARY

Drug overdose deaths in Washington State continue upward, with almost 3,000 lives lost in 2023.¹ The most used drugs in Washington are methamphetamine and fentanyl, aligning with the rise in overdoses in those drug categories. One in six deaths involve fentanyl, and a combination of methamphetamine and fentayl contributed to 35 percent of all overdose deaths in 2023.

In response, per a recommendation from the Washington State Substance Use and Recovery Services Advisory Committee (SURSAC), the state legislature directed the Health Care Authority (HCA) to form a Workgroup in 2023 to examine the concept of safer supply and make recommendations for implementation.

For the purposes of the following recommendations, "Safer Supply" refers to an expansion of regulated pharmaceutical options for people with substance use disorder. There are varying degrees of evidence for different models. The most studied and evidence-based include long-acting hydromorphone and diacetylmorphine as treatment options alongside methadone. Canadian doctors prescribe a wider range of drugs, including short-acting opioids, benzodiazepines, and stimulants.² Documented and evaluated benefits across all modalities include decreased crime³, decreased street drug use among participants⁴, increased social well-being, increased access to employment and housing⁵, and – most notably – a decrease in risk of overdose death.^{6,7}

The Safer Supply Workgroup (Workgroup) is comprised of 12 members appointed by the Governor of Washington. They met 11 times from March to September of 2024. All meetings were virtual except for one in-person meeting to review final recommendations. Meetings included didactic presentations, group discussions, and consensus building. The Workgroup came up with the following recommendations, which are further detailed later in this report:

Recommendation 1: Remove barriers to the implementation of a randomized clinical trial of safer supply for people with opioid use disorder in Washington

With federal government cooperation, researchers can implement randomized controlled clinical trials (RCT) for Schedule I drugs (such as diacetylmorphine) and demonstrate a new use of a Schedule II drug (such as hydromorphone). RCTs have not been done before in the US; however, in multiple countries, diacetylmorphine and hydromorphone were demonstrated as effective as methadone with RCTs over 30 years ago.

Recommendation 2: Propose state legislation that establishes a scalable safer supply pilot program

The state legislature can pass a state law authorizing the establishment of a safer supply pilot program in accordance with certain rules and expectations. In a safer supply program, people are offered regulated, pharmaceutical grade drugs as an alternative to the illicit market. Safer supply programs offer prescription opioids like hydrocodone and fentanyl patches, and they allow a greater amount of patient agency in care delivery.



Recommendation 3: Enhance and expand existing harm reduction and substance use disorder treatment services statewide

Washington has unmet behavioral health and harm reduction needs. The Workgroup recognizes highimpact changes to increase access to the existing system of care, many of which are underway. These include – but are not limited to, the following: repealing subsection 2 of.612RCW Section 2, 69.50.612, which has the potential to restrict local implementation of harm reduction services; invest in provider education on safer supply and harm reduction; improve patient agency in opioid treatment program settings; allow for mobile harm reduction and treatment service delivery; and increase funding for syringe service programs.



GLOSSARY OF TERMS

Below are various terms and definitions used in the realm of harm reduction and safer supply that will be a useful reference throughout this report.

Agency: The ability to act with intentionality and in alignment with one's own will. In the context of patient care, it refers to patient choice and facilitating an active role in care management and decisions that affect them.

Evidence-Based Practice (EBP): An approach to care that integrates the best available reseach evidence with clinical expertise and patient values.

Harm Reduction: According to the Nation Harm Reduction Coalition, harm reduction is a set of practical strategies and ideas aimed at reducing negative consequences associated with drug use⁸. Harm reduction is also a movement for social justice built on a belief in – and respect for – the rights of people who use drugs. Harm reduction involves safer use of supplies as well as care settings, staffing, and interactions that are person-centered, supportive, and welcoming.

Low threshold-low barrier treatment: This is an approach to providing treatment that attempts to remove as many barriers as possible. Its essential features are same-day treatment entry, a harm reduction approach that prioritizes accountability without termination, provides flexibility for patient, and a wide availability in places where people with no appointment required simultaneously manage withdrawal, and ongoing as needed for maintenance therapy, e.g. opioid agonist therapy and fentanyl patches.

- Counseling is always offered, not mandated as a prerequisite to receiving medication services.
- Urine drug screens are used to inform clinical care and adjust use disorder go for treatment course as needed, not as a punitive measure⁹.
- Cessation of street drug use is not an expectation nor a requirement to remain in care.

Recovery: Recovery is a process of change through which individuals improve their health and wellness, live self-directed lives, and strive to reach their full potential.¹⁰

Safer Supply: Refers to providing prescribed medications as a safer alternative to the toxic illegal drug supply to people who are at high risk of overdose. Safer supply services build on existing approaches that provide medications to treat substance use disorder.

Syringe Service Programs: Comprehensive hubs of healthcare for people who use drugs that provide a range of critical preventative and treatment services, including sterile injecting supplies and other safer drug use equipment; safe syringe disposal; and linkage to heatlhcare, treatment, and support. SSPs protect and improve the health of individuals and communities

Supervised Consumption Sites or Overdose Prevention Centers: Designated sites where people can use pre-obtained drugs under the supervision of medical personnel trained to respond in the event of an overdose. These centers often additionally provide day shelter, referrals, and other peer support services on-site.



BACKGROUND

More than 100,000 people die of overdose every year in the US.¹¹ The Center for Disease Control and Prevention (CDC) has characterized it as a crisis that has evolved over 30 years and in three distinct waves.¹² The first wave is attributed to the overprescribing of prescription opioids and related overdose deaths. The second wave occurred as prescriptions for opioids decreased and street heroin became more accessible. People switched from the former to the latter and deaths attributed to heroin increased. The third wave came with the introduction of fentanyl and other synthetic opioids into the drug supply. Fentanyl is now sold and used on its own or in combination with other drugs.

Fentanyl has become the dominant opioid in the US drug supply and accounts for over 80 percent of annual deaths.¹³ Fentanyl is a synthetic opioid. It is manufactured in labs, typically in China or Mexico, and trafficked into the US at all points in the supply chain.¹⁴ It has a shorter half-life than heroin and is used in greater quantities and more frequent intervals. People who use it are more likely to experience overdose if they do not have tolerance. Other synthetic opioids have been identified through drug checking programs. These results show the drug supply changes rapidly, unpredictably, and dangerously. This unpredictability places people who use any drugs at high risk of overdose.

Drug overdose deaths in Washington continue upward, with over 3,400 lives lost in 2023.¹⁵ The most commonly used drugs in Washington are methamphetamine, a stimulant, and fentanyl, a synthetic opioid, aligning with the rise in overdoses in those drug categories.Of all overdose deaths, 76% involves only fentanyl and 55% involved a psychostimulant. Over 36% of all deaths include a combination of both fentanyl and methamphetamine.

Washington State has a drug checking program. The WA State Community Drug Checking Network (CDCN) is a partnership of organizations that provide communitylevel drug checking and related harm reduction services.^{*} Community drug checking is an evidence-informed harm reduction intervention in which small samples of drugs or drug residue can be analyzed via multiple technologies to determine the chemical components of the sample. Drug checking is provided along with safer use supplies, overdose prevention education, harm reduction services, and referrals or linkages to care. Results show the contents of the drug sample and are used to inform overdose risk strategies. Summary information is made available to the public for educational purposes and to inform public health intervention.



FOR CONSIDERATION

Given the complexity and unpredictability of the current illicit drug market, and inadequate access to needed health and social services in Washington, it is rational to consider an approach to stabilizing people's experience and reducing their risk of overdose death.

^{*} For more information about the WA State CDCN, go to: https://adai.uw.edu/wordpress/wp-content/uploads/THE_DC_Network_Infosheet.pdf.



Tested samples in Washington often contain a different composition and potency of substances than the person expected to purchase. The inclusion of precurors, analogs, and cutting agents make the drugs more or less potent and produce different psychoactive effects than fentanyl alone.¹⁶ The results of the drug checking program demonstrate the unpredictability of the illicit drug market. The following chart reflects both drugs that were tested that people believed already to be fentanyl, and they wanted to check for adulterants, and drugs that people believed were not fentanyl and they wanted to be sure is not "cut" with fentanyl without their knowledge.



Shares of samples sold as fentanyl positive for key substances

Behavioral Health Treatment

People also have unmet behavioral health needs in Washington. Medications currently available for OUD treatment in the US are methadone, buprenorphine, and naltrexone. Methadone is a full opioid agonist available as a maintenance therapy for people with severe OUD. It is only available for the treatment of OUD in oral formation at a SAMHSA-approved Opioid Treatment Program (OTP). It is consumed daily and orally in a supervised manner with some opportunity for take home dosing. Buprenorphine and naltrexone can be prescribed in a broader range of provider settings and dosed unsupervised on a patient's own time.



The National Institute on Drug Abuse (NIDA) has noted that after decades of research demonstrating the efficacy of MOUD, more research on their benefits for substance use treatment is not needed.

Treatment is not easily accessible, and 32 percent of respondents of a recent survey at syringe service programs said they "tried to get help to reduce their drug use but didn't/couldn't get it."¹⁷ Nationally, just over 50 percent of people who had opioid use disorders received treatment for it in 2022, and even fewer received gold standard medications (methadone and buprenorphine) for treatment (1 in 4 people.)¹⁸ The top reasons are long waitlists, no availability, or a lack of transportation. Housing access would likely improve treatment access and retention, but over half (55%) of the respondents to that same survey were living unhoused.

Gaps in OUD treatment access have deadly consequences. Treating OUD without medications in an abstinence-based treatment program places someone at higher risk of overdose death relative to no treatment at all.¹⁹ Discontinuation of methadone prior to 12 months is associated with increased risk of overdose, and according to a 2022 analysis by Burns et. al, 67% of Medicaid beneficiaries left treatment prior to 12 months²⁰.

Some safer supply modalities, ie hydromorphone and diacytelmrophine, are considered treatment for OUD and expand the options people have alongside methadone, buprenorphine, and Vivitrol.



Safer Supply Overview

Safer supply is a broad term used to describe a range of models that provide access to legal and regulated mind altering substances as an alternative to illicit markets. Given the complexity and unpredictability of the current illicit drug market, and inadequate access to needed health and social services, it is rational to consider an approach to stabilizing people's experience and reducing their risk of overdose death.

Clinical setting examples include injectable opioid antagonist treatment (iOAT), which is prescribed hydrocodone or diacetylmorphine that the patient receives and consumes on-site in a supervised manner. Typically, a patient doses multiple times (2-3 times) per day with strict expectations about timeliness for dosing appointments.

Prescribed Safer Supply (PSS) programs allow for greater flexibility for both provider and patient. They allow for prescribed full agonist opioids to be picked up from a clinic, pharmacy, or community setting and consumed without medical supervision on the patient's own time. Drugs used in this manner are tablet hydromorphone, prescription fentanyl, other short-acting opioids, and stimulants.

The example of a program that allows for full patient choice is the Compassion Club²¹. This model requires membership, of which the criteria is a period of sustained drug use. Members can access drugs that were purchased on the illicit market and rigorously tested using laboratory equipment that provides insight into the contents, including adulterants and the strength/concentration. The drugs are resold at or below cost to members. The goal is to remove the unpredictability that drives the risk associated with drugs purchased on the illicit market, reduce funds that go to cartels, and mitigate overdose risk.

History and Evolution of Safer Supply

Medication has been accepted as a treatment for substance use disorder since the early 1960s²². Before the availability of methadone, medical providers prescribed heroin or cocaine to patients who wanted to gradually stop their drug use over time, or for whom the consequences of withdrawal and abstinence were untenable or previous attempts had failed, making them not viable options. Methadone became the leading treatment option, appreciated for its long half-life and less euphoric effects than heroin, and has been approved to treat opioid use disorder in the US since 1972.²³

Dating back to 1980, the earliest clinical trials compared "heroin-assisted treatment," or prescribed diacetylmorphine, to methadone. In 1994, the first full-scale efficacy trial was conducted in Europe. Researchers evaluated the impact on cravings, changes in the use of street-purchased/unregulated substances, neighborhood effects, quality of life measures of recipients, and the impact of treatment on infectious disease incidence and treatment adherence.



In 2006, the North American Opiate Medications Initiative brought this approach to our continent. Just over 250 people from Montreal and Vancouver participated in the trial. Their eligibility criteria included having used opioids for five years and experienced two previous attempts at treatment using methadone. People were separated into a methadone and a diamorphine group. The trial evaluated criminal activity retention and street drug use.

Due to the success of these early trials, diacetylmorphine and hydromorphone are approved forms of treatment for opioid use disorder in the UK, Switzerland, the Netherlands, and Canada. These medications are covered by publicly funded healthcare systems.

During the COVID-19 pandemic, with its associated lockdowns, service interruptions, and social distancing, overdose deaths increased, and Canada significantly expanded what has become known as a safer supply. This was a pragmatic policy intervention to quickly scale services for people at the highest risk of overdose, and provide them with options safer than the unpredictable supply they were obtaining on the streets.

Canada has initiated what is now called a prescribed safer supply (PSS) program. PSS allows providers to offer short-acting opioids and stimulants for the treatment of a substance use disorder. PSS offers more flexiblility in dosing, route of administration, and settings than traditional opioid treatment programs. Safer supply is now viewed across a spectrum of medication options that are each available through different program models.

Figure 1: Spectrum of Harm Reduction with Safer Supply Modalities from Health Canada²⁴

Health Canada: Safer supply is defined as "providing prescribed medications as a safer alternative to the toxic illegal drug supply to people who are at high risk of overdose".

uction	Tablet iOAT (TiOAT)	Fentanyl patches	Slow-rele morp	ase oral hine	Trea
red		Spectrum of inter	ventions		atm
Harm	Prescribed hydromorphone (PSS)		Injectable OAT (iOAT)	Methadone / buprenorphine	ent



DIN 02145928 500 mg/ ur perfusion sous-cutanée ou intraveineuse, dilué ou tel que ISOTONIQUE Analgésique opioïde Fiole à usage unique Sans agent de conservatio NDOZ

Harm Reduction Spectrum

Harm reduction is not only the provision of tools that reduce the risk of drugs, but also an approach to substance use that is centered on non-judgment, compassion, and respect. Health and social service providers can practice harm reduction by having open conversations about someone's drug use, offering practical risk reduction education, and supporting people with setting their own goals for addressing substance use and their general health and well-being. Harm reduction is pragmatic, giving patients choice in determining their type of care, accountability without termination, and embracing any positive change an individual makes in their health and well-being.

Safer supply programs apply harm reduction principles when program participants are able to select the treatment substance that works best for them, can obtain and ingest or administer the substance in their own time, are allowed take-home doses, are not required to engage in any other services to obtain access to medication, and are held accountable to self-determined goals without termination. Care is based on individual needs.

The other end of the spectrum is safer supply programs (most notably iOAT) that provide treatment in a controlled setting. Patients have limited options and consumption is observed by a nurse or other clinical provider. Patients do not have a say in opportunities for take-home dosing or other flexibilities with their care. While still considered a safer alternative to the illicit drug market, the programs in which the prescribed alternatives are delivered are not fully oriented to harm reduction or low-barrier treatment.

HMA

Safer Supply in the United States

Safer supply is not currently practiced in the US, but has been historically considered as an approach to the treatment of behavioral health disorders and overdose deaths.

A 2009 exploratory analysis of heroin-assisted treatment in Baltimore by the Abell Foundation found enough evidence to merit consideration of its potential for implementation, both in Baltimore and the wider US. Almost a decade later in 2018, among the conclusions of a groundbreaking RAND Corporation publication was, "assessing the impact of injectable hydromorphone via clinical trials (with or without an iOATarm) would inform future regulatory decisions about using it as a medication treatment for OUD."

Prescription heroin was part of a national discourse after its approval in Canada in 2016. Articles appeared in outlets like National Public Radio, Vox, VICE, and the Washington Post, asking whether America is ready for prescription heroin. In 2016, the Senate Homeland Security and Governmental Affairs Committee of the 114th Congress (2015-2016) held S.Hrg. 114-722 — AMERICA'S INSATIABLE DEMAND FOR DRUGS. During this hearing, they discussed prescription heroin and the results of the clinical trials that led to its approval in Canada.

With national awareness of Canada's program, states proposed bills to facilitate and pay for pilot studies. A Maryland legislator proposed a bill for a "poly-morphone-assisted treatment pilot program" in 2016 that was ultimately withdrawn. The Nevada State General Assembly was the first to hear arguments for a bill proposing a four-year pilot study of "heroin-assisted treatment" in 2017.²⁵ The bill passed favorably in the health committee. This demonstrates momentum and potential for state-directed safer supply pilot programs.

Current Legal Context

The Controlled Substances Act (CSA), 21 U.S.C. § 801 affects all drug access and use in the United States. It regulates controlled substances into one of five schedules. Schedule I have the highest risk of abuse, with no recognized medical use in the United States, and Schedule V have the least potential for abuse. Federal drug statutes, 21 U.S.C. §§ 841, 960, prohibit manufacture, distribution, importation, and exportation of controlled substances. The implementation of this statute affects how drugs are prescribed and distributed to individuals. Statutory penalties for all drug-related offenses vary based on quantity, the defendant's prior felonies, and serious death or injury resulting from use.

The Drug Enforcement Agency (DEA) determines the schedule of controlled substances. The Food and Drug Administration (FDA) may approve a drug on Schedule II to V for medical purposes. Currently, diacetylmorphine is a Schedule I drug that could not be approved in any circumstances. Hydromorphone injectable and tablets (Dilaudid), fentanyl patches, and slow-release oral morphine are Schedule II, so they can be prescribed for pain management, but are not approved for OUD treatment. Oral methadone is Schedule II and is approved for OUD treatment.



According to 21 U.S.C. § 811, interested parties (including state or local government agencies) can petition the federal government to reschedule substances. Washington regulations schedule substances according to federal regulations, but can be changed at the state level by revising RCW <u>69.50.201</u>. The state legislature could also propose an exemption for a public health program to address an emergency such as the overdose crisis. Even with rescheduling, prescribers would be in violation of the Controlled Substances Act if they prescribed these drugs to treat opioid use disorder.

WORKGROUP STRUCTURE

As part of the Washington State Substance Use Recovery Services Plan submitted in early 2023, the Substance Use and Recovery Services Advisory Committee (SURSAC) set forth a recommendation to the state to establish a Workgroup to recommend a system to provide safer supply services in Washington State. The SURSAC specifically called for centering the perspective of people who use drugs.

<u>Senate Bill 5187</u>, Section 215(124), was enacted in 2023, granting authorization for the allocation of \$300,000 from the opioid abatement settlement account as a state appropriation. The Washington Health Care Authority contracted with Health Management Associates (HMA), a national healthcare consulting firm with substance use disorder treatment and harm reduction expertise, to facilitate the Workgroup.

Workgroup Membership

Members were recruited, vetted, and appointed by the Washington Governor's Office with support from HCA. Members of the SSW included representatives of the categories listed in the table below.

Efforts were taken to fill all areas of representation as directed in 5187 Section 215, Proviso 124(a). However, due to the report deadline, HCA and HMA requested permission from the Governor's Office to initiate the Workgroup before all the seats were filled so that the Workgroup would have at least six months to convene and finalize recommendations before their deadline. This request was granted, but five seats remained vacant throughout the Workgroup cycle. Multiple efforts were made to fill these vacant positions, but were ultimately unsuccessful. In three cases, nominations were either not received or the nominees did not meet the requirements of the proviso. In two cases, nominees were identified and received applications from the Governor's Office, but applications were not returned. Even so, the Workgroup convened regularly to complete the tasks as outlined by the legislature. A great deal of thought and effort from the identified Workgroup members went into this report.

Since the proviso allowed for Workgroup membership to include additional areas of representation, a "harm reduction services provider" representative was added.

Given the importance of including perspectives from those with lived experience, a special effort was made to solicit input from youth in recovery. HCA requested for HMA to conduct outreach for youth to solicit their input on safe supply options, and HMA was able to achieve this with a youth focus group.



Area of Representation	Government Appointed Individual
Adult in recovery from substance use disorder	Robert Nelson
Expert from Addictions, Drug, and Alcohol Institute (ADAI) at the University of Washington	Addie Palayew, PhD
Outreach services provider	Devin Majkut, MSW, CDPT
Peer recovery services provider	Robert James Leyden
Recovery housing provider	Tanikka Watford
Expert in serving persons with co-occurring substance use disorders and mental health conditions	Laura Healy
Expert in antiracism and equity in healthcare delivery systems	Dr. Tania Hernandez, DO
Representative from the Association of Washington Healthcare Plans	Melissa Saiz, JD
Representative of local government	Mike French
Harm reduction services provider*	Malia Lewis, MSW
Youth in recovery from substance use disorder	Vacant
Substance use disorder treatment provider	Vacant
Employee who provides substance use disorder (SUD) treatment or services as a member of a labor union representing workers in the behavioral health field	Vacant
Representative of Sheriffs and Police Chiefs	Vacant
Representative of a federally recognized tribe	Vacant

Meetings

HMA scheduled, planned, facilitated, and documented meetings for the Workgroup. The Workgroup met virtually at least once a month from March through September of 2024 for 10 web–based meetings. The meetings were held via Zoom and open to the public. The Workgroup also participated in one in-person meeting in September of 2024 to review and discuss the final report. Meeting agenda are <u>available online</u>.

The format of the meetings included community participation, didactic education, and discussion. Meetings were open to the public and the agenda included time for public comment. When possible, each meeting opened with statements from people with lived and living experience of substance use. These testimonies grounded the Workgroup's process in real-world scenarios and the perspectives of people who would or could be eligible for a safer supply program. Recordings of the meetings were sent to workgroup members, only, after the meeting to help ensure that individuals who may have missed a meeting had access to relevant content and critical information.

Meetings also featured local speakers who have conducted extensive research into the drug market and drug use in Washington State. The Workgroup learned about trends in drug administration, the types of preferred drugs being bought and consumed, and the current barriers and gaps in the treatment and harm reduction system of care throughout the state. Research conducted and published in 2024 was also presented on people who use drugs' perspectives of safer supply²⁶.

Consensus Building

HMA facilitated consensus building discussions among the Workgroup members. HMA applied group discussion techniques to elicit diverse perspectives from members. Techniques include active listening, giving all members time to speak, and nurturing an open process by paying attention to the process, content, and interpersonal dynamics of the discussion all at the same time. From the beginning, HMA fostered openness and a "learning environment". Discussion started with brainstorming sessions, during which there were "no bad ideas", and members identified remaining questions they have about safer supply. HMA conducted background research to support the Workgroup and answer their questions.

Aligning discussion with research, speaker conclusions, and surveys of youth and substance use disorder treatment providers, HMA identified trends and themes that guided recommendation development. The recommendations grew from an informed foundation of compassion and shared motivation to end the overdose crisis in Washington State. The Workgroup members reached a consensus that people who use drugs and have a substance use disorder deserve the full continuum of possible services, including more treatment and harm reduction options.



Methods

In close collaboration with the Workgroup, HMA expanded on the research questions identified in the preliminary report by applying an implementation science lens. The original questions evaluated safer supply's efficacy in reducing overdose and its potential to have negative community impacts. With consensus that more options are needed to reduce risk and improve treatment options for people with substance use disorder, the Workgroup shifted focus to how to best approach a potential program. These questions included:

- What are implementation considerations?
- What are the political considerations?
- How can health insurance payors support this work (e.g., workforce development, funding, diagnosis and billing codes, reimbursement)?
- How will this be operationalized?
- Is there a cost effectiveness to safer supply?
- Does safer supply have impact on criminal activity?
- Does safer supply contribute to community safety?
- What have other states and countries have done?

Literature Review

Relevant studies were identified using PubMed, Embase, and Web of Science. Search terms included "safe supply," "safer supply," "prescription opioid agonist," "prescription heroin," and "heroin assisted treatment." Studies were excluded if safer supply is mentioned as a recommended solution to the public health problem of substance use or the overdose crisis, but not as the primary focus of the study or paper.

Injectable opioid agonist treatment (iOAT) with diacetylmorphine has been rigorously evaluated in other countries since the late 1980s. A search of the literature identified 197 relevant research articles from 1989 to 2024. Researchers evaluated the impact on cravings, changes in the use of street-purchased/unregulated substances, neighborhood effects, quality of life measures of recipients, and the impact of treatment on infectious disease incidence and treatment adherence. Fewer than 50 articles have been published on "safer supply" and to date no RCTs have been conducted.

Provider Survey

In collaboration with the Workgroup, HMA created and distributed a survey for behavioral health providers to explore provider perspectives of safer supply. The survey, distributed virtually using Qualtrics, asked providers to imagine safer supply regimens available and allowable to treat opioid use disorder, to better understand and anticipate individual experiences and social and legal barriers. The survey was distributed to a sample of providers randomly selected from a list provided by HCA.

Almost all (97%) of the 35 respondents reported that they were currently working in or had previously worked in substance use disorder treatment in Washington State, and 24 percent currently or had previously been a medical director of a substance use disorder treatment program. Survey responses were received from across the state, including the Northwest, Southwest, Northeast, and Southeast regions.



The HMA team monitored and cleaned survey data for completeness, consistency, and accuracy, and removed/addressed any invalid responses (i.e., incompleteness). Survey data/responses were presented during a Workgroup meeting through visual representations and summaries of key findings. Some of the analysis points included:

- Respondent demographics (e.g., age, geographic location)
- Respondent professional roles (e.g., physicians vs. social workers)
- Thematic analysis completed to identify common themes and grouping of similar responses to create categories that reflected the key findings

Input from People Who Use Drugs

Between May 2023 and September 2023, a research team at the University of Washington interviewed 457 people in Seattle who used drugs. Of that number, 351 people injected drugs and 106 smoked opioids as their primary mode of consumption. Of the people who injected, 369 (77%) injected opioids at some point in the last year. The most common other substance injected was methamphetamine²⁴.

The HMA team partnered with the Department of Health, HCA's Division of Behavioral Health, and Recovery's "Prenatal through 25 (P-25)" program to connect with young adults who have lived experience with drug use. The HMA team developed and distributed an online survey explore young adult perspectives of safer supply. The survey received a total of seven responses with only one of them being conclusive.

The HMA team also held 30-minute interviews over a two-week period for young adults who may be interested in sharing their experiences with our team. Details on the purpose and process were shared widely along with an online scheduling tool for participants to book according to their schedules. Given the limited time for data collection, the HMA team was not able to gather youth input. It is recommended that including young adult voices be prioritized as this work moves forward.





WORKGROUP FINDINGS

The Workgroup examined the full range of safer supply models, including their pros, cons, and unintended consequences. The meetings were educational opportunities on the various models of safer supply. Speakers were recruited from Canada, where safer supply has been a practice for over a decade. Speakers included leaders in safer supply access, having served as prescribers, nurse practitioners, and researchers. They all had experience directly providing safer supply in clinic and street settings from urban Vancouver to rural Ontario.

The Workgroup concluded that safer supply programs do not increase fatal or nonfatal overdose risk. The overwhelming majority of studies demonstrate a reduction in experiences of nonfatal overdose and zero overdose deaths among people enrolled in a safer supply program (all models). ^{27,28} Safer supply is just one intervention that has the potential to impact overdose rates and must fit within a context of services that comprehensively support people who use drugs.²⁹

People and providers deserve more options to prevent death and treat substance use disorder.

Diversion

The Workgroup examined the challenges of safer supply programs. Diversion of drugs provided by safer supply programs (the drugs ending up in the hands of individuals for whom they were not prescribed) continues to be a concern among community members. The Workgroup reviewed available information about diversion, including asking this question of providers of safer supply in Canada and examining qualitative research. Even in countries with multiple safer supply programs, there are critics concerned with its impact on individual and community health.^{30,31} Diversion may increase the end recipient's risk of overdose, since the medication is being taken without medical supervision, and undermines the program's effectiveness for the actual enrolled patient.



Diversion occurs for a few reasons, including lack of access to needed care. There is little evidence that diverted safer supply drugs are used to initiate drug use among individuals, especially youth. Moreover, use of diverted drugs from a regulated, reliable safer supply is less likely to increase someone's risk of overdose than the use of street-purchased drugs. Therefore, the proper support should be in place for providers to minimize chances of diversion, but fear of diversion is not a justification for prohibiting safer supply from being implemented.

Community Pushback

Another major risk of safer supply programs is community discomfort and pushback. The Workgroup examined how this sentiment already exists for opioid treatment programs that provide methadone and/or buprenorphine. There is also existing scrutiny and public concern about syringe service programs. With limited existing support for these lifesaving services, the Workgroup was concerned about the challenges providers may face when opening or implementing safer supply programs. This is

All models of safer supply offer people an opportunity to pursue and achieve selfdetermined goals[:] to use fewer drugs purchased on the illicit market, to use less overall, and to reduce participation in criminal activity.

accompanied by concern that resources are limited to support all programs, and allocation needs to be equitable across the state.

Fear of public pushback was affirmed by Workgroup guest speakers based in Canada. While they have implemented injectable opioid agonist treatment (iOAT) for many years, and these programs are well established in the evidence, the recent shift to offering additional safer supply options has come with public outcry. There has been extensive media attention on safer supply that has led to the closing of some programs and a reduction in federal funding anticipated in 2025. Speakers from Canada encouraged the Workgroup to consider rebranding from "safe" to "safer" supply to acknowledge that all drug use, even those that are prescribed, carries risk and prescribed alternatives are simply safer options than the illicit drug market.

Benefits to Patients and Providers

All models of safer supply offer people an opportunity to pursue and achieve self-determined goals²¹. These goals are often to use fewer drugs purchased on the illicit market, to use less overall, and to reduce participation in criminal activity.^{32,33} To date, there are no documented overdose deaths among people actively participating in safer supply. Safer supply programs experience high retention; when people are initiated into them, they stay engaged long-term.

Further, safer supply offers providers opportunity to try new strategies when navigating the ever-changing illicit drug market. Fentanyl has affected long-established approaches to managing opioid withdrawal and medication induction, and use of short-acting opioids shows promise for making that transition easier for the patient. Providers deserve to have access to all tools and resources that can help them in their front-line response to the overdose crisis.



After examination of the evidence of associated health and community impacts, the Workgroup concluded that implementing a safer supply strategy would create more good than harm, and the benefits outweigh the risks. The Workgroup expressed a desire to continue meeting to guide the pursuit of safer supply options in Washington, given the expertise they have developed and their unique vantage point of patient and community needs.



RECOMMENDATIONS

Recommendation 1: Remove barriers to the implementation of a randomized, controlled clinical trial of hydromorphone or diacetylmorphine to expand treatment options for people with opioid use disorder in Washington.

Overview

Access to medications for opioid use disorder, the gold standard treatment for opioid use disorder, is patchwork in Washington state. The state's implementation of OUD treatment using medications is behind the scientific consensus on how to treatment substance use disorder, and more options are necessary to curb the overdose crisis. From 2018 to 2023, initiation to any medications for opioid use disorder (MOUD) treatment among Medicaid enrollees with OUD in Washington State remained steady at 7 percent from 2018 to 2023³⁴. During this time, overall MOUD prescribing, including methadone, buprenorphine, and naltrexone, increased slightly from about 32 to 37 percent. This increase was mainly because of an increase in buprenorphine-naloxone prescribing in 2019 that has since remained stable through 2023. A little more than half of those prescribed buprenorphine continue use of it after 180 days. Overall, these data suggest access and utilization are extremely low, especially considering the public health burden of the overdose crisis; however, more information is needed to draw conclusions about treatment access.

Researchers, with federal government cooperation, can implement randomized controlled clinical trials (trials) for Schedule I drugs such as diacetylmorphine and to demonstrate a new use of a Schedule II drug, like hydromorphone. Trials have not been done before in the US; however, in multiple countries diacetylmorphine and hydromorphone were demonstrated as effective as methadone with trials over 30 years ago. These treatments are considered evidence-based and are covered by public healthcare systems in Canada and European countries like the UK, Switzerland, and Denmark, among others. A trial is necessary to facilitate future Medicaid coverage of new drug options in the US.

The challenges of this recommendation include the likelihood of public pushback, similar to the resistance faced by current opioid treatment programs and harm reduction programs in Washington. Diacytelmorphine is the prescribed equivalent to heroin, and is historically referred to as "heroin-assisted treatment". There is a low risk of diversion of prescribed medication due to its being administered in a controlled environment under clinical supervision. A RCT can also be costly, while likely funded by federal research agencies, and there is no sustainability until the trialed medications receive federal approval.

Academic institutions provide coverage for the implementation of a trial, but buy-in, community engagement, and support is paramount to any study. To avoid unnecessary pushback, the researchers and academic institution should have a community engagement plan prepared in advance. This may include community notification, listening sessions, hotline for information, or public education sessions on the topic. The trial should be implemented with local county consideration and engage diverse participation across the state, both east and west of the Cascades.

These challenges could also be mitigated with support from public officials, including the Department of Health, Health Care Authority, and Governor's Office. Public statements, funding, and engaging other state agencies in discussion about the intention and purpose of the trials would reduce public concern.



Recommendation 2: Propose state legislation that expands opioid use disorder treatment options through a scalable safer supply pilot program.

A state general assembly can pass a state law authorizing the establishment of a safer supply pilot program in accordance with certain rules and expectations, which should be set by medical, harm reduction, and policy experts in safer supply. In a safer supply program, people are offered regulated, pharmaceutical grade drugs as an alternative to the illicit market. Safer supply programs can offer prescribed alternatives to the illicit market such as short-acting opioids and fentanyl patches, and allow a greater amount of provider and patient choice in care delivery. Pilot programs can be implemented in collaboration with interested counties, both east and west of the Cascades to reach diverse communities impacted by the overdose crisis.

Washington State is uniquely positioned to learn from the Canadian safer supply experience, and the Workgroup recommends adapting what worked abroad to our local context. This recommendations builds on recent success statewide with increased peer navigation resources, drug checking programs, low-barrier buprenorphine programs, and Health Engagement Hubs (RCW <u>71.24.112</u>). A safer supply program could increase effectiveness and reach of these, and other, current programs.

A pilot program could be guided by an advisory committee, implemented pursuant to regulations established by the Washington State Health Care Authority and Washington State Department of Health, and available to people who meet certain criteria. Diversion can be addressed with open communication with patients and communities, medical professional supervision of the use of the medication, and increasing availability of all substance use disorder treatment.

Funding for this program need also be considered. The average cost of starting up one safer supply program in a major city in Canada is \$3.5 million USD equivalent. This program would be eligible for opioid abatement or settlement funds at the state or local level.³⁵

Recommendation 3: Enhance and expand existing harm reduction and substance use disorder treatment services statewide.

Washington already has unmet behavioral health and harm reduction needs. The Workgroup recognizes high-impact changes to increase access to the existing system of care, many of which are underway. Local governments should receive more funding for the improvement of their behavioral health system of care, including harm reduction services. Examples include, but are not limited to:

- Investing in provider education on safer supply and harm reduction principles
- Integrating harm reduction services and philosophy into opioid treatment programs
- Ensuring that there is opioid treatment program availability in every county in Washington
- Improving patient agency in existing opioid treatment programs in accordance with updated Substance Abuse and Mental Health Services Administration (SAMHSA) guidelines, including take-home dosing assessment and mobile delivery
- Increasing the number of community-based syringe service programs

Moreover, the Workgroup recommends that the Washington State Legislature revisit <u>2E2SSB 5536</u>³⁶, section 8, subsection 2, codified as RCW 69.50.612(2)). This subsection allows local city, county, or regional jurisdictions to put forth legislation that could limit harm reduction operations and contradicts the state's preemption and protections intended to support necessary operations of public health harm reduction programs. The Workgroup's resounding recommendation is to repeal the following language from chapter 69.50.612 RCW:

"(2) Nothing in this chapter shall be construed to prohibit cities or counties from enacting laws or ordinances relating to the establishment or regulation of harm reduction services concerning drug paraphernalia."

CONCLUSIONS

After examination of the evidence of associated health and community impacts, the Workgroup concluded that a safer supply would create more good than harm and that the benefits outweigh the risks. The treatment system needs change to become more accessible for all people, and doctors deserve the right to prescribe all available evidence-based options to meet the needs of their patients.

Recommendations include changes to the treatment system, increasing pharmaceutical alternatives to the illicit market for people who use drugs to reduce risk of death, and increasing engagement in treatment over time for long-term health and well-being improvement.

"Safe Supply is a typical "pebble-in-the-pond" scenario, where the positive ripple effects go out beyond just the recipients themselves. Because their immediate family, their extended family, friends, colleagues, the community they live in, etc., can all benefit as well." – Certified Peer Counselor

The Workgroup members expressed a desire to continue meeting to guide the pursuit of safer supply options in Washington, given the expertise they have developed and their unique vantage point of patient and community needs.



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