THE HARM REDUCTION COMMISSION

established by Section 100 of Chapter 208 of the Acts of 2018

March 1, 2019

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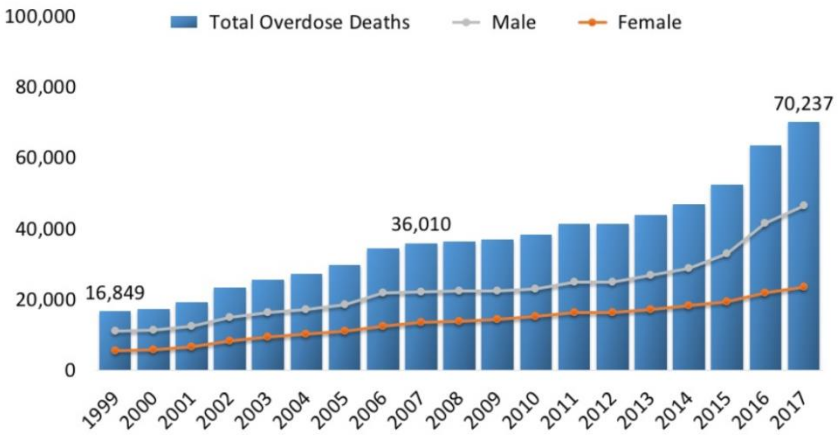
Overview of the Ongoing Opioid Crisis

A National Epidemic

- In the United States, there were 70,237 overdose deaths in 2017, a 9.6% increase from the previous year. More than two-thirds of those deaths (~47,600) were opioid-related.
- Accidental opioid overdose deaths now exceed deaths from motor vehicle accidents and deaths from firearms in the United States.[1]
- The federal government declared the opioid crisis a public health emergency on October 26, 2017.
- The introduction of illegally manufactured synthetic opioids, such as fentanyl, is one of the primary drivers of the spike in overdose deaths.
    - The effect of fentanyl on the body is quicker than heroin; overdoses can occur within minutes of ingestion.

National Drug Overdose Deaths
Among all ages, by gender, 1999-2017

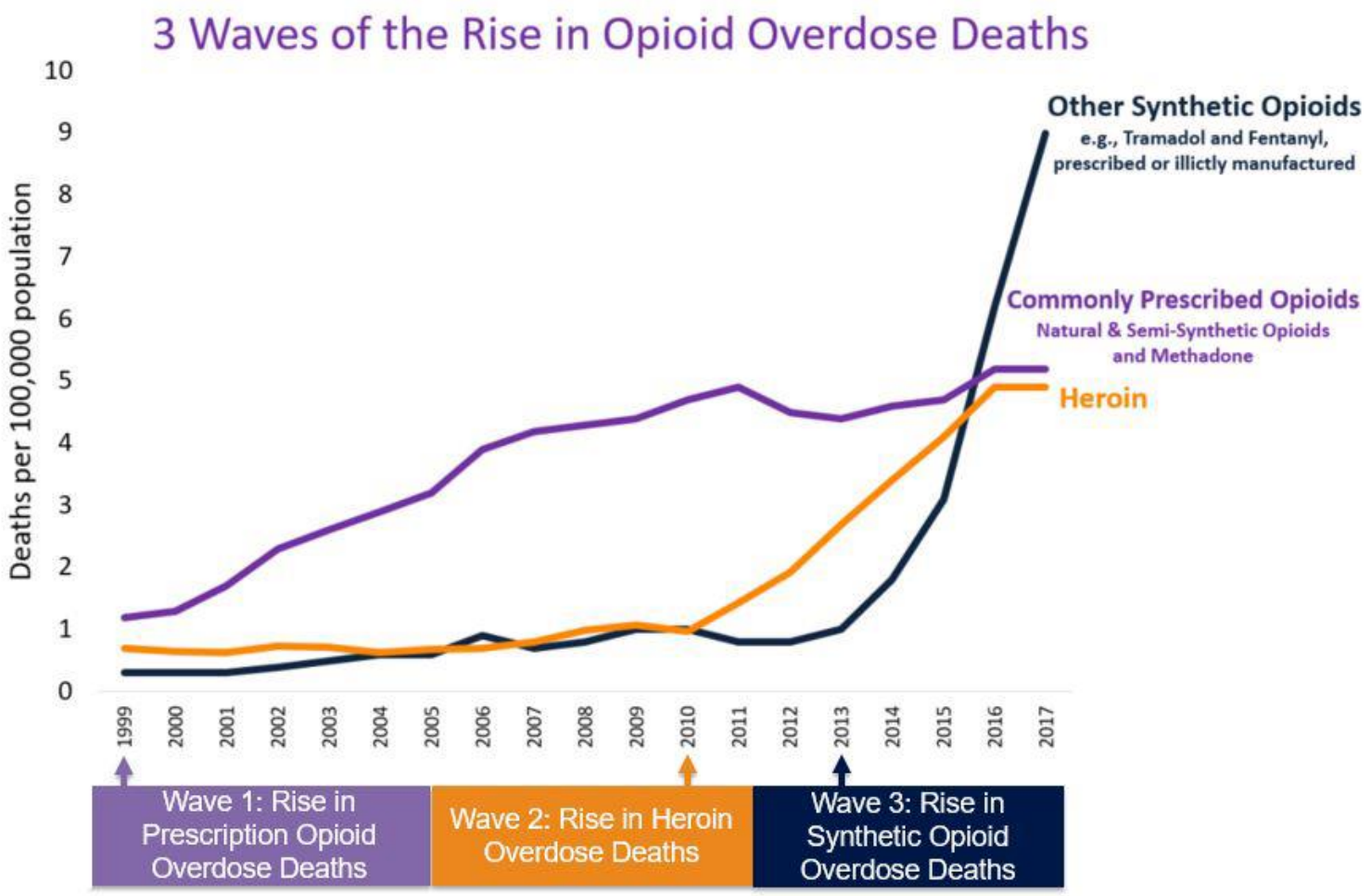


Source: : Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2017 on CDC WONDER Online Database, released December, 2018

- In addition to fatal overdose, other individual consequences include neurological damage caused by non-fatal overdose, infectious disease spread through needle sharing, and soft-tissue infection.

[1] https://injuryfacts.nsc.org/all-injuries/preventable-death-overview/odds-of-dying/

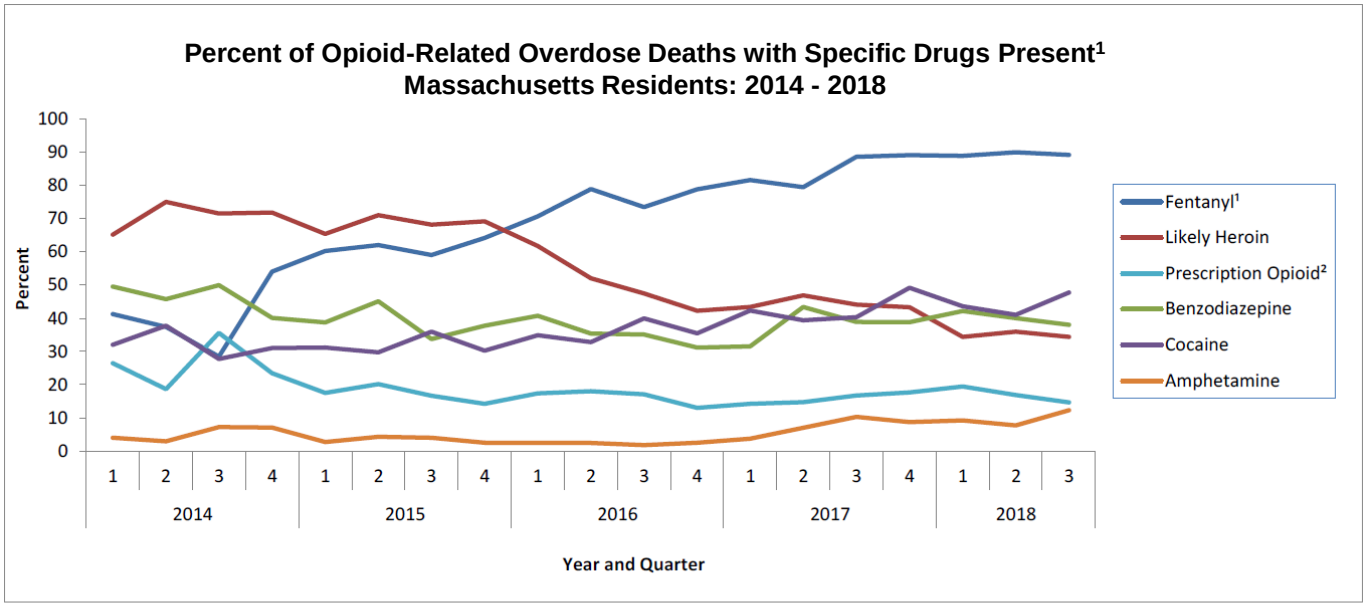
Overview of the Ongoing Opioid Crisis



SOURCE: National Vital Statistics System Mortality File.

Impact on the Commonwealth

- Massachusetts is among the top ten states with the highest rates of opioid-related overdose deaths.
- Massachusetts declared the opioid crisis a public health emergency on March 27, 2014.
- While overdose deaths in Massachusetts have declined, non-fatal overdose emergencies have increased.
- Fentanyl is present in 89% of opioid-related overdose deaths in Massachusetts.[1]



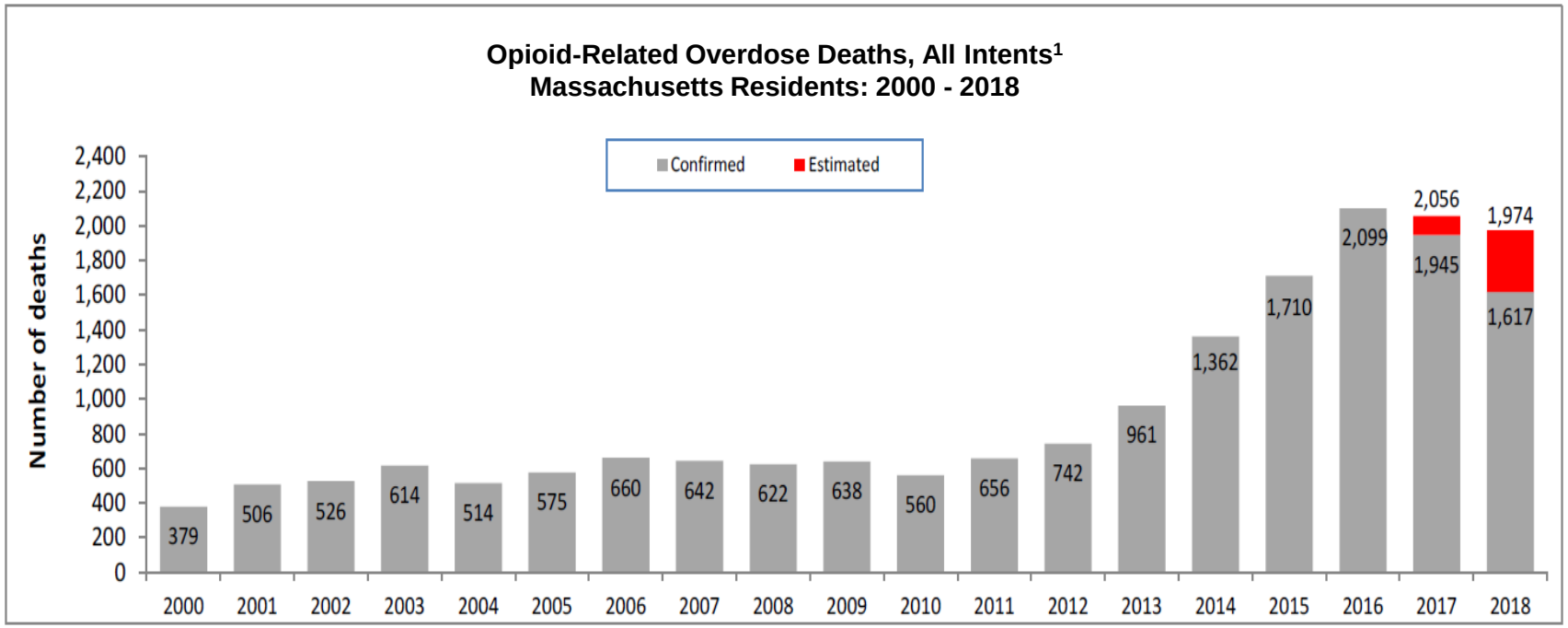
1. This is most likely illicitly produced and sold, **not** prescription fentanyl
2. Prescription opioids include: hydrocodone, hydromorphone, oxycodone, oxymorphone, and tramadol

Please note that previous estimates may change slightly as DPH routinely receives updated toxicology data from the Office of the Chief Medical Examiner and the Massachusetts State Police.

[1]Massachusetts Department of Public Health Data Brief: Opioid-Related Overdose Deaths among Massachusetts Residents (Feb. 2019)

Impact on the Commonwealth

- Opioid-related overdose deaths have declined 6% between 2016 and 2018. Only a handful of states have experienced a decline in opioid-related deaths.[1]



[1]Massachusetts Department of Public Health Data Brief: Opioid-Related Overdose Deaths among Massachusetts Residents (Feb. 2019)

Commission Overview

- The Harm Reduction Commission was established in Section 100 of Chapter 208 of the Acts of 2018.
- The Commission's full charge may be found in Appendix A. In developing its findings, the Commission was charged with reviewing the evidence base and experiences of other states/countries that have established harm reduction strategies – including supervised consumption sites – to address substance use disorder.
- The Commission's findings were to be submitted to the Legislature by February 1st, 2019. By vote of the Commission, the Senate and House Clerks were notified that the findings would be issued no later than March 1st, 2019.
- The Commission met seven times from October 2018 through February 2019. All meetings were subject to the open meeting law and minutes were taken and approved for each meeting. Copies of all presentations and reading materials requested and considered by the Commission are posted on a publicly available webpage: http://www.mass.gov/orgs/harm-reduction-commission.
- Minutes of the Commission's meetings may be found online: http://www.mass.gov/lists/harm-reduction-commission-meeting-minutes.
- An email address was created for members of the public to submit comments and questions: (EHS.HarmReductionCommission@MassMail.State.MA.US).

Harm Reduction Commission Members

Name	Title / Affiliation
Marylou Sudders (Chair)	Secretary, Executive Office of Health and Human Services, Massachusetts
Leo Beletsky, JD, MPH	Associate Professor of Law and Health Sciences, Northeastern University
Monica Bharel, MD, MPH	Commissioner, Massachusetts Department of Public Health
Deirdre Calvert, LICSW	Director of Psychotherapy, Column Health
Matilde Castiel, MD	Commissioner, Worcester Department of Public Health
Aubri Esters	Massachusetts Resident
Cindy F. Friedman	Massachusetts State Senator
Jessie M. Gaeta, MD	Chief Medical Officer, Boston Health Care for the Homeless Program
Armando Gonzalez	Massachusetts Resident
Gary Langis	Training and Technical Assistance Specialist, Education Development Center
Marc McGovern	Mayor of Cambridge
Robert Roose, MD	Chief of Addiction Medicine and Recovery Services, Trinity Health of New England
Jeffrey N. Roy	Massachusetts State Representative
Frederick Ryan	Chief of Police, Arlington Police Department (now retired)
Martin J. Walsh	Mayor of Boston

The Work of the Commission

- Based on input by individual Commission members, presentations and panel discussions were organized and delivered by individuals who are knowledgeable about subjects specified in the commission's charges (listed in full in Appendix A).

- The Commission's overall findings are based on the presentations, resources shared, and discussions that occurred during its meetings, which can be found on the Commission's webpage.

- The Commission acknowledges that its deliberations did not cover the entire scope of harm reduction that exists internationally or nationally. For example, the majority of the Commission's discussion on the efficacy of supervised consumption sites focused on facilities located in Canada. As agreed at its meeting on February 21st, the Commission did not address whether it is feasible to operate a harm reduction site in the Commonwealth.

- The following table provides a summary of all meetings, with names of presenters, topics discussed, and links to copies of all presentations. This complete list is available on the Commission's webpage.

Summary of Meetings and Input Provided to the Commission

Presenters	Topics Discussed	Resources and Supporting Documents
October 24, 2018		
Secretary Sudders Commission Chair	Discussion of the Commission's charges, members' expectations, and proposed schedule for each meeting	**Commission presentation**
November 20, 2018		
Monica Bharel, MD, MPH Commissioner, Massachusetts Department of Public Health	Existing harm reduction efforts in Massachusetts	**Commissioner Bharel's presentation**
Jessie Gaeta, MD Chief Medical Officer, Boston Health Care for the Homeless Program	Supportive Place for Observation and Treatment (SPOT)	**Dr. Gaeta's presentation**
Devin Larkin Director of the Bureau of Recovery Services, Boston Public Health Commission	City of Boston's Engagement Center and existing harm reduction services	**Director Larkin's presentation**

Summary of Meetings and Input Provided to the Commission

Presenters	Topics Discussed	Resources and Supporting Documents
December 17, 2018		
Bonnie Henry, MD, MPH Provincial Health Officer for British Columbia *(via video conference)*	Overview of Canada's supervised consumption services	**Dr. Henry's presentation**
Scott Elliott Executive Director of the Dr. Peter Centre *(via video conference)*	Overview of the Dr. Peter Centre in Vancouver, British Columbia	**Mr. Elliott's presentation**
Paul Loo Director of the Office of Controlled Substances for Health Canada *(via video conference)*	Overview of Canada's supervised consumption services	**Director Loo's presentation**
David Solet Chief Legal Counsel, Massachusetts Executive Office of Public Safety and Security	Federal and state laws pertaining to the potential operation of a harm reduction site in Massachusetts	**Mr. Solet's presentation**
Adam Chapdelaine Arlington Town Manager	Local zoning issues related to operating a harm reduction site in Massachusetts	**Mr. Chapdelaine's presentation**

Summary of Meetings and Input Provided to the Commission

Presenters	Topics Discussed	Resources and Supporting Documents
January 9, 2019		
Jessie Gaeta, MD Chief Medical Officer, Boston Health Care for the Homeless Program	Key public health research on supervised consumption sites	**Dr. Gaeta's presentation**
Leo Beletsky, JD, MPH Associate Professor of Law, Northeastern University	Legal and policy considerations related to supervised consumption sites and opportunities in harm reduction	**Professor Beletsky's presentation**
Matilde Castiel, MD Commissioner, Worcester Department of Public Health	Harm reduction approaches currently implemented in coordination with the Worcester Department of Public Health	**Commissioner Castiel's presentation**
January 28, 2019		
Paul Bowman, Sonjia, & Ralph Representatives of the Boston Users Union	The Boston Users Union members' preferences and recommendations related to harm reduction services	**Boston Users Union's presentation** **Boston Users Union's list of necessary services, best practices, and requests** **Boston Users Union's presentation overview**
Elsie Taveras, MD, MPH Executive Director of the Kraft Center for Community Health	Overview of Kraft Center for Community Health's mobile health program	**Dr. Taveras's presentation**
Marc McGovern Mayor of Cambridge	Observations from fact-finding trip to Montreal	**Mayor McGovern's presentation**

Key Definitions

Harm reduction

- A spectrum of evidence-based and evidence-informed strategies including safer use, managed use, and abstinence to meet people who use drugs (PWUD) "where they're at," preserve their dignity, and address conditions of use along with the use itself.
- There is no universal definition or formula for implementation. As harm reduction approaches and interventions should reflect specific individual and community needs, program and policy design must reflect the diversity of settings and input from all relevant stakeholders.

Supervised consumption site (SCS)*

- SCSs are a tool of harm reduction that primarily aim to reduce the acute risks of disease transmission through unhygienic injection and prevent drug-related overdose deaths. Most SCSs focus on injection drug use, however, some allow or include space for other types of consumption. Some SCSs connect individuals with addiction treatment and other health and social services. SCSs provide drug users with sterile consumption equipment and emergency care in the event of overdose.
- Safe injection facilities (SIFs) are a subset of SCSs, and are spaces where people who inject drugs (PWID) can inject pre-obtained substances in the presence of trained staff who provide clinical monitoring.
- SCSs may be free-standing, mobile, or attached to or part of another facility. SCSs tend to be located in settings that are experiencing problems of public use and primarily support sub-populations of users with limited opportunities for hygienic consumption.
- SCSs may offer additional services such as sterile injecting equipment to take home, counseling services before, during and after drug consumption, primary medical care, testing for HIV and Hepatitis C, and referral to appropriate services.

* The Legislature used the terms "harm reduction site" and "supervised drug consumption site" in its enabling statute. For the remainder of the Harm Reduction Commission's report, the term "supervised consumption site" will be used.

Key Definitions continued

Addiction*

- Addiction is a primary, chronic disease of brain reward, motivation, memory and related circuitry.
    - Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations.
    - This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors.
- Addiction is characterized by inability to consistently abstain, impairment in behavioral control, craving, diminished recognition of significant problems with one's behaviors and interpersonal relationships, and a dysfunctional emotional response.
    - Like other chronic diseases, addiction often involves cycles of relapse and remission.
- Without treatment or engagement in recovery activities, addiction is progressive and can result in disability or premature death.

* American Society of Addiction Medicine (ASAM), as cited in San Francisco Safe Injection Services Task Force final report: https://www.mass.gov/files/documents/2019/01/29/San%20Francisco%20SIS%20Task%20Force%20final%20report%20(2017).pdf

Commission's Recommendation and Overall Findings

Recommendation

In order to continue to combat the opioid crisis, the Commonwealth, in partnership with its municipalities, must foster a culture of harm reduction throughout the state and expand the array of harm reduction resources. Supervised consumption sites are an effective harm reduction tool in the countries where they have been implemented. These sites keep people who use drugs alive and help reduce the public health risks of disease transmission. These sites can also provide a safe space where people may receive harm reduction materials and linkages to other services. A pilot program of one or more supervised consumption sites should be part of the Commonwealth's efforts to combat the opioid crisis. Any pilot program must receive local approval and include a rigorous evaluation of the outcomes for individuals and impact on the surrounding area and municipality. In order to pursue a pilot program of one or more supervised consumption sites, the challenges the Commonwealth must address include any gaps in legal protections for organizations and individuals who would staff a supervised consumption site and any state criminal and civil laws that may pose a barrier. An additional challenge is the federal government's strongly stated current stance against supervised consumption sites. Action on the federal level is needed to shift policy in regards to the federal prohibitions on supervised consumption sites.

Findings

- The Commonwealth, in partnership with its municipalities, must foster a culture of harm reduction. Although there are existing harm reduction programs, there is no comprehensive statewide strategy. A strategy should be developed to expand harm reduction resources across the state, targeting areas with the highest rates of opioid-related overdoses. The strategy should have a strong education component focusing on the public at large and the health care community.

Overall Commission Findings continued

- SCSs are one type of harm reduction, with a primary goal of keeping people alive regardless of whether they choose to enter treatment.
  - Outside the U.S., there are more than 100 SCSs located in 11 countries.
  - There have been no overdose deaths reported inside existing SCSs.
  - Services offered at SCSs vary and reflect the particular characteristics of their communities.

- Legal defenses based upon states' rights and statutory interpretation, which support the establishment of a SCS, have not been tested in federal court. The U.S. Department of Justice has consistently offered the opinion that SCSs are illegal and prohibited under the Controlled Substances Act.
  - If a public or private entity in Massachusetts proceeds with developing a SCS, the entity would need to be deliberate in understanding the potential federal civil and criminal risks and liabilities in order to respond to legal repercussions.

- There is increasing attention in the United States and in the Commonwealth on SCS as a harm reduction strategy. Although some states have filed legislation, no state has enacted legislation allowing for the implementation of a SCS. Some local municipalities and counties are exploring opening a SCS (e.g. Baltimore, Denver, Philadelphia, San Francisco, Seattle/King County).

Overall Commission Findings continued

- State professional licensing, criminal, and civil laws that pose a barrier to opening a SCS will have to be amended for a SCS to operate in Massachusetts.
    - Professional licensure boards would need to revise regulations and issue appropriate guidance in order for their members to work or volunteer in a SCS.

- A number of existing harm reduction approaches and interventions are effective at reducing the risk of overdose and transmission of blood-borne diseases among PWUD and should be expanded through a statewide strategy.
    - The availability of naloxone without an individual prescription reduces the risk of opioid-related overdose.
    - The availability of sterile and safe injection equipment and syringe disposal services are effective at reducing the risk of transmission of blood-borne diseases among PWUD.
    - Fentanyl testing strips/drug-checking services are a promising harm reduction intervention.

Commission's Findings: Charge 1 and 2

1. Existing harm reduction efforts in the Commonwealth and whether there is potential for collaboration with existing public health harm reduction organizations

2. Opportunities to maximize public health benefits, including educating persons utilizing the sites of the risks of contracting HIV and viral hepatitis and on proper disposal of hypodermic needles and syringes

Findings	Presentations and Documents
Existing Commonwealth harm reduction efforts are primarily focused on increasing access to naloxone and the expansion of needle exchange programs, implementing promising practice pilots, and public awareness campaigns. Services that could be expanded as part of a comprehensive statewide strategy include, but are not limited to: • Bulk Purchasing Program • Naloxone Dispensing via Standing Order • Overdose Education and Naloxone Distribution (OEND) Program • First Responder Naloxone Grant • Post-Overdose Follow-Up with First Responders • Syringe Service Programs • Outreach program and community syringe pick up programs • Programs based upon the Supportive Place for Observation and Treatment (SPOT) model • Low threshold engagement programs • Mobile Health or Support programs • Fentanyl testing More information on the Commonwealth's efforts can be found online at: Massachusetts responds to the opioid epidemic	*See sources in Appendix B:* 4, 16, 18, 17, 55 *See a compilation of Massachusetts Community-based Harm Reduction Services in Appendix C*

Charge 1: Spotlight

Spotlight on Select Harm Reduction Programs		
Program	**Overview**	**Services Offered**
Boston Engagement Center (EC)	• Implemented by the City of Boston with support and collaboration from the Boston Public Health Commission (BPHC) Bureau of Recovery Services, Boston Health Care for the Homeless Program (BHCHP), and the Mass. Department of Public Health. • Creates a comfortable space for individuals to begin or continue engagement in services, and provide a safe, low-threshold space for neighborhood residents to spend time during the day. • Offers law enforcement, first responders, and street outreach workers a place to guide individuals in need of services and support.	• Water, snacks, coffee, and bathrooms • Medical care from BHCHP • Referral to medical care, behavioral health care, recovery services, and housing services • Fitness and writing groups • Services requested by clients, including foot care, dental care, and workforce development
Supportive Place for Observation and Treatment (SPOT)	• Implemented by BHCHP. • Offers engagement, support, and medical monitoring. • Serves as an entry point to primary care and treatment on demand for 8-10 individuals at a time who are over-sedated from the use of substances and are at high risk of overdose. • Since opening in 2016, the program has recorded over 800 unique participants in more than 7,100 encounters.	• Medical monitoring during sedation • Treatment of overdose (oxygen, IV fluids, naloxone) • Counseling on safer injection techniques • Connection to primary care, behavioral health services, and addiction treatment • Naloxone rescue kit distribution

Commission's Findings: Charge 3

3. Other harm reduction opportunities, including but not limited to, broadening the availability of narcotic testing products, including fentanyl test strips	
Findings	**Presentations and Documents**

• In the Commonwealth, distribution of fentanyl test strips is not widespread.
  ○ Fentanyl test strips are manufactured in Canada and are affordable (approx. $1 per strip). They have not been approved by the FDA, so are not available in stores.
  ○ Results from a 2018 Brown University study reported that most individuals desired to know about the presence of fentanyl before using drugs and knowing drugs contained fentanyl would lead them to modify their drug use behavior.
  ○ The *Care*ZONE currently conducts fentanyl testing.
  ○ Legislative reforms to expand drug checking services (e.g. MGL Chapter 94C, sections 1 and 32I).
 
• Availability of narcotic testing technology is limited in the Commonwealth.
  ○ Costs and liability issues present challenges to access.
 
	See sources in Appendix B:
	
	4, 12, 55

Charge 3: Spotlight

Spotlight on *Care*ZONE Program

Overview

- *Care*ZONE is a mobile health program that serves individuals not well-connected to health care, or who are experiencing homelessness, and/or living with addiction.
- In its first year of operation, the van provides services in Boston's Dudley Square, Downtown Crossing and the West End, communities with high numbers of fatal opioid overdoses *(refer to presentation).*
- The van is staffed by a team of buprenorphine-waivered doctors from Boston Health Care for the Homeless, harm reduction specialists and outreach workers from the Access, Harm Reduction, Overdose Prevention and Education (AHOPE) Program.
    - Virtual access to specialists is available (e.g., dermatologists and behavioral health).
    - The addition of recovery support staff is anticipated.
- The van operates four days a week, parking in the same spot each week.
- The van offers new syringes, collects used syringes, and distributes naloxone.
- Staff engage potential patients in the immediate surrounding areas.
- Outreach workers escort patients to nearby pharmacies to fill prescriptions for buprenorphine immediately.
- Staff can facilitate access to a Office-Based Addiction Treatment (OBAT) program and provide weekly follow-up until an in-person hand-off is made.
- *Care*ZONE is privately funded.

Commission's Findings: Charge 4

4. Alternatives and recommendations to broaden the availability of naloxone without prescription	
Findings	**Presentations and Documents**

• Established in 2015 for municipalities and state agencies purchasing naloxone, the Commonwealth's Municipal Bulk Purchasing Program provides naloxone at a reduced cost.
  ○ Since FY16, 177 municipal entities have purchased naloxone through the Municipal Bulk Purchasing Program.
  ○ In FY19, legislation expanded the program so other groups, including non-profit organizations that contract with the DPH Bureau of Substance Addiction Services and the DOC Houses of Correction, can purchase naloxone at a reduced cost.
• Chapter 208 of the Acts of 2018 expanded access to naloxone in Massachusetts, authorizing a single statewide standing order rather than requiring each pharmacy to secure and file one.
• All retail pharmacies located in Massachusetts and licensed by the Board of Pharmacy must stock naloxone.
	See sources in Appendix B:
	4, 11

Commission's Findings: Charge 5 and 6

5. The potential public health and public safety benefits and risks of harm reduction sites

6. Ways to support persons utilizing the sites who express an interest in seeking substance use disorder treatment, including providing information on evidence-based treatment options and direct referral to treatment providers

Findings	Presentations and Documents
• Supervised consumption sites are established with a primary goal of harm reduction and keeping people alive. • There have been no overdose deaths reported inside existing supervised consumption sites. • There is access to sterile, safe injection and smoking equipment (a variety of syringes, wipes, tourniquets, pipes) for safe consumption, syringe disposal services, harm reduction information, as well as HIV and hepatitis C education. • Supervised consumption sites provide safe spaces for PWUD to use without fear of abuse or harassment.	*See sources in Appendix B:* 17, 22, 28, 29, 45, 52, 63, 64

Commission's Findings: Charge 5 and 6 continued

5. The potential public health and public safety benefits and risks of harm reduction sites

6. Ways to support persons utilizing the sites who express an interest in seeking substance use disorder treatment, including providing information on evidence-based treatment options and direct referral to treatment providers

Findings	**Presentations and Documents**
• Supervised consumption sites may serve as entry points for treatment, but that is not their primary purpose. ○ According to studies completed in Vancouver, Canada and Sydney, Australia, SCS attendance was associated with an increase in PWUD seeking addiction treatment options. • There is evidence that the neighborhood burden of drug use (e.g., public injections, discarded syringes, injection-related litter) is lessened after the establishment of a harm reduction site, especially when paired with outreach workers and syringe pick-up programs.	*See sources in Appendix B:* 17, 22, 28, 29, 45, 52, 63, 64

Charge 5 and 6: Spotlight

Spotlight on Comparison of Harm Reduction Initiatives and Opioid and Overdose Data by City/State					
Indicator		**Boston**	**Massachusetts**	**Montreal**	**Toronto**
Population		685,094 (2017)	6.86 million (2017)	1.70 million (2017)	2.92 million (2017)
Supervised consumption sites		0	0	4 (incl. 1 mobile unit)	9
Opioid-related overdose deaths		191 (Boston Residents) 272 (ODs occurred in Boston)	1,938 (MA Residents) 2,013 (ODs occurred in MA)	95 (2017)	308 (2017)
Syringe service programs (SSPs)		1 program operating in two sites	24 operating 27 approved	4 programs (178 Injection Equipment Access Centres[1])	47 programs
No. of engagements at SSPs[2]		Over 20,000	Over 56,000	N/A	120,000
No. of syringes distributed		710,282 (2018)	1.46 million (2018)	1.29 million (2017)	2.47 million (2018)
No. of naloxone kits distributed		16,927 (2018)	44,480 (2018)	7,838[3] (2017)	20,217 (2017)
HIV	**# of new cases**	141 (2015)	627 (2015)	318[4] (2015)	500 (2017)
	rate per 100,000	20.58 (2015)	9.14 (2015)	18.71 (2015)	17.12 (2017)
Hepatitis C	**# of new cases**	875[5] (2018)	7,766[5] (2018)	1,073 (2015)	694 (2017)
	rate per 100,000	127.72 (2018)	113.21 (2018)	63.12 (2015)	23.77 (2017)

[1] Injection equipment access centres (CAMIs) are places where people who use drugs can obtain new injection equipment anonymously
[2] These numbers include duplicate engagements at SSPs.
[3] Total distributed in Quebec; Montreal data is not available yet.
[4] Average for 2011-2015
[5] This is a count only of newly reported cases, not prevalent cases. These numbers represent people who were able to access care, received testing for HCV and for whom those test results were reported to MDPH. This data is current as of 11/20/18 and is subject to change.

Commission's Findings: Charge 7

7. Appropriate guidance that would be necessary and required for professional licensure boards and any necessary changes to the regulations of such boards	
Professional Licensure Board Findings	**Presentations and Documents**
Board of Registration in Medicine Findings • Legislation would be required pertaining to the "good moral character" provision. • Physicians would be liable and subject to discipline for violation of federal and state laws. • Exemption from criminal persecution would be required. • Legislation would be required pertaining to potential violation(s) of the standard of care. • Discipline for violation of state law and regulation regarding the practice of medicine should be anticipated. • Amendment of Board policy on "Prescribing Practices Policy and Guidelines" would be required. **Board of Registration in Nursing Findings** • Potential waiver or exemption related to asepsis and infection control may be required. • Legislation would be required to make otherwise illegal behavior lawful. • Legislation would be required to waive or exempt aiding and abetting. • Legislation would be required to allow nurses to administer medications outside of prescribing orders. • Legislation would be required to provide civil and professional immunity to align with Good Samaritan provisions. **Board of Registration of Social Workers Findings** • Violation of federal law could result in disciplinary action due to unethical conduct. • There must be considerations around informed consent of an individual who may be under the influence of a substance.	*See sources in Appendix B:* 42, 43, 44

Commission's Findings: Charge 8

8. The potential federal, state and local legal issues involved with establishing harm reduction sites	
Findings	**Presentations and Documents**
Federal Legal Issues Federal law prohibits the possession of controlled substances not obtained directly, or pursuant to a valid prescription or order, from a practitioner (21 U.S.C. Sec. 844). • Federal law prohibits the use of any place to open, lease, rent, use, or maintain any place for the purpose of using any controlled substance, which includes owners, lessees, agents, employees, or occupants (21 U.S.C. Sec. 856). • In August 2018, then Deputy US Attorney General Rod Rosenstein stated that "cities and counties should expect the Department of Justice to meet the opening of any consumption site with swift and aggressive action." The US Attorney for the District of Massachusetts, Andrew Lelling, has made similar statements. • The courts have not reviewed the Department of Justice's interpretation of the Controlled Substances Act (CSA) with regard to supervised consumption sites. A case is now pending in Philadelphia. • The CSA provides immunity to tribal, or local officers "lawfully engaged in the enforcement of any law or municipal ordinance relating to controlled substances." (21 USC Sec. 885(d)). While this applies primarily to drug investigations, it could form the basis for a defense if local or state law authorizes harm reduction sites.	*See sources in Appendix B:* 9, 31, 33, 34, 46, 65

Commission's Findings: Charge 8

8. The potential federal, state and local legal issues involved with establishing harm reduction sites	
Findings	**Presentations and Documents**
Federal Legal Issues continued • Even if state law is changed, a locality/entity that establishes a SCS may have to defend a federal lawsuit. Federal prosecutors have publicly indicated that they will not use prosecutorial discretion to allow a SCS. • When medical marijuana statutes were enacted, Courts continued to uphold the validity of the Controlled Substances Act (CSA). It took 20+ years of voter approved referenda across more than 30 states to impact federal policy on the enforcement of the CSA against individuals involved in the medical marijuana industry. **State Legal Issues** • State criminal laws parallel those at the federal level related to illegality of possession, distribution, aiding and abetting, and forfeiture of property. • Protections for organizations and individuals who would staff a SCS, including licensed professionals and non professionals, would need to be established by the Legislature. • Offsite personal injury or property damage may leave sites vulnerable to tort law action.	*See sources in Appendix B:* 9, 31, 33, 34, 46, 65

Appendix A: Legislative Mandate

CHAPTER 208, SECTION 100 OF THE ACTS OF 2018

There shall be a harm reduction commission to review and make recommendations regarding harm reduction opportunities to address substance use disorder.

The commission shall consist of 15 members: the secretary of health and human services or a designee, who shall serve as chair; the commissioner of public health; the house and senate chairs of the joint committee on mental health, substance use and recovery or their designees; the mayor of the city of Boston or a designee; the mayor of the city of Cambridge or a designee; a representative from the Massachusetts Medical Society; a representative from the Massachusetts Health and Hospital Association, Inc.; and 7 members appointed by the secretary, 2 of whom shall be persons with a substance use disorder, 1 of whom shall be a clinician with experience providing direct care to individuals with a co-occurring mental health and substance use disorder, 1 of whom shall be a person working in an established harm reduction program providing direct support to persons with substance use disorders, 1 of whom shall be a representative of the Massachusetts Chiefs of Police Association Incorporated, 1 of whom shall have expertise in relevant state and federal law and regulation and 1 of whom shall be a representative of local municipal boards of health. In making appointments, the secretary shall, to the maximum extent feasible, ensure that the commission represents a broad distribution of diverse perspectives and geographic regions.

As part of its review, the commission shall consider:

(i) the feasibility of operating harm reduction sites in which (A) a person with a substance use disorder may consume pre-obtained controlled substances, (B) medical assistance by health care professionals is made immediately available to a person with a substance use disorder as necessary to prevent fatal overdose, and (C) counseling, referrals to treatment and other appropriate services are available on a voluntary basis;

(ii) the potential public health and public safety benefits and risks of harm reduction sites;

(iii) the potential federal, state and local legal issues involved with establishing harm reduction sites;

(iv) appropriate guidance that would be necessary and required for professional licensure boards and any necessary changes to the regulations of such boards;

(v) existing harm reduction efforts in the commonwealth and whether there is potential for collaboration with existing public health harm reduction organizations;

(vi) opportunities to maximize public health benefits, including educating persons utilizing the sites of the risks of contracting HIV and viral hepatitis and on proper disposal of hypodermic needles and syringes;

(vii) ways to support persons utilizing the sites who express an interest in seeking substance use disorder treatment, including providing information on evidence-based treatment options and direct referral to treatment providers;

(viii) other harm reduction opportunities, including but not limited to, broadening the availability of narcotic testing products, including fentanyl test strips;

(ix) alternatives and recommendations to broaden the availability of naloxone without prescription; and

(x) other matters deemed appropriate by the commission.

In developing its report, the commission shall review the experiences and results of other states and countries that have established supervised drug consumption sites and other harm reduction strategies and report on the impact of those harm reduction sites and strategies.

The commission shall submit its findings and recommendations to the clerks of the senate and the house of representatives, the joint committee on mental health, substance use and recovery, the joint committee on public health, the joint committee on the judiciary and the senate and house committees on ways and means not later than February 1, 2019. The secretary shall also make the report publicly available on the executive office of health and human services' website.

Appendix B: Resources Reviewed by the Commission

October 24, 2018

1. Harm Reduction Commission presentation.
2. Massachusetts Department of Public Health Chapter 55 Data Brief. (2017) "An Assessment of Opioid-Related Overdoses in Massachusetts 2011-2015 (2017).
3. Massachusetts Department of Public Health Opioid-related Overdose Deaths among MA Residents (August 2018).
4. Briefer on Massachusetts harm reduction efforts.
5. Briefer on supervised injection facilities in other countries.
6. Legal Overview of SIF in US 2008.
7. Massachusetts Medical Society Task Force on Opioid Therapy and Physician Communication Report (2017).
8. New York City Department of Health and Mental Hygiene: Overdose Prevention in New York City: Supervised Injection as a Strategy to Reduce Opioid Overdose and Public Injection (2018).
9. Briefer on supervised legal challenges and status of supervised injection facilities legislation in key states.
10. Press announcement regarding Governor Brown's veto of pilot supervised injection legislation.
11. Press announcement regarding the Baker-Polito administration expansion of naloxone access (10/18/2018).
12. WBUR article. "Fentanyl Test Strips Reduce Risk Of Overdose In Small Study" (10/18/2018).

Appendix B: Resources Reviewed by the Commission

November 20, 2018

13. Harm Reduction Commission Presentation.
14. Harm Reduction Commission Meeting Agenda.
15. Massachusetts Department of Public Health Opioid-related Overdose Deaths among MA Residents (November 2018).
16. Presentation from Monica Bharel, MD, MPH on harm reduction efforts in Massachusetts.
17. Presentation from Jessie Gaeta, MD on Boston Health Care for the Homeless Program's SPOT program.
18. Presentation from Devin Larkin on the City of Boston's Engagement Center.
19. Briefer on international supervised injection facility models.
20. List of supervised injection facilities and overdose prevention sites operating in Canada.
21. Leon, C. et al. (2017) Changes in public order after the opening of an overdose monitoring facility for people who inject drugs. International Journal of Drug Policy 53 (2018) 90–95.
22. Leon, C. et al. (2017) The willingness of people who inject drugs in Boston to use a supervised injection facility. Substance Abuse, V. 39.
23. Ropes & Gray supervised injection facility memorandum regarding a legal framework for proposed pilot program to research supervised injection facilities in New York State (2017).
24. European Monitoring Centre for Drugs and Drug Addiction. Drug consumption rooms: an overview of provision and evidence (2018)
25. Scheim, A., Werb, D. (2018) Integrating supervised consumption into a continuum of care for people who use drugs. CMAJ;190:E921-2.

Appendix B: Resources Reviewed by the Commission

December 17, 2018

26. Harm Reduction Commission Presentation.
27. Harm Reduction Commission Meeting Agenda.
28. Presentation from Bonnie Henry, MD, MPH on supervised injection facilities and harm reduction in British Columbia.
29. Presentation from Paul Loo on supervised consumption services in Canada.
30. Presentation from Scott Elliott on the Dr. Peter Centre.
31. Presentation from David Solet on the federal and state legal landscape related to supervised injection.
32. Presentation from Adam Chapdelaine on the local zoning laws relevant to supervised injection.
33. United States Attorney's Office. Joint Statement of the US Attorney's Office and the Denver Field Office of the Drug Enforcement Agency (12/4/2018). 2018).
34. Article from Governing.com. "Feds threaten jail for opening a supervised injection site in America" (Dec. 2018).
35. Canadian HIV/AIDS Legal Network. Overdue for a change: Scaling up supervised consumption services in Canada (2018).
36. AIDS United Report. Bringing Safer Consumption Spaces to the United States (2018)
37. Briefer on legal status of supervised injection legislation in key states.

Appendix B: Resources Reviewed by the Commission

January 9, 2019

40. Harm Reduction Commission Presentation.
41. Harm Reduction Commission Meeting Agenda.
42. Massachusetts Board of Registration in Medicine Response to the Harm Reduction Commission (2018)
43. Massachusetts Board of Registration in Nursing Response to the Harm Reduction Commission (2018)
44. Massachusetts Board of Registration of Social Workers response to the Harm Reduction Commission (2018)
45. Jessie Gaeta, MD presentation on supervised injection research.
46. Leo Beletsky, JD, MPH presentation on legal and policy perspectives on supervised injection and harm reduction.
47. Mattie Castiel, MD presentation on harm reduction opportunities in Worcester.
48. Wall Street Journal (1/2/2019). Fentanyl's New Foe: A Quick Test Strip That Can Prevent Overdoses.
49. Harm Reduction Wish List (2018)

Appendix B: Resources Reviewed by the Commission

January 28, 2019

50. Harm Reduction Commission Meeting Presentation.
51. Harm Reduction Commission Meeting Agenda.
52. Boston Users Union Presentation.
53. Boston Users Union Best Practices and Requests.
54. Boston Users Union Presentation Overview.
55. Presentation from Elsie Taveras, MD, MPH on CareZONE.
56. British Columbia Coroners Report - Overdose Deaths (2018).
57. Gaeta, J., Bock, B., Takach, M. (2016) Providing A Safe Space And Medical Monitoring To Prevent Overdose Deaths. Health Affairs Blog.
58. Professor Beletsky cover memo to the Harm Reduction Commission (1/14/2019).
59. Oviedo, E. et al. (2016) Hydromorphone Compared With Diacetylmorphine for Long-term Opioid Dependence: A Randomized Clinical Trial.
60. Strang, J. et al. (2015) Heroin on trial: systematic review and meta-analysis of randomised trials of diamorphine-prescribing as treatment for refractory heroin addiction. JAMA Psychiatry. 2016;73(5):447-455
61. San Francisco Safe Injection Services Task Force - Final Report (2017).
62. New York State legislation regarding supervised injection facilities (2017)
63. Potier, C. et al. (2014) Supervised injection services: What has been demonstrated? A systematic literature review.
64. Marc McGovern - Harm Reduction Strategies in Montréal.
65. US Attorney Lelling's op-ed in The Boston Globe (1/28/2019)
66. RAND Corporation Research Report (2018) Considering Heroin-Assisted Treatment and Supervised Drug Consumption Sites in the United States

Appendix C: MA Community-based Harm Reduction Services*

Access to Sterile Syringes	• Syringes can be legally purchased and possessed. • Anyone can purchase syringes at pharmacies. There are no limits on the quantity or type of syringes that can be purchased. • Pharmacies are strongly encouraged all pharmacies to stock single unit-of-use syringes. • There is no age limit to purchase syringes.

Bulk Purchasing of Naloxone	• Discount bulk purchasing of naloxone is available through the state.
	  ○ Available to all police, fire, and Sherriff's Departments.
	  ○ Since FY16, 177 organizations have purchased through the program.
	• Adapt Pharma (manufacturer of naloxone) offers the public interest price bulk purchasing to qualified programs.

Condom Distribution	• There are publically funded condoms distributed to providers upon request. In FY18, 110 agencies received condoms.
Distribution of risk reduction materials (bleach kits)	• There are publically funded kits distributed to providers upon request. In FY18, 41 agencies received kits.
Drug checking	• There are some prevention programs that distribute fentanyl test strips to program participants.
Good Samaritan law	• State social media campaign and other limited print materials educate the general public.
Harm reduction educational materials development and distribution for persons who inject drugs (PWID)	• DPH "Stop an Overdose" Pamphlet and other materials are available through the Massachusetts Health Promotion Clearinghouse • The Harm Reduction Coalition makes materials available online.
Integrated HIV/HCV/STI testing for PWID	• Integrated screening exists in DPH funded programming including those programs that provide services to PWID.

**This is a compilation of private and public-funded services*

Appendix C: MA Community-based Harm Reduction Services*

Knock and Talk/ Post Overdose Follow-up	• There are seven Post Overdose Follow-Up with First Responders programs. • BMC recently received federal funding to conduct a statewide assessment of public health/public safety partnerships in post-overdose programming; several municipalities have received federal funding, private funding and other state agency funding for local post-overdose follow-up programs. • In 2016, there were at least 23 municipalities that had either a fire, police, or EMS post-overdose follow-up program
Linkage to HIV, HCV and STI treatment for PWID	• Referrals and referral agreements exist in DPH funded services including those programs that provide services to PWID.
Linkage to substance use disorder (SUD) treatment	• Linkage and/or referral to SUD treatment exists within DPH funded programs. • New low-threshold opioid agonist therapy (OAT) sites are being implemented.
Low-threshold opioid agonist therapy (OAT)	• Boston Medical Center Opioid Urgent Care Center and Bridge Clinic • Expansion of low threshold OAT has been awarded to Spectrum, Northeast Additions Treatment Center (NEATC), Behavioral health Network (BHN). • Expansion of OAT in Hoc is currently under development. • MGH Bridge Clinic, Kraft CareZONE van, Greater Lawrence Family Health Center van; Lynn Community Health Center outreach
Naloxone education and distribution	• 24 program sites provide Overdose Education and Naloxone Distribution (OEND). This includes all SSPs operated by local boards of health. o In FY18, 44,480 kits (88,960 doses) distributed by DPH to OEND programs. • Municipal initiatives partner with the Police Assisted Addiction and Recovery Initiative (PAARI) to distribute naloxone. • Family and other support groups (e.g. Learn to Cope) distribute naloxone.
Non-occupational post-exposure prophylaxis (nPEP)	• Available at certain clinical sites and funded for those with no insurance coverage through the Integrated Drug Assistance Program (IDAP). • Emergency rooms are general points of access .

**This is a compilation of private and public-funded services*

Appendix C: MA Community-based Harm Reduction Services*

Police Assisted Addiction Recovery Initiative (PAARI)	• PAARI supports recovery coach post overdose follow-up with first responders. • PAARI exists in 112 member police departments in Massachusetts. 73 of the 112 have a post-overdose outreach program.
Pharmacy Access Naloxone	• A statewide standing order exists to access naloxone at pharmacies. • Public information campaigns promote pharmacy access to naloxone. • Coverage by MassHealth and increasing insurance coverage by commercial carriers.
Pre-Exposure Prophylaxis (PrEP) for PWID	• Limited provider uptake, and barriers to treatment for PWID due to potential for lack of stable infrastructure. • Participants in SSPs have requested access to PrEP to prevent the transmission of HIV; few SSPs have funding to incorporate this clinical service into current programming.
Safe Syringe Disposal	• More than 200 sharps disposal sites exist or events occur across the state. Some private facilities have sharps disposal, primarily in restrooms.
Supportive Place for Observation and Treatment (SPOT)	• One program exists in Boston.
Supervised consumption sites	• None exist in Massachusetts.

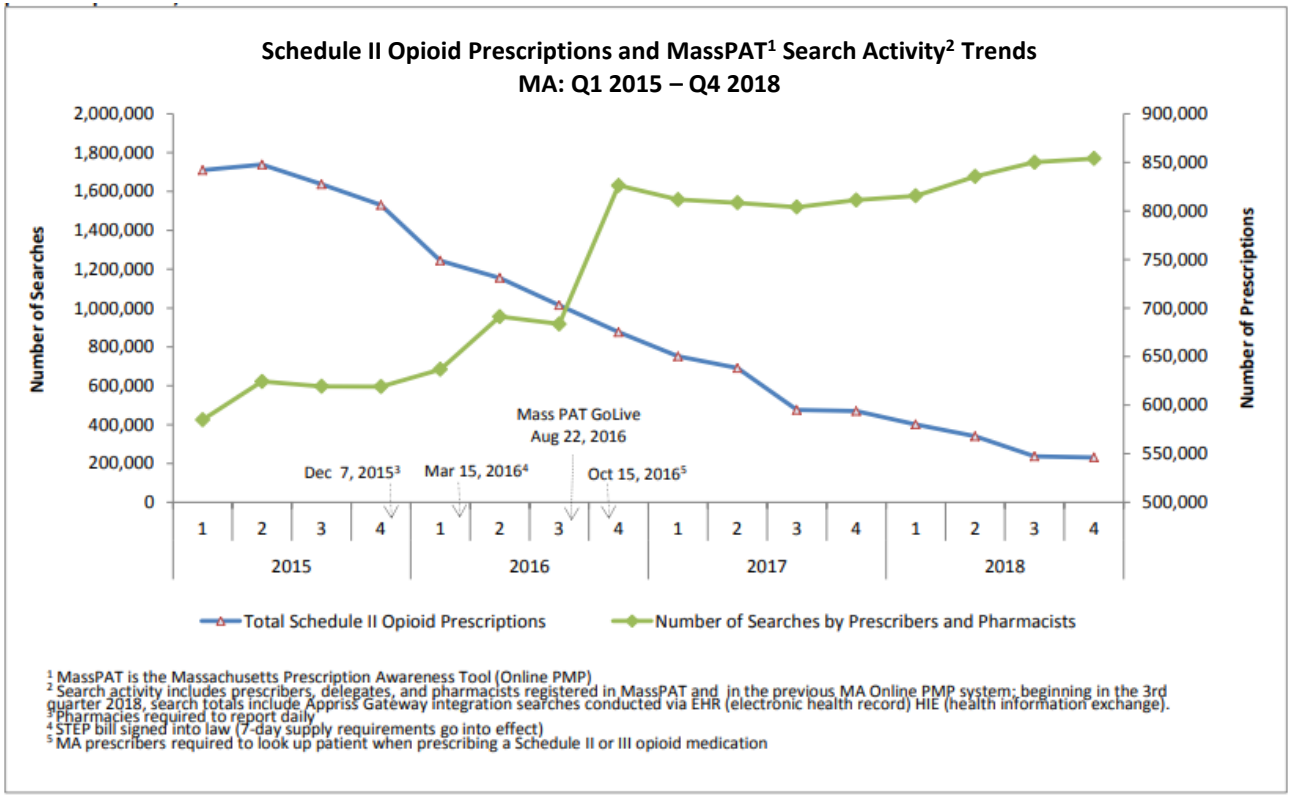
Syringe Services Programs (SSPs) (Needle Exchanges)	• 25 SSPs operate across the state.
	  o 24 SSPs are approved by local boards of health and receive public funding. Services include Overdose Education and Naloxone Distribution (OEND), sterile syringes, referrals to drug treatment and other services.
	  o One SSP is privately funded and allowed to operate per a Supreme Judicial Court decision.

Training for First Responders in Medically Assisted Treatment (MAT), OEND, SSP and other referrals	• DPH is developing a training for first responders.
Training in harm reduction practices for direct care providers serving PWID	• DPH is developing a training for front line staff.
Vein and wound care	• Limited capacity—some SSPs have clinical capacity to provide vein and wound care and/or referrals to appropriate clinical providers.

**This is a compilation of private and public-funded services*

Appendix D: Prescription Monitoring Program (PMP)[1]

- As of October 15, 2016, all Prescribers of Schedule II-III prescriptions are required to check the Massachusetts Prescription Awareness Tool (MassPAT) before prescribing a Schedule II-III prescription.
- More than 14 million searches have been completed.
- There was a 35% decline in opioid prescriptions from the first quarter of 2015 to the fourth quarter of 2018.



[1]Massachusetts Department of Public Health Data Brief: Opioid-Related Overdose Deaths among Massachusetts Residents (Feb. 2019)

Appendix E: Additional Resources Shared by Individual Members after 1/30/19, but not Reviewed by the Entire Commission

- Abell Foundation Report "Safe Drug Consumption Spaces: A Strategy for Baltimore City" (2017)
- *Canada v. PHS Community Services Society et al.,* 2011 SCC 44, 3 SCR 134, File No.: 33556. (2011).
- Complaint for Declaratory Judgment filed in the Eastern District of Pennsylvania, *United States v. Safehouse et al., Case 2:19-cv-00519-GAM*, February 5, 2019.
- Rhode Island's Narcotic Testing Product Statute, enacted July 2, 2018. *See* RI ST § 21-28.9-3.1, located at http://webserver.rilin.state.ri.us/statutes/title21/21-28.9/21-28.9-3.1.htm.
- Sections 1 and 32I of Chapter 94C of the Massachusetts General Laws, located at:

  https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXV/Chapter94c/Section1
  https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXV/Chapter94c/Section32i
- Additional Research Studies, printed on March 1, 2019 from https://paperpile.com/shared/wL5ZDg
- American Medical Association (AMA) statement: AMA wants new approaches to combat synthetic and injectable drugs, June 12 ,2017, located at: https://www.ama-assn.org/press-center/press-releases/ama-wants-new-approaches-combat-synthetic-and-injectable-drugs.

Appendix F: Comments Received from Commission Members on Commission's Last Draft

Comments received from Leo Beletsky, JD, MPH

Slide 5: Replace "overdose deaths in MA have declined" with "overdose deaths in MA **appear to be levelling off**" or "overdose deaths in MA **appear to be declining**"
Explanation: The downward trend observed to date is not statistically-significant and therefore the proposed language is misleading. See the DPH quarterly report for last quarter of 2018, demonstrating that the confidence intervals for the year-over-year trends are overlapping, which evidences that the observed decline could be due to chance and/or within the margin of error.

Slide 6: Same comment as item 1 above

Slide 8: My official title is "Associate Professor of Law **and Health Sciences**"

Slide 13: a. Replace "a spectrum of evidence-informed strategies" with "a spectrum of **evidence-based and** evidence-informed strategies"
Explanation: there is overwhelming amount of published evidence that supports positive impact of SCS. Interventions based on this evidence have replicated prior experience of positive impact. This evidence is not "emerging," as suggested by the term "evidence-informed."

b. Replace "Because harm reduction approaches and interventions reflect specific individual and community needs, there is no universal definition or formula for implementation" with "Because harm reduction approaches and interventions reflect specific individual and community needs, **program and policy design must reflect the diversity of settings and input from relevant stakeholders**."

Explanation: As written, this statement is not accurate as a general matter. There are, in fact, numerous established best practices and guidelines in harm reduction policy and practice, including those articulated by the CDC and NASTAD.

c. Replace "SCSs tend to be located in settings that are experiencing problems of public use and primarily support sub-populations of users with limited opportunities for hygienic injection" with "**SIFs** tend to be located in settings that are experiencing problems of public use and primarily support sub-populations of users with limited opportunities for hygienic injection"

Slide 14: Add bullet point: "Under established clinical definition, addiction/severe substance use disorder is characterized by continued compulsive use despite negative consequences."
Explanation: DSM 5 and every preceding definition includes the "despite negative consequences" element; its significance is high, because many policy approaches attempt to regulate problematic substance use through negative consequences, missing the very core of this definition.

Appendix F: Comments Received from Commission Members on Commission's Last Draft

Comments received from Leo Beletsky, JD, MPH

Slide 15: a. Recommendations are customarily offered as a list, with bulleted or numbered points. Suggest revising based on that framework.
b. Replace "In order to continue to combat the opioid crisis, the Commonwealth, in partnership with its municipalities, must create a culture of harm reduction throughout the state and expand the array of harm reduction resources" with "In order to continue to combat the opioid crisis, the Commonwealth, in partnership with its municipalities, must create a culture of harm reduction throughout the state and expand the array of harm reduction resources**; those harm reduction measures should include SCS and other evidence-based and evidence-informed approaches.**"
Explanation: The Commission must articulate its stance on SCS in its recommendations. Failure to do so is a dereliction of its statutory mandate. We also need to include other measures among the recommendations, since that was the stated statutory mandate.
c. Replace "In order to pursue a pilot program of one or more supervised consumption sites, there are several challenges the Commonwealth must address, including enacting legal protections for organizations and individuals who would staff a supervised consumption site and amending any state criminal and civil tort laws that may pose a barrier" with "In order to pursue a pilot program of one or more supervised consumption sites, there are several challenges the Commonwealth must address, including enacting legal protections for organizations and individuals who would staff a supervised consumption site and amending **any** state criminal and civil **tort** laws that may pose a barrier."
Explanation 1: "any state criminal and civil" creates an impression that ALL state criminal and civil laws that pose ANY barrier must be amended. That sets an insurmountably high bar; few harm reduction or other public health programs currently in operation meet this standard. Simply saying that the legal barriers is sufficient. 2. The term "tort" is a legal term of art that would apply in this context to personal injury or other related issues and so doesn't apply to licensing or other issues. It is not accurate and should be redacted.
d. Replace "Congressional action is needed to amend current federal law that prohibits supervised consumption sites" with "Federal policy opposing SCS needs to shift.
Explanation: This statement is inaccurate. Federal law does not explicitly prohibit SCS (this is a matter of statutory interpretation and other legal arguments we discussed). Also, Federal policy shift can occur on legislative, judicial or executive levels, so Congressional action is not actually imperative.
e. Somewhere in the Recommendations, there should be a statement that state legislation is needed to put SCS operations in Mass on the strongest legal footing and confer the strongest legal protections for Mass clients and providers.
f. Somewhere in the Recommendations, there should be a strong statement that SCS and other harm reduction measures are a key element of the emergency public health response.

Slide 16: a. It is puzzling that the US Department of Justice is offered as the heading here, since the content addresses both federal and state legal issues. Suggest replacing with "Legal barriers to implementation of SCSs should be addressed in order to maximize the viability, sustainability, and positive impact of these programs"

Appendix F: Comments Received from Commission Members on Commission's Last Draft

Comments received from Leo Beletsky, JD, MPH

Slide 16: b. Replace "The U.S. Department of Justice has made it clear that SCSs are illegal and prohibited under the Controlled Substances Act" with "The U.S. Department of Justice has made it clear **that it considers** SCS to be prohibited under the Controlled Substances Act.
Explanation: Interpretation of federal law is the function of the judicial branch. US DOJ can opine on how they interpret the law, but those opinions are not determinative.
c. Replace "civil tort laws" with "civil laws" (see item above)
d. For the "Legal issues" heading, add the following bullet point: "**Policy innovation in Massachusetts and elsewhere has, at times, proceeded in the face of federal opposition, including in areas of drug policy (e.g. cannabis legalization), immigration policy (e.g. sanctuary cities), and other domains.**"
e. Under "existing harm reduction approaches," add the following bullet point: "**Other harm reduction strategies, including injectable opioid agonist therapy and drug-checking services should be considered as part of the Commonwealth's emergency response to the current overdose crisis**."

Slide 19: Under "Availability of…" add the bullet point: "**State reform in criminal and civil laws is needed to facilitate the expansion of drug-checking services**"
Explanation: state criminal law currently considers this technology drug paraphernalia

Slide 22: Replace "Supervised consumption sites are established with a primary goal of harm reduction and keeping people alive" with "Supervised consumption sites are established with a primary goal of harm reduction and keeping people alive **and empower them to make healthy choices**."

Slide 24: a. Strongly object to the characterization of these findings as being the findings of the Commission. It should be clear that these are opinions submitted by the relevant Boards. Some of these are not, in fact, accurate as noted below.
b. Issue with "persons who are knowingly present where heroin is kept." Has already been addressed and does not require legislation. Aubri has already rightly mentioned this.
c. From a legal perspective, it is not at all clear what "Legislation would be required to make otherwise illegal behavior (possession of a controlled substance) lawful" is referring to. Nurses working at SCS would not be in possession of controlled substance and therefore not subject to liability from the same. Perhaps the Board is not aware what the operational scope of SCS would be.
d. Same goes for "Legislation would be required to allow nurses to administer medications outside of prescribing orders."

Slide 25: a. Strongly object to the exclusion of articulated legal arguments, legal history, and legal interpretation made in support of SCS. Presenting only the arguments against, but not arguments in support could make this report vulnerable to charges of bias.
b. At a minimum, suggest amending the last bullet point to: "**A number of statutory interpretation, state rights, and other legal theories exist in support of SCS against adverse federal action based on the Controlled Substances Act**. For instance, The CSA provides immunity …."

Appendix F: Comments Received from Commission Members on Commission's Last Draft

Comments received from Aubri Esters

General: We recommend that two or more pilot safe consumption sites be established in Massachusetts as soon as possible to reduce unnecessary overdoses and related deaths in our communities.

Harm Reduction is a philosophy regarding the choice of engaging in levels of harms in life that applies to many non-drug related activities. Common examples include wearing seat belts, getting vaccinated, clearing roads of ice during winter weather, etc…

When referring to harm reduction as it relates to substance use it is a practice that offers EVIDENCE-BASED public health approaches.

Slide 14: Remove ***"Spiritual Manifestations"*** (This is the 21st century – not the age of spirits and spiritualism. This in no way relates to people who use drugs or to chaotic substance use even and I'm embarrassed something like this would be even *considered* appropriate to have added in a document from the state EOHHS)

Substance dependence and substance use is NOT the same as a substance use disorder.

Dependence and use of substances has been common through the history of humanity and consumption in and of itself is not pathological.

Slide 15: The need for "amending state criminal laws" is also not true. This suggests that all possession, property and paraphernalia laws would need to be changed before a SCS could be sited? Not the case for cannabis, syringe exchange, or drug testing.

Congressional action ***MAY*** be needed to amend federal law – **this IS NOT DEFINITE** and is still an unknown. Assuming that the US Congress would need to intervene in a local and state public health response to a health emergency is an ENORMOUS assumption that is stretching the boundaries of what this commission was tasked with.

FEDERAL OBJECTIONS, need to be "paired" with arguments made/provided by Leo that support moving WITHOUT FEAR of Federal action.

Slide 16: SCSs are one type of harm reduction, with primary goals of keeping people healthy and alive regardless of whether they choose to enter treatment. The description of SUD, chemical dependence and "addiction" are biased and seeped in prohibitionist stigma.

The stated symptoms are not accurate for many if not all people who use drugs, not to mention the 10% of people who use drugs that have chaotic relationships with those substances. These definitions need to be edited and described at length apparently.

Seattle/King County **CURRENTLY HAS** legal authority to open an SCS now and has had no state or federal threats leveled against is health workers so far. The SCS has been funded by their local public health department and they are currently looking for ideal locations .

Appendix F: Comments Received from Commission Members on Commission's Last Draft

Comments received from Aubri Esters

Slide 27: Charge 8 - Suggesting law enforcement charging medical professionals for dispensing controlled substances doesn't apply for SCS where the substances are PRE-OBTAINED.

Staff working in and monitoring SCS locations do not need to be all medically licensed staff –the vast majority of harm reduction staff in harm reduction programs are NON-medical staff and concerns over medical licensure concerns in that case would not apply at all.

The current US DOJ has made it clear that SCS's are illegal, but it is unknown what, if any action they will take if Massachusetts pursues a site.

Again, the suggestion that state criminal and civil tort laws would need to be amended in order to operate is just not true. There can be a carve out that allows for SCS's and grants immunity to participants/staff without changing all possession and paraphernalia laws.

Does not address Leo's belief that tort laws would not actually be broken

Strange to not mention that drug testing is technically illegal under paraphernalia laws. Yet we allow it to happen and are not "amending state criminal laws"

Appendix F: Comments Received from Commission Members on Commission's Last Draft

Comments received from Senator Cindy Friedman

Slide 13: Bullet 1: A spectrum of **evidence-based and** evidence-informed strategies from safer use, to managed use, to abstinence, to meet people who use drugs (PWUD) where they're at, preserve their dignity, and address conditions of use along with the use itself.

Slide 14: What is the source of this definition of substance use disorder? I don't recognize it.

Slide 15: Recommendation Paragraph: Supervised consumption sites are an effective harm reduction tool in the countries where they have been implemented. These sites keep people who use drugs (PWUD) alive and help reduce the public health risks of disease transmission. These sites can also provide a safe space where people may receive harm reduction materials and linkages to other services. In order to continue to combat the opioid crisis, the Commonwealth, in partnership with its municipalities, must create a culture of harm reduction throughout the state and expand the array of harm reduction resources. **A pilot program of one or more supervised drug consumption sites could be part of this effort**. In order to pursue a pilot program of one or more supervised consumption sites, there are several challenges the Commonwealth must address, including **any gaps in ~~enacting~~** legal protections for organizations and individuals who would staff a supervised consumption site and **~~amending~~** any state criminal and civil tort laws that may pose a barrier. **~~Any pilot program must receive local approval and include a rigorous evaluation of the outcomes for individuals and impact on the surrounding area and municipality.~~ [moved to the final sentence]** An additional challenge is the federal government's strongly stated current stance against supervised consumption sites. **Action on the federal level is needed to shift policy in regards to the ~~Congressional action is needed to amend current~~** federal **~~law that~~** prohibit**ions~~**s on supervised consumption sites. **Any pilot program must receive local approval and include a rigorous evaluation of the outcomes for individuals and impact on the surrounding area and municipality.**

Slide 16: Bullet 2: Outside the U.S., there are more than 100 SCSs located in 11 countries**, some of which have been in existence for 30 years**.

Insert *new* bullet after Bullet 4 (as a fourth sub-bullet in the first section): **There is increasing attention among healthcare providers in the Commonwealth on safe or supervised injection facilities (SIFs) as a harm reduction strategy.** (see Source 7)

****The Massachusetts Medical Society's task force on establishing a SIF pilot in Massachusetts is extremely relevant to the Commission's report.****

Bullet 7: If a public or private entity in Massachusetts proceeds with developing a SCS, the entity would need to be deliberate in understanding **~~the full federal civil and criminal~~** risks and liabilities in order to respond to potential legal repercussions.

Insert *new bullet* at the end of the page (as a third sub-bullet in the last section): **Fentanyl testing strips are a promising harm reduction intervention.** (see Source 12 -- 2018 Brown University study)

Appendix F: Comments Received from Commission Members on Commission's Last Draft

Comments received from Senator Cindy Friedman

Slide 19: Bullet 3: Results from a 2018 Brown University study reported that **most** individuals **desired to know about the presence of fentanyl before using drugs and that knowing that their drugs contained fentanyl would lead them to modify their drug use behavior ~~were more cautious when consuming drugs that tested positive for fentanyl~~.**

Bullet 6: ~~**High initial c**~~**C**osts and questions of liability present challenges to access.

Insert *new bullet* at the end of the page (as a second sub-bullet in the last section): **At least one state (Rhode Island) has passed legislation to relieve concerns about civil or criminal responsibility as it relates to the use of narcotic testing products, including fentanyl test strips.**

Slide 22: Bullet 5: Supervised consumption sites may serve as entry points for treatment~~**, but that is not their primary purpose**~~.

Bullet 6: ~~**One of the six injection facilities visited during the Mayors' trips to Montreal and Toronto offered data that showed that referrals to treatment are made.**~~ **According to several cohort studies completed in Vancouver, Canada and Sydney, Australia, supervised consumption site attendance was associated with a meaningful increase in PWUD seeking a wide variety of addiction treatment options.** (see Source 63, pages 62-63)

Slide 26: Insert *new bullet* after Bullet 3: **Under state law, a declaration of a public health emergency by the governor gives the DPH commissioner broad authority to "take such action and incur such liabilities as he may deem necessary to assure the maintenance of public health and the prevention of disease." (MGL Ch. 17, Sec. 2A)**

Bullets 4 and 5:

~~**Federal Prosecutorial Discretion**~~

~~**Even if state law is changed, a locality/entity that establishes a SCS may have to defend a federal lawsuit. Federal prosecutors have publicly indicated that they will not use prosecutorial discretion to allow a SCS.**~~

~~**When medical marijuana statutes were enacted, Courts continued to uphold the validity of the Controlled Substances Act (CSA). It took 20+ years of voter approved referenda across more than 30 States to impact federal policy on the enforcement of the CSA against individuals involved in the medical marijuana industry.**~~

Appendix F: Comments Received from Commission Members on Commission's Last Draft

Comments received from Jessie Gaeta, MD

Slide 13: Change "evidence-informed" to "**evidence-based**"
There are established best practices with regards to narcan distribution and syringe exchange, however! Recommend changing this bullet to explain that interventions should be tailored to the specific needs within an individual community.

Slide 14: In reference to definition of substance use disorder, a better way to state this is "**continued use of substance despite negative consequences**."
This implies that negative consequences are unlikely to change the pattern of use - but many addiction programs use negative consequences to attempt to change behavior, so it's important to use this definition.

Slide 15: This paragraph is unwieldy enough that bullets would make it easier to digest.

I would like the Commission Recommendations to include an explicit statement that the array of harm reduction resources should include SCS.

Congressional action may not be needed. This is inaccurate. Judicial action may be enough.

Slide 20: Add "**Downtown Crossing**" to list of locations the CareZONE services in Boston.

Appendix F: Comments Received from Commission Members on Commission's Last Draft

Comments received from Mayor Marc McGovern

First off I just want to thank Secretary Sudders' staff for putting all this together so quickly. Great work.

Slide 14: First bullet, first sub-bullet, it says "spiritual manifestations" what does that mean?

Slide 15: The last line in the "Recommendation" section says: "Congressional action is needed to amend current federal law that prohibits supervised consumption sites." I think it's important to put in some of the information presented by Leo. I think there is an argument to be made that we have a national health crisis and that some believe that states have the right to act despite federal law. I'm not an attorney, so I don't know the proper language, but I agree with Leo that there is a case to be made that states have the right to act despite federal law. Maybe this should also be included in the Charge 8 slide as well.

I believe that Seattle currently has legal authority to open a SCS now and has had no state or federal threats leveled against their health workers so far. From what I have been told, the SCS has been funded by their local public health department and they are currently looking for locations. if this is indeed true, it is important to mention as it shows that despite federal law, SCS' can happen. Maybe someone can confirm?

Slide 27: Under the legal issues (Charge 8) it may be important to note that substances are not distributed at these these sites, unlike with marijuana dispensaries, also against federal law, which actually distribute controlled substances.

I also wonder if we should include something about this being a social justice issue. Those with means are able to find safer places to use then those without means.

Thank you all again for your hard work. This has been a great experience and I've been honored to be part of it. I hope I offered some useful insight.

Appendix F: Comments Received from Commission Members on Commission's Last Draft

Comments received from Robert Roose, MD, MPH, FASAM

Slide 15: I would consider revising this statement to read: "The strategy should have a strong education component focusing on the public at large**, as well as the legal, criminal justice**, and ~~**the**~~ health care communit**ies**~~**y**~~."

I believe that education regarding harm reduction in those sectors will prove to be particular important if wish to create a culture of harm reduction and move forward with SCSs or a variety of other strategies in a given community.

Slide 17: I would consider an additional bullet under existing harm reduction strategies such as: "**Injectable opioid agonist therapy (e.g. heroin or hydromorphone) is a harm reduction strategy utilized in some other countries that was not discussed in detail by the commission.**"

This would just clarify that the commission was not in favor nor against this strategy as it was not thoroughly discussed or reviewed.

I do believe the document represents the work and discussions, which included areas of consensus and differences, quite well overall.

Appendix F: Comments Received from Commission Members on Commission's Last Draft

Comments received from Representative Jeffrey Roy

Secretary Sudders,

Here are my comments on the latest draft report. I'll begin by thanking you and your staff for the hard work and diligence in pulling this all together. And I appreciate your tenacity and skill in running the meetings and seeking feedback. It was a pleasure working with you on this important matter and I thank you for your continued service and commitment to the Commonwealth of Massachusetts. I look forward to seeing you again on Tuesday afternoon.

I offer the following attachments for inclusion in the Appendix:

1. *Canada v PHS*, 2011 SCC 44, [2011] 3 SCR 134 decision. It is the leading Supreme Court of Canada case dealing with SCSs. The MMS report which is already in the Appendix and several of the other materials we reviewed make specific reference to this decision. It would be helpful to include the entire decision in the Appendix for those wishing to get further amplification of the issues.
2. The complaint in *United States v. Safehouse et al*, 2:19-cv-00519-GAM. This is the lawsuit in Philadelphia challenging SCSs that is referred to in slide 25.

For the remainder of my thoughts, I have listed the slide and my comments.

Slide 3: We should add a footnote for the third bullet point describing the significance of a "public health emergency" at the federal level and the date it was declared.

Slide 5: We should add a footnote for the second bullet point describing the significance of a "public health emergency" at the state level and the date it was declared.

Slide 6: In the footnote, can we include the handful of states that have also experienced a decline in opioid-related deaths?

Slide 9: It was not clear to me from the minutes why we were not addressing feasibility. Moreover, it appears that we did, in fact, include some information on that topic in slide 15. And the MMS report which is included in our appendix discusses feasibility on pages 5-6. As such, it seems to me that there is enough included in our findings on that topic to say that we did address feasibility.

Appendix F: Comments Received from Commission Members on Commission's Last Draft

Comments received from Representative Jeffrey Roy

Slide 13: In the definitions for SCSs, I would like to see the following additional language:

Many of the health risks of injection drug use are caused by the use of unsanitary equipment, techniques, and procedures for injection which permits the transmission of those infections, illnesses or diseases from one individual to another. Addicts share needles, inject hurriedly in alleyways and dissolve heroin and dirty puddle water before injecting it into their veins. In these alleyways, users who overdose are often alone and far from medical help. Shared needles transmit HIV and hepatitis C and unsanitary conditions result in infections. Missing a vein in the rush to inject can mean the development of abscesses. Not taking adequate time to prepare can result in mistakes in measuring proper amounts of the substance being injected. It is not uncommon for injection drug users to develop dangerous infections or endocarditis. These dangers are exacerbated by the fact that injection drug users are a historically marginalized population that is been difficult to bring within the reach of healthcare providers.

Slide 16: Second bullet should read: "Some employees of the U.S. Department of Justice have **offered the opinion** that SCSs are illegal and prohibited under the Controlled Substances Act. **These opinions, however, have not been tested in any court of law.**

There is a case filed in Philadelphia on February 6, 2019 that may be instructive (*United States v. Safehouse et al*, 2:19-cv-00519-GAM, complaint included in Appendix)." In addition, I would replace the word "full" with "**potential**" when discussing federal civil and criminal risks and liabilities in the second bullet point under that sentence.

Slide 22: I would like to see the following language included:

The SCSs we studied were strictly regulated health facilities run by medical professionals as a continuum of health care. Other models include peer-run sites and mobile sites where the personnel are guided by strict policies and procedures. They do not provide drugs to its clients, who must check in, sign a waiver, and are closely monitored during and after injection. The clients are provided with health care information, counseling, community linkages, dietary guidance, and referrals to various service providers or an on-site, on demand detox center.

The research we reviewed supports SCSs as successful. The MMS Task Force report and Dr. Gaeta presentation provide much of the evidence. The Rand study is included in the Appendix as well.

If SCSs are implemented in Massachusetts, a strong research component should be incorporated into those efforts.

Slide 26: I agree with Prof Beletsky's comments on tort liability issues from the 2/21/19 minutes and urge that the third bullet point under State Legal Issues be stricken. And I agree with his request for language that cannabis has moved forward despite similar federal opposition.