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Establishment of a Pilot Medically Supervised Injection Facility in Massachusetts

Report of the Task Force on Opioid Therapy and Physician Communication

APRIL 2017

Massachusetts Medical Society Task Force on Opioid Therapy and Physician Communication, 2016–2017

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Establishment of a Pilot Medically Supervised Injection Facility in Massachusetts

EXECUTIVE SUMMARY

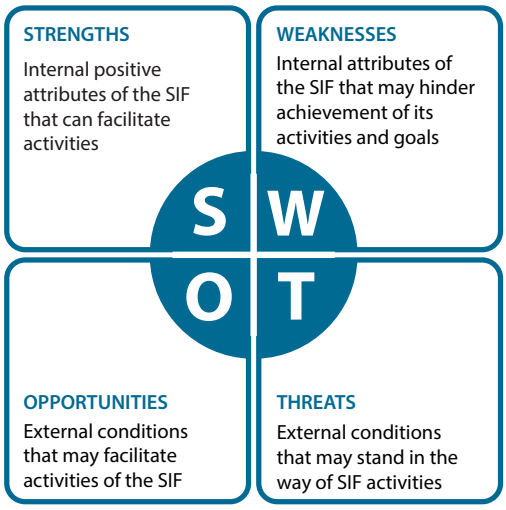
At the Massachusetts Medical Society's Annual Meeting in 2016, the Society's policymaking body, the House of Delegates (HOD), adopted as amended Resolution A-16 A-104, *Establishment of a Pilot Medically-Supervised-Injection Facility in Massachusetts*. The Society's Board of Trustees (BOT) referred item 1 of the Resolution to the Task Force on Opioid Therapy and Physician Communication (Task Force), in consultation with the Committee on Public Health, Committee on Ethics, Grievances, and Professional Standards, the Committee on Professional Liability, and the MMS Office of the General Counsel, and item 2 to the MMS Presidential Officers:

1. That the MMS perform an internal evidence-based study of the ethical, legal, and liability considerations and feasibility of a medically-supervised injection facility (MSIF) in Massachusetts.
2. That at the conclusion of an internal study of medically-supervised injection facilities (MSIF), the Board of Trustees will report back to the House of Delegates, no later than A-17, with recommendations for an MMS advocacy position on MSIF.

MEDICALLY SUPERVISED INJECTION FACILITIES

Medically supervised injection facilities, also known as supervised or safe injection facilities (SIFs) or supervised consumption facilities, are a harm-reduction strategy designed to reduce overdoses and other harms associated with illegal drug use. Specifically, a SIF is a legally approved "public health facility that offers a hygienic environment where people can inject illicit drugs under the supervision of trained staff. Some facilities also allow people to smoke illicit drugs. The primary goals of supervised consumption facilities include: reducing drug-related risks including the transmission of human immunodeficiency virus (HIV), hepatitis B and C (HCV) and other blood-borne infections; decreasing the number of overdoses; minimizing public order problems (including public drug use); and improving access to health and social services, including drug treatment and recovery services."[17]

The Task Force completed the following report, an evidence-based study of the ethical, legal, and liability considerations and feasibility of a medically supervised injection facility in Massachusetts. The Task Force chose to utilize a SWOT analysis process to evaluate the strengths, weaknesses, opportunities, and threats of establishment of a SIF.



A summary of the SWOT analysis is provided and an overview is included in the following report. The detailed, full Task Force SWOT analysis is included in Appendix A. The Massachusetts House of Delegates adopted this report and recommendations as official policy during its April 2017 Annual meeting.

Summary: SWOT Research Analysis

- Most of the research on SIFs has been conducted on two sites in Canada and Australia. Therefore, generalizing findings to the United States is not assured.
- The existing research is rigorous and has been endorsed by many experts and published in peer-reviewed journals, including the *Lancet* and the *New England Journal of Medicine*, providing evidence that SIFs achieve positive outcomes. For example, in Vancouver, British Columbia, SIF utilization reduced overdose mortality by 35% and significantly increased access to drug treatment.
- Despite a lack of research on the direct impact SIFs have on viral transmission rates, SIFs are associated with safer injection practices that lead to a reduction in serious illness and disease including HIV and HCV. Persons who inject drugs (PWIDs) also report positive behavior changes including a reduction in unsafe injection practices after using a SIF.
- There are mixed findings on the research associated with public nuisances. For example, research at several sites demonstrates a reduction in injection-related litter and fewer complaints about public injection but no change in the number of drug deals in the surrounding area. However, research does show that SIFs do not increase the number of PWIDs or crime in the areas surrounding the SIF.
- There are mixed opinions on SIFs from local residents, police, and business owners. However, in Vancouver, despite initial opposition, police and local business leaders wrote letters of support to Canada's government recommending that their SIF continue to operate three years after it opened.
- Research shows SIFs are cost effective but, according to experts, the estimates of overall savings may be high. Therefore, more research is needed.

Summary: SWOT Ethical Analysis

- In a Supreme Court case in British Columbia, the presiding judge defined the Vancouver SIF as health care:

  "While users do not use Insite (Vancouver's SIF) directly to treat addiction, they receive services and assistance at Insite which reduce the risk of overdose that is a feature of their illness, they avoid risk of being infected or of infecting others by injection and they gain access to counseling and consultation that may lead to abstinence and rehabilitation. All of this is healthcare."
- SIFs are in keeping with the MMS Code of Ethics whereby physicians are obligated to provide compassionate and respectful medical care to all people while respecting individual human dignity and rights.
- Medical associations in Canada and Australia support SIFs from an ethical standpoint. These organizations have over a decade of experience in observing the societal and health outcomes associated with SIFs and remain supportive of the continuation and expansion of this harm-reduction strategy in their countries.
- Informed consent is a complex ethical issue when evaluating SIFs given that research subjects may be under the influence of a controlled substance. Therefore, informed consent models and institutional review board approval guidelines established by SIFs in Canada and at syringe exchange programs in Boston should serve as model principles for informed consent for a pilot SIF in Massachusetts (MA). The rights of PWIDs should be respected and voluntary participation in research and evaluation of a pilot SIF should be assured.

Summary: SWOT Legal Analysis

- MA law includes several examples of successful harm-reduction strategies (e.g., needle exchange programs).
- There is precedent for introduction of legislation in Massachusetts to allow for being in the presence of heroin. The legislation did not pass and, if reintroduced, would likely need support from a broader coalition in order to become law.
- The legal risk to physicians and health care providers is too great to pilot a SIF that is not legal in Massachusetts or is operating without exemptions from state and federal laws.
- The federal government allowed the states to legalize marijuana without federal interference and with explicit guidance. Massachusetts may want to apply for a similar federal exemption from the Controlled Substances Act to pilot a SIF program where small amounts of heroin could be injected. However, it is likely that a pilot SIF program would need to include a rigorous, scientific evaluation to demonstrate that exemption from federal law is beneficial.

Summary: SWOT Professional Liability Analysis

- The Task Force consulted with the Professional Liability Foundation Ltd. (PLF) on the liability issues associated with opening a pilot SIF in Massachusetts.
- Overall, board members were consistent in their belief that SIFs are not a service that would be covered under existing professional liability policies and that development of such coverage would be extremely difficult under current Massachusetts laws.
- While not an area where coverage is provided, board members can see where it might meet a need. The major impediment is that supervising the injection of heroin would be an illegal activity under MA law and hence outside their written policies. Criminal activity is generally excluded from the specific terms of coverage. Additionally, there may be public policy issues where courts would not allow it.
- Also of issue is what exactly the informed consent of the "patient" would be. The question is, what is the physician promising to do for the patient? A physician may be at risk for liability associated with bad outcomes.

Summary: SWOT Political Feasibility Analysis

- SIFs have been operating across the world for decades, and Vancouver business owners and police support the first North American SIF in that city.
- The 2016 presidential election makes it uncertain how federal authorities will respond to a proposed pilot SIF program in the United States.
- The U.S. surgeon general recognized the benefit of harm-reduction strategies in a report released in November 2016.
- A growing number of U.S. cities are exploring SIFs to address the opioid crises in their cities and communities and at least one underground SIF is currently operating in the United States.
- The Washington State and New York State medical societies will likely debate SIFs in the coming months as groups discuss piloting SIFs in New York City and Seattle.
- The MA Department of Public Health has a long history of providing harm-reduction services to citizens in the Commonwealth. This agency has the expertise to convene and direct a task force to explore a pilot SIF program in Massachusetts.

- Public support for a SIF is crucial to piloting a SIF in Massachusetts. Community and law enforcement opposition are likely. Therefore, public opinion education and outreach will be crucial prior to developing a pilot SIF in Massachusetts using a multi-stakeholder approach.
- Opioid use disorder is widely recognized as a public health crisis in Massachusetts and beyond. Legislation has been introduced.
- MMS policy supports increasing access to services for opiate treatment. Therefore, SIFs and harm-reduction strategies are likely in keeping with MMS policy on drug addiction.

Upon completion of the analysis, the Task Force determined that agreement exists that supervised places of treatment and medically supervised injection facilities are in fact medical treatments, which offer an opportunity to engage some of the most vulnerable and difficult-to-reach individuals such as the homeless population who may prefer anonymity and often shun lifelong health contacts. The current opioid epidemic represents the greatest public health crisis our state and the nation has faced in recent memory. It will take a variety of aggressive ongoing efforts to change its course. The Task Force voted unanimously on a set of recommendations which would allow for advocacy for the establishment of a pilot SIF program in Massachusetts.

CONCLUSION

The BOT reviewed the Task Force report at its meeting on February 8, 2017, and voted unanimously by those in attendance to present the following recommendations to the House of Delegates for consideration. The Massachusetts Medical Society House of Delegates adopted the report and recommendations as official policy during its April 2017 Annual Meeting.

RECOMMENDATIONS

That the MMS advocate for a pilot supervised injection facility (SIF) program in Massachusetts under the direction and oversight of a state-led task force convened by a state authority, such as the MA Department of Public Health, to discuss the legal considerations and paths forward, and that the task force:

- **Advocate for an exemption from federal drug laws for the pilot SIF program as well as pursue state legislation legalizing the pilot SIF program, and consider partnering with other states or entities in seeking such a waiver of the applicable federal laws.**
- **Include an advisory board of experts, which includes experts from the Vancouver SIF as well as state and federal government officials if possible, under the jurisdiction of the task force, to design the evaluation protocol (including careful design of informed consent protocols regarding research) for the pilot.**
- **Consider building on a program such as a supportive place for observation and treatment (SPOT), given its expertise providing comprehensive, high-quality, harm-reduction services to populations that would be served by SIFs, and its reputation with government officials and other stakeholders in Boston.**
- **Consider harm-reduction strategies (counseling, referral, and placement on demand for all types of drug treatment) as a component of the pilot beyond SIFs to ensure comprehensive health care is available to marginalized persons who inject drugs.**

Establishment of a Pilot Medically Supervised Injection Facility in Massachusetts, February 2017

At A-16, the House of Delegates adopted as amended Resolution A-16 A-104, *Establishment of a Pilot Medically-Supervised-Injection Facility in Massachusetts*. The Board of Trustees referred item 1 to the Task Force on Opioid Therapy and Physician Communication, in consultation with the Committee on Public Health, Committee on Ethics, Grievances, and Professional Standards, the Committee on Professional Liability, and the MMS Office of the General Counsel, and item 2 to the MMS Presidential Officers:

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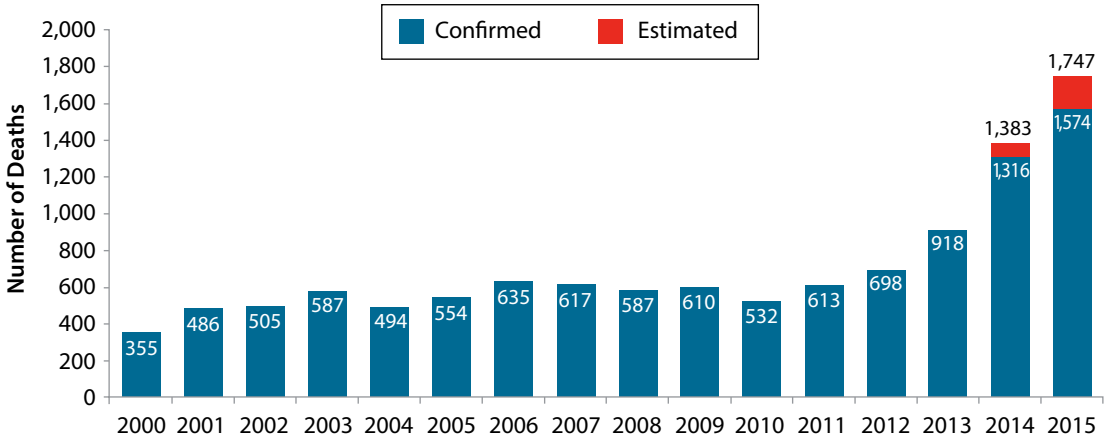
BACKGROUND

The opioid epidemic in Massachusetts continues to worsen. The 1,574 confirmed opioid overdose deaths in 2015 is a 20% increase over the number of opioid overdose deaths in 2014 (n=1,316) and a 43% increase over 2013 opioid overdose deaths (n=918).

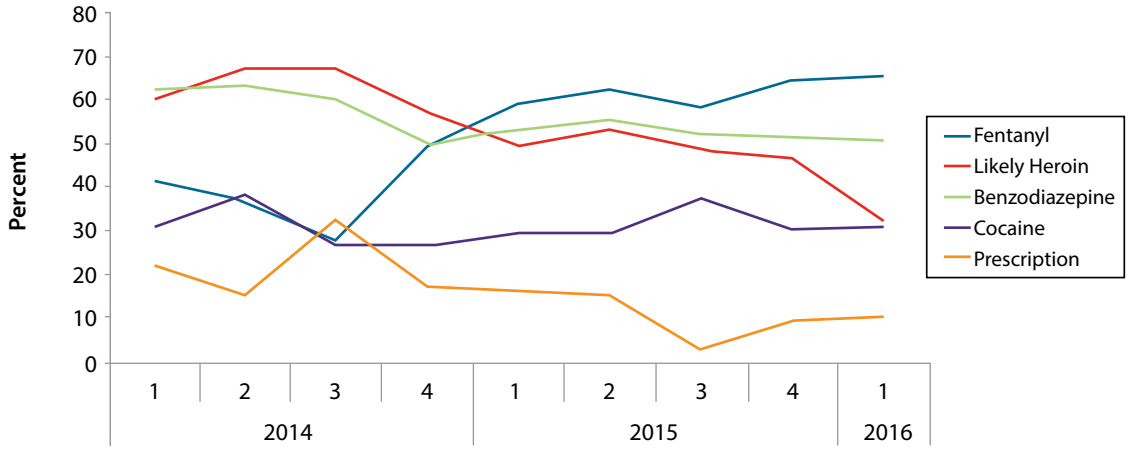
Opioid-Related Deaths, Unintentional/Undetermined
Massachusetts: January 2000–December 2015



Source: Massachusetts Department of Public Health[1]

While deaths attributed to heroin are down, deaths attributed to fentanyl, a synthetic opioid that is 50 to 100 times more powerful than morphine, are on the rise.

Percent of Opioid Deaths with Specific Drug Present
MA: 2014–2016



Source: Massachusetts Department of Public Health[2]

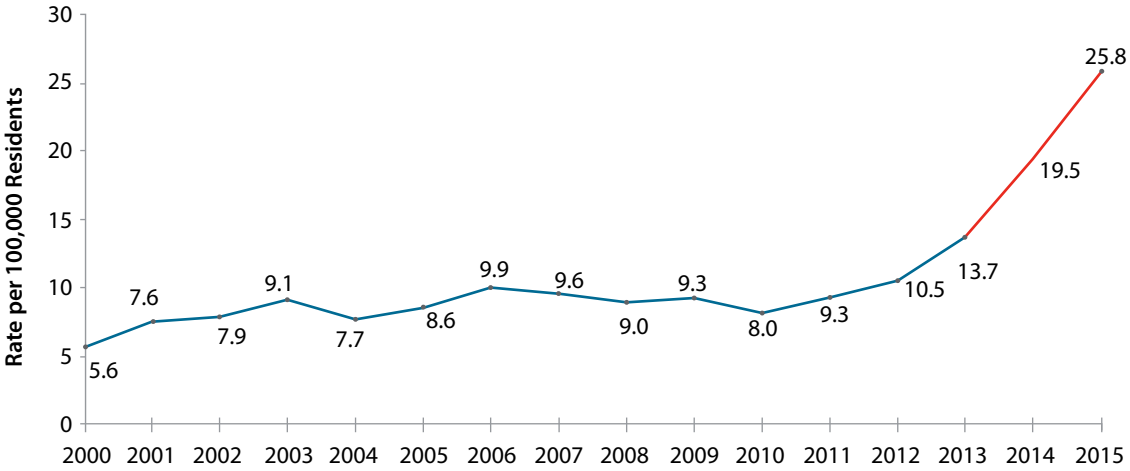
In the second quarter of 2016, polysubstance use was prevalent in opioid-related deaths; benzodiazepines were present in 50% of opioid-related deaths and cocaine was present in 30%.[3]

Massachusetts has undertaken a comprehensive approach to the opioid epidemic, utilizing several harm-reduction strategies, including medication-assisted treatment. Harm reduction is a term used to describe policies, interventions, and programs designed to lessen the "health, social and economic harms of substance use to individuals, communities and societies."[4] The Massachusetts Department of Public Health stated the following:

"Increasing the availability of harm reduction strategies and interventions that target Heroin, Fentanyl, and polysubstance use (especially benzodiazepine and cocaine use) could significantly reduce the opioid-related death rate," which has increased 350% since 2000.[5]

The 2015 estimated rate of unintentional opioid-related overdose deaths is the highest ever at 25.8 deaths per 100,000 residents, a 32% increase from the previous year.[6]

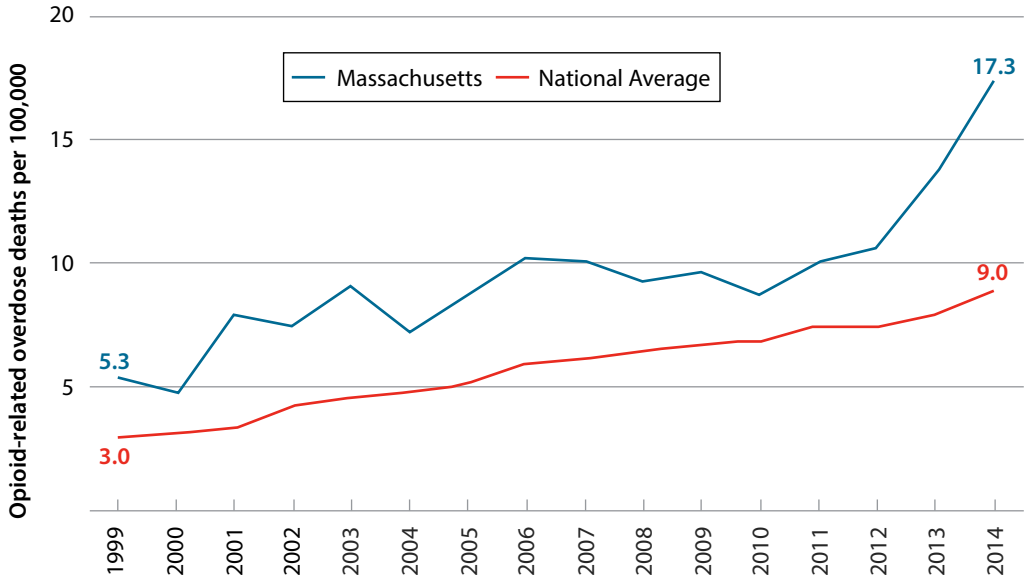
Rate of Unintentional/Undetermined[7] Opioid[8]-Related Deaths
Massachusetts Residents: 2000–2015



Source: Massachusetts Department of Public Health[9]

Opioid-related deaths are increasing at a faster rate in Massachusetts compared to the rest of the United States.

Opioid-related drug overdose deaths per 100,000, 1999–2014, Massachusetts and United States[10]



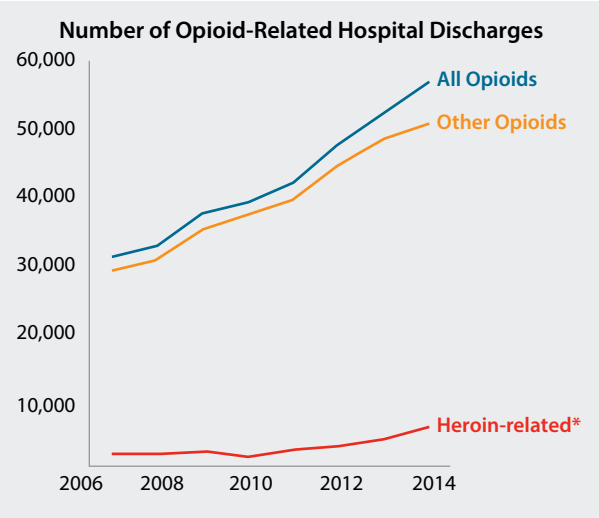
Source: Commonwealth of Massachusetts, Health Policy Commission[11]

In the past five years, opioid-related deaths in Massachusetts increased by 150% from 613 in 2011 to more than 1,500 in 2015 due, in part, to an increase in the use of fentanyl.[12,13] A recent health advisory from the Boston Public Health Commission said that Boston emergency medical services had responded to 2,370 narcotic-related emergency medical incidents between January and October 2016, an increase of 14% from the same time period last year.[14]

The impact of the opioid epidemic on the Massachusetts health care system is significant as well. The rate of opioid-related hospital discharges has been steadily climbing while heroin-related hospital discharges have increased by over 200% between 2007 and 2014.

Opioid-related hospital discharges, Massachusetts, 2007–2014[15]

HPC analyses show the number of opioid-related hospital discharges increased substantially since 2007, driven by illicit and prescription opioids



Rate of Change of Opioid-Related Hospital Dischages

Years	Heroin-related	Other opioids
2007–2008	6%	6%
2008–2009	11%	15%
2009–2010	–29%	6%
2010–2011	52%	6%
2011–2012	23%	13%
2012–2013	35%	8%
2013–2014	43%	5%

201%
increase in heroin-related hospital discharges between 2007 and 2014

Source: HPC Analysis — CHIA, Hospital Inpatient Discharge Database, Outpatient Observation Database, and Emergency Department Database, 2007–2014.

Note: Hospital discharges include ED discharges, inpatient discharges, and observation stay discharges. The remainder of analyses do not include observation stay discharges. Discharges with both a "heroin-related" and "other opioid" discharge code are counted only once in the "all opioids category," as well as in both of the sub-categories. For example, a patient coded with a heroin overdose and non-heroin overdose would be counted once in the "heroin-related" category and once in the "other opioid" category. However, if a discharge had mutliple diagnoses for the same sub-category (e.g., both a heroin overdose and heroin poisoning), the discharge would be counted only once in the heroin-related sub-category.

*This analysis is based on ICD-9 codes and includes discharges with an opioid-related primary or secondary diagnosis. As with all analyses dependent on ICD-9 codes, provider coding may not always accurately reflect the patient's clinical condition. In particular, heroin-related codes are considered specific, but not necessarily sensitive. For example, some hospitals may only use heroin-related codes for cases of poisoning/overdose. As result, some heroin abuse/dependence is likely captured in the "other opioids" category. Furthermore, some non-heroin opioid cases are likely captured in the "heroin-related" category.

Source: Commonwealth of Massachusetts, Health Policy Commission[16]

MEDICALLY SUPERVISED INJECTION FACILITIES

Medically supervised injection facilities, also known as supervised or safe injection facilities (SIFs) or supervised consumption facilities, are a harm-reduction strategy designed to reduce overdoses and other harms associated with illegal drug use. Specifically, a SIF is a legally approved "public health facility that offers a hygienic environment where people can inject illicit drugs under the supervision of trained staff. Some facilities also allow people to smoke illicit drugs. The primary goals of supervised consumption facilities include: reducing drug-related risks including the transmission of human immunodeficiency virus (HIV), hepatitis B and C (HCV) and other blood-borne infections; decreasing the number of overdoses; minimizing public order problems (including public drug use); and improving access to health and social services, including drug treatment and recovery services."[17]

The first official, legal SIF opened in Bern, Switzerland, in 1988.[18] Sites in Sydney, Australia, and Vancouver, British Columbia, began operating in 2001 and 2003, respectively. As of 2014, there are 90 such facilities operating across the globe on three continents.[19,20] SIFs in Europe are referred to as "drug consumption rooms" or "supervised consumption rooms" as they allow for the consumption of drugs using methods that go beyond injecting. Most of these international facilities are open 6–7 days a week for 7–8 hours per day with an average of seven injection spaces available.[21]

Globally, SIFs most frequently offer the following services for people who use drugs:

- Health services including education, distribution and disposal of drug using equipment
- A variety of medical, nursing, and social work services
- Access to medical care and emergency services in case of overdose
- Hygiene services including laundry, showers and bathrooms
- Drug treatment referrals including drug substitution treatment such as methadone maintenance therapy, detoxification, and rehabilitation[22]

Photo credit: courtesy Vancouver Coastal Health

Photo credit: courtesy Vancouver Coastal Health

SIFs are designed to address the health consequences of intravenous drug use by targeting "high-risk, socially marginalized IDUs who would otherwise inject in public spaces or shooting galleries."[23]

In a systematic review of published research on SIFs, researchers developed a description of SIF users.[24] The majority had the following characteristics:

- Male
- 30–35 years of age
- Experienced frequent housing insecurity and unemployment
- Had a previous history of incarceration
- 10%–39% were engaged in prostitution

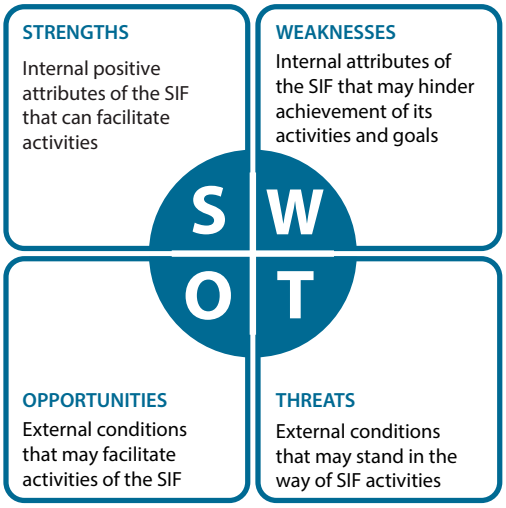
The review also found that the most frequent drugs used were, in descending order, heroin, cocaine, opiates and amphetamines and that, prior to the opening of the SIF, Vancouver SIF users had more episodes of overdose, a higher frequency of daily drug injection, and a higher likelihood of sharing syringes. A majority (85%) were seropositive for HCV and 2%–30% were HIV positive.

A Canadian survey of persons who inject drugs (PWIDs) found that those who were most likely to use a SIF were homeless, unsure of how to access clean drug equipment such as needles, had overdosed in the past, and tended to inject in public spaces. These findings suggest that SIFs are used by the most vulnerable of the drug-using population and should be located in an area where people are already using drugs in public spaces or are homeless.[25]

SIFs are a space where health care providers from multiple disciplines — including physicians, nurses, counselors and social workers — supervise PWIDs as they actively inject drugs. SIF staff do not provide the drugs or assist in the injection, although at some sites, staff test the substances prior to injection. SIF staff also provide sterile injection equipment, educate clients on safer drug use, injection, communicable disease prevention and vein care, monitor vital signs in an effort to prevent overdose, and provide first aid and resuscitation for onsite overdose. SIFs also serve as a gateway to drug treatment and social services through onsite counseling services and referrals.[26,27]

SWOT ANALYSIS

In order to examine the feasibility of a SIF in Massachusetts, this study will utilize a SWOT Analysis, a method used to evaluate the strengths, weaknesses, opportunities, and threats that exist for a public health intervention such as a SIF. The Centers for Disease Control and Prevention (CDC) recommends a SWOT Analysis to assess the environment in which a public health intervention functions. A SWOT analysis examines internal and external factors that may impact the intervention. The internal factors, including strengths and weaknesses, are those that exist within the intervention and its staff. External factors, opportunities, and threats are external factors to address that may impact the intervention. Once critical factors are identified, they are used to create an action plan and recommendation for the intervention.[28] In summary, a SWOT is an examination of the following:



According to the CDC, a SWOT Analysis "identifies planning and performance-level needs, promotes proactive and creative thinking, highlights critical issues for decision-making, supplements known information or knowledge about a topic or problem, provides a framework for reviewing a strategy, clarifies values or priorities of different stakeholders, encourages the development of an action plan and helps clarify whether a project or objective is obtainable."[29]

The following report provides a summary of the SWOT analyses and findings for the research, ethical, legal, professional liability and political factors for a pilot SIF in Massachusetts. Appendix A provides the full, detailed SWOT analyses for all sections.

SUMMARY OF SWOT ANALYSIS AND FINDINGS

Research Factors

A review of the literature published in the international journal *Drug and Alcohol Dependence* in 2014 demonstrates that SIFs reduce harms associated with drug use: SIFS reduce overdose deaths; provide an alternative to unsafe injection practices that lead to HIV, HCV, and other diseases; and facilitate entry into drug treatment. Cost estimates suggest that SIFs are cost effective and the impact on the communities in the areas around the SIFs has been positive. Despite threats from government officials, the evaluation of Insite, the SIF in Vancouver, provides us

with the most rigorous scientific study we have on SIFs and these results are overwhelmingly positive. However, with most of the evidence on SIFs concentrated at one site in Vancouver, due in part to limitations imposed by the Canadian government, there are issues in generalizing these findings to other sites, suggesting a need for further evaluation pilots in other communities.[30] The evaluation process should also address both the societal and individual benefits of SIFs. To this end, the design of the program structure and the evaluation protocol should ensure that the evaluation answers this fundamental question.

No deaths by overdose have been reported at a SIF in any of the studies cited. In Vancouver, researchers found a 35% decrease in the number of lethal overdoses after a SIF opened in that area.[31] Over 1,000 lethal overdoses avoided by the Vancouver SIF including 453 life-threatening and 2–12 lethal overdoses per year.[32] Calls for ambulances related to overdoses were 68% lower during SIF operation in Sydney, Australia.[33]

While there have been concerns that SIFs encourage and foster drug use, there has been no increase in the number of people using drugs intravenously in localities where such facilities operate.[34] Further, evaluation work undertaken in Vancouver revealed that the opening of Insite was not associated with increased crime or rates of initiation into injection drug use but did shelter female PWIDs from violence.[35,36,37] Drug dealing, prostitution, violence, and other crimes are not allowed at Insite and there is no associated literature on this issue.[38]

Boston's Health Care for the Homeless Supportive Place for Observation and Treatment (SPOT) serves a population of PWIDs who would benefit from the services provided by a SIF but with the added benefit of reducing the harms that are associated with unsupervised illegal drug injection: SPOT offers medical monitoring to persons after they have injected drugs but does not supervise injections. SPOT serves as an example of how harm-reduction strategies beyond syringe exchange programs (SEP) can augment existing strategies to combat opioid addiction in a local community.

In summary, the SWOT analysis (see Appendix A) on research factors found the following:

- Rigorous, scientific evidence suggests that SIFs reduce harms associated with drug use and provide positive improvements to the local communities they serve.
- Most of the research on SIFs has been conducted on two sites in Canada and Australia. Therefore, generalizing findings to the United States is not assured.
- Randomized control trials (RCTs) are not an ethical choice for evaluating SIFs, due to the need for placebo control in RCTs, so other rigorous methods for evaluating SIF outcomes should be considered. However, the existing research is rigorous and has been endorsed by many experts and published in peer-reviewed journals, including the *Lancet* and the *New England Journal of Medicine*, providing evidence that SIFs achieve positive outcomes.
- In Vancouver, SIF utilization reduced overdose mortality by 35%.[39]
- SIF utilization is associated with an increase in referral to addiction treatment, including a 30% increase in the rate of detoxification use and an increase in initiation of methadone maintenance therapy.[40,41]
- Despite a lack of research on the direct impact SIFs have on viral transmission rates, SIFs are associated with safer injection practices that lead to a reduction in serious illness and disease including HIV and HCV. PWIDs also report continuing to practice safe methods of injection following SIF use, even when not in the SIF. Modeling studies (by Pinkteron et al., 2010, and Bayoumi et al., 2008, for example) also suggest HIV and HCV prevention benefits from SIFs.
- Research at the majority of SIFs demonstrates a reduction in public injecting and injection-related litter but some found little change in the number of drug deals in the surrounding area. However, research does show that SIFs do not increase the number of PWIDs or crime in the areas surrounding the SIF.

- SIFs appear to shelter women who use the SIFs from the violence they are exposed to as part of their drug use. Specifically, qualitative research conducted by interviewing 25 women who used Insite found that the SIF worked to "mediate the adverse impacts of violence on women's risk environment and injection process," provided "refuge from the structural and interpersonal violence of the street," served "to facilitate the safe preparation and injection of drugs," and gave women "greater agency and control over resources in the process of drug consumption."[42]
- There are mixed opinions on SIFs from local residents, police, and business owners. However, in Vancouver, despite initial opposition, police and local business leaders there wrote letters of support to Canada's government recommending that Insite continue to operate three years after it opened.
- Research shows SIFs are cost effective but according to experts, the estimates of overall savings may be inflated. However, the cost effectiveness analyses only focused on reduction in HIV infections, so other cost benefits may be underexplored.

Therefore, more research is needed. However, specific cost savings documented in the literature include the following:

- Cost savings over 10 years of Vancouver's SIF would include an incremental net savings of $18 million and life-years gained of 1,175 due to a reduction in needle sharing, increased use of safe injection practices, and increased referral to methadone maintenance.[43]
- It is estimated that Vancouver's SIF prevents 83.5 incident HIV infections per year for a cost saving of $17.6 million (Canadian) in life-time HIV-related medical care costs which exceeds the SIF's operating costs of approximate, annual costs of $3 million.[44]
- Researchers estimate that potential savings from averted HIV and hepatitis C virus (HCV) infections, reduced skin and soft tissue infection, averted overdose deaths, and increased medication-assisted treatment uptake for total annual net saving of $3.5 million for a single 13-booth SIF.[45]

Ethical Factors

The MMS Committee on Ethics, Grievances and Professional Standards members requested information on the ethics of SIFs from the standpoint of organized medicine in cities where SIFs were operating. The following passages are excerpted from the Canadian Medical Association's (CMA) written testimony submitted in response to a legal challenge to the continued operation of Insite:

> *Harm reduction is part of health practice:*
>
> *Harm reduction is not restricted to services for people who use drugs; it is an approach that is adopted routinely in every health and social program. For example, seat belts, air bags and helmets are encouraged and even mandated to reduce some of the possible harmful consequences of driving or cycling — regardless of who is at fault. Many medications do not cure diseases, and are essential to prevent complications. An example is the use of insulin by people with diabetes. There are many programs created to reduce the harms created by alcohol, a legal substance that contributes to a significant burden of disease, disability and deaths. Examples include low risk drinking guidelines, designated driver or alternate driver programs for drinkers, graduated licenses and changes in the hours of liquor stores to reduce the use of non-beverage alcohol. While the risk is still present, this approach reduces harms.*
>
> *Harm reduction related to psychoactive substances, "refers to policies, programmes and practices that aim primarily to reduce the adverse health, social and economic consequences of the use of legal and illegal psychoactive drugs without necessarily reducing drug consumption. Harm reduction benefits people who use drugs, their families and the community". They are part of a comprehensive approach which also includes abstinence-based programs.*

> *The CMA fully supports harm reduction strategies as they aim to reduce mortality and morbidity even in the face of continued exposure to a potentially harmful substance. Addiction is an illness, and harm reduction is a clinically mandated and ethical method of care and treatment. Physicians must treat patients as a matter of good medical practice and ethical obligation, whether the patient is believed to contribute to his or her injury or not. Section 31 of CMA's Code of Ethics provides that all physicians must "recognize the responsibility of physicians to promote fair access to health care resources".*
>
> *Harm reduction information, services and interventions are respectful and non-judgmental, and have the purpose of promoting health and safety. These strategies were developed in response to critical situations and high costs to the health, social and criminal justice systems. Harm reduction approaches are evidence-based, cost-effective and have a high impact on individual and community health. Such programs for injection drug users are now well established within every province and territory in Canada, in the form of needle and syringe distribution programs, methadone maintenance and the provision of sterilized equipment.*[46]

In a Supreme Court case in British Columbia, the presiding judge defined the Vancouver SIF as a form of health care:

"While users do not use Insite (Vancouver's SIF) directly to treat addiction, they receive services and assistance at Insite which reduce the risk of overdose that is a feature of their illness, they avoid risk of being infected or of infecting others by injection and they gain access to counselling and consultation that may lead to abstinence and rehabilitation. All of this is healthcare." (p. 51, para. 136)[47]

In summary, based on the opinion of the Canadian Medical Association, the Supreme Court decision in British Columbia, and the SWOT analysis outlined in Appendix A, the following is acknowledged:

- SIFs are in keeping with the MMS Code of Ethics whereby physicians are obligated to provide compassionate and respectful medical care to all people while respecting individual human dignity and rights. (For a full analysis of the MMS Code of Ethics, as it pertains to SIFs, please see Appendix A.)
- Medical associations in Canada and Australia support SIFs from an ethical standpoint. These organizations have over a decade of experience in observing the societal and health outcomes associated with SIFs and remain supportive of the continuation and expansion of this harm reduction strategy in their countries.
- Informed consent is a complex ethical issue when evaluating SIFs, given that research subjects may be under the influence of a controlled substance. Therefore, informed consent models and institutional review board approval guidelines established by SIFs in Canada and at syringe exchange programs (SEPs) in Boston should serve as model principles for informed consent for a pilot SIF in Massachusetts. The rights of PWIDs should be respected and the option of opting out of research while participating in a pilot SIF should be assured.
- While SIFs are a high-level, high-risk intervention, the severity of the opioid epidemic in Massachusetts and the failure of existing efforts to curtail the harms associated with the epidemic in marginalized PWIDs thus far justify the implementation of a SIF in Massachusetts.
- The SWOT analysis in Appendix A examines the ethics of SIFs through the framework of the ethical principles of autonomy, non-maleficence, beneficence, and justice.

Legal Factors

SIFs are a way for physicians and health care providers to provide marginalized PWIDs with medical care in a structured setting in the communities where they publicly inject drugs. Physicians do not provide PWIDs with illegal

drugs and do not help PWIDs inject illegal drugs. The physicians' and health care providers' roles are to supervise the injection and educate the PWID about safer injection practices in an effort to reduce the harms associated with existing intravenous drug use. SIFs also provide PWIDs with counseling and resources if they are interested in drug treatment and recovery services. Some SIFs also test the drugs that PWIDs are injecting on a voluntary basis.

In summary, the SWOT analysis (see Appendix A) conducted on the legal considerations of a pilot SIF in Massachusetts found the following:

- Multiple state drug laws would prohibit SIFs from legally operating in the state at present. State elected officials and government agencies have the power to legalize a pilot SIF program in Massachusetts and Massachusetts law includes several examples of modifying laws to facilitate successful harm reduction strategies (e.g., needle exchange programs).
- There is precedent for introduction of legislation in Massachusetts to legalize being in the presence of heroin. However, the legislation did not pass in the 2015–2016 session and would likely need support from a broader coalition in order to become law.
- The legal risk to physicians and health care providers is too great to pilot a SIF without the modification of laws in Massachusetts or without obtaining explicit exemptions from state and federal laws.
- The federal government allowed states to legalize marijuana without federal interference and with explicit guidance (see the Cole Memo in Appendix B). Therefore, Massachusetts may want to apply for a similar federal exemption from the Controlled Substances Act to pilot a SIF program where small amounts of heroin could be injected. However, it is likely that a pilot SIF program would need to include a rigorous, scientific evaluation to demonstrate that exemption from federal law is beneficial. It is unclear how the Trump administration will respond to these types of waivers. In seeking a federal waiver, Massachusetts would need to develop an expanded political base to maximize opportunities for success. The Massachusetts Board of Registration in Medicine (BRM) has authority to suspend and revoke medical licenses for physicians who practice medicine in violation of law or in deviation from good and acceptable medical practices. This provides further support for explicit clarification in statute that physicians' roles in SIFs are fully compliant with the law and have the state's endorsement that it is good medical practice and cannot be interpreted by the BRM as being medical practice that poses a threat to public health, safety, or welfare.

Professional Liability Factors

The MMS consulted with the Committee on Professional Liability (CPL) regarding liability factors associated with a pilot SIF in Massachusetts. Members of the CPL suggested contacting the Professional Liability Foundation Ltd. (PLF) given that many of the liability issues would be a matter of whether it is possible to get coverage for the care a physician would provide in a SIF as the care itself would not deviate much from care provided in an emergency department, for example. In addition, issues of informed consent would likely be the same informed consent issues physicians' encounter in an emergency department.

The MMS consulted with the PLF, as recommended by the CPL, on the liability issues associated with opening a pilot SIF in Massachusetts. The PLF "is a non-profit Massachusetts corporation established in 1995 aimed at improving the quality and affordability of patient health care by promoting reforms in the medical tort and professional liability insurance system, supporting legislation and/or administrative regulation consistent with its goals, and participating in litigation where necessary to express the views of its members." The members of PLF represented by its advocacy voice include Baystate Health, Inc., Boston Medical Center, Coverys, Lahey Health, Massachusetts Hospital Association, Massachusetts Medical Society, Reliant Medical Group, Risk Management Foundation of the Harvard Medical Institutions Inc., Southcoast Health System, Inc., Steward Health Care System, Tufts Medical Center, and UMass Memorial Health Care, Inc.

The general consensus of PLF board members when asked about SIFs from a professional liability perspective is that this is not an area where coverage is provided, although board members can see where it might meet a need. The major impediment is that supervising the injection of heroin would be an illegal activity under Massachusetts law and, hence, outside their written policies. Criminal activity is generally excluded from the specific terms of coverage. Additionally, there may be public policy issues where courts would not allow it.

Second was the issue of exactly what the informed consent of the "patient" would be. The question is, what is the physician promising to do for the patient? There are instances where, once they have injected, users cannot be saved from death or serious injury. In these situations, the physician may be at risk for liability associated with these bad outcomes. Certifying and testing the drugs or recommending a dosage would be of questionable legality at a minimum. Also, PLF board members wondered if SIF "patients" can provide a valid waiver for care if the person is already under the influence of illegal drugs or impaired.

Overall, the PLF board members were consistent in their belief that SIFs are not a service that would currently be covered under existing professional liability policies and that development of such coverage would be extremely difficult, especially under the current Massachusetts laws.

Professional Licensure

Physicians must have insurance coverage for all medical activities as a condition of medical licensure in Massachusetts, or they must post a personal approved bond. In the case of a SIF, the BRM might well not approve such a bond or the underlying activity.

Political Factors

The opioid epidemic is recognized nationally as a growing public health crisis. The November 2016 Surgeon General's Report, *Facing Addiction in America,* recognizes that harm-reduction strategies are effective in addressing the epidemic. In the United States, political support is growing for SIFs in cities such as New York and Seattle.[48] Globally, SIF pilot programs have spread from Europe to North American and beyond, including pilot programs in Iran.[49]

In Massachusetts, city and state officials are eager to address the opioid epidemic. Massachusetts law, Chapter 52 of the Acts of 2016, *An act relative to substance use, treatment, education and prevention*, in part, directs the Massachusetts Health Policy Commission (HPC) to take further steps to address the impact of the opioid epidemic on the health care system.[50]

Cost savings have been modeled by researchers examining Vancouver's SIF data and outcomes. Estimates in one study associated with the SIF health benefits — including decreased needle sharing, increased use of safe injection practices, and increased referral to methadone maintenance — found that incremental net savings over 10 years could exceed $18 million and the number of life-years gained reaching 1,175.[51] Another study of the Vancouver data estimated that Vancouver's SIF prevents 83.5 incident HIV infections per year for a cost saving of $17.6 million (Canadian) in life-time HIV-related medical care costs which exceeds the SIF's operating costs of approximate annual costs of $3 million.[52] However, one expert consulted said that these estimates may be high. Therefore, a pilot SIF program should include a strong cost-benefit analysis to determine if SIFs are an appropriate use of limited resources in Massachusetts. Massachusetts Law, Chapter 55, is a law that permits the linkage and analysis of state government data sets to better understand the opioid epidemic. This law will likely provide evaluators with the necessary data to produce a robust cost-benefit analysis not yet undertaken at other SIFs.

In summary, the SWOT analysis (see Appendix A) found the following:

- SIFs have been operating across the world for decades and Vancouver business owners and police support the first North American SIF in that city.
- Reframing SIFs as a public health crisis may not be enough to gain political traction as threats from the Canadian federal minister and police force serve to demonstrate. The recent presidential election and congressional elections make it uncertain how federal authorities will respond to a proposed pilot SIF program in the United States.
- The U.S. surgeon general recognized the benefit of harm-reduction strategies in a report released earlier this month.
- A growing number of U.S. cities are exploring SIFs to address the growing opioid crises in their cities and communities and at least one underground SIF is currently operating in the United States.
- The Washington State and New York State medical societies will likely debate SIFs in the coming months as groups discuss piloting SIFs in New York City and Seattle.
- Massachusetts (MA) Department of Public Health (DPH) has a long history of providing harm-reduction services to citizens in the Commonwealth. This agency has the expertise to convene and direct a taskforce to explore a pilot SIF program in Massachusetts.
- Public support for a SIF is crucial to piloting a SIF in Massachusetts. Community and law enforcement opposition are likely. Therefore, public opinion education and outreach will be crucial prior to developing a pilot SIF in Massachusetts using a multi-stakeholder approach.
- Opioid use disorder is now recognized as a public health crisis in Massachusetts and beyond. Given that the *Boston Globe*[53] is supporting SIFs locally, it is likely that the idea of SIFs is gaining more mainstream acceptance. Meanwhile, although he has not commented on SIFs, Boston Mayor Martin Walsh said that "everything is on the table" when it comes to fighting the opioid crisis.
- The MMS's policy supports increasing access to services for opiate treatment. Therefore, SIFs, and other harm-reduction strategies, are likely in keeping with MMS policy on drug addiction.
- Given that there are many obstacles to establishment of a SIF, the first step in the process should be development of a prioritized list of steps that would be required to create a successful program in order to reduce the risk of embarking on the project, only to find that some fundamental impediment has not been resolved.

Conclusions and Proposed Recommendations on a Pilot SIF in Massachusetts

Based on the SWOT analysis conducted in this report on the consideration and feasibility of SIFs in Massachusetts, the Task Force unanimously approved the following proposed recommendations:

1. It is reasonable for the MMS to advocate for a pilot SIF program in Massachusetts under the direction and oversight of a state-led task force convened by a state authority, such as the MA DPH, to discuss the legal considerations and paths forward. The MA DPH has the authority and expertise to convene and direct such as state-led task force which should include a multi-stakeholder approach.

2. The MMS should recommend that the state-led task force advocate for an exemption from federal drug laws for the pilot SIF program as well as pursue state legislation legalizing the pilot SIF program. The legal risk to physicians and health care providers is too great to pilot a SIF that is not legal in Massachusetts or is operating without exemptions from state and federal laws. The state-led task force should consider partnering with other states or entities in seeking the federal waiver to expand the political base.

3. An advisory board of experts, under the jurisdiction of the state-led task force, should be assembled to design the evaluation protocol for the pilot and that board should include experts from the Vancouver SIF as well as state and federal government officials if possible. An important part of the evaluation protocol should be the careful design of informed consent protocols that respect the rights and voluntary participation of PWIDs participating in the research on SIFs, modeled on the Vancouver SIF research protocol.

4. SPOT could be a potential site for a pilot SIF program given its expertise providing comprehensive, high-quality, harm-reduction services to populations served by SIFs and its reputation with government officials and other stakeholders in Boston.

5. The state-led task force should consider harm-reduction strategies beyond SIFs to ensure comprehensive health care is available to marginalized PWIDs. Therefore, counseling, referral, and placement on demand for all types of drug treatment should be a key component of a pilot SIF.

CONCLUSION AND FINAL POLICY RECOMMENDATIONS

The Opioid Task Force presents the following recommendations to the Board of Trustees. The BOT reviewed the Task Force report at its meeting on February 8, 2017, and voted unanimously by those in attendance to present the following recommendations to the House of Delegates for consideration. The Massachusetts Medical Society House of Delegates adopted the report and recommendations as official policy during its April 2017 Annual Meeting:

That the MMS advocate for a pilot supervised injection facility (SIF) program in Massachusetts under the direction and oversight of a state-led task force convened by a state authority, such as the MA Department of Public Health, to discuss the legal considerations and paths forward, and that the task force:

- Advocate for an exemption from federal drug laws for the pilot SIF program as well as pursue state legislation legalizing the pilot SIF program, and consider partnering with other states or entities in seeking such a waiver of the applicable federal laws.
- Include an advisory board of experts, which includes experts from the Vancouver SIF as well as state and federal government officials if possible, under the jurisdiction of the task force, to design the evaluation protocol (including careful design of informed consent protocols regarding research) for the pilot.
- Consider building on a program such as Boston Health Care for the Homeless Supportive Place for Observation and Treatment (SPOT), given its expertise providing comprehensive, high-quality, harm-reduction services to populations that would be served by SIFs, and its reputation with government officials and other stakeholders in Boston.
- Consider harm-reduction strategies (counseling, referral, and placement on demand for all types of drug treatment) as a component of the pilot beyond SIFs to ensure comprehensive health care is available to marginalized persons who inject drugs.

Appendix A: SWOT Analyses For All Factors

SWOT Matrix

Versions of the following matrix are used in to examine the feasibility of a SIF in Massachusetts.

	FACTORS TO MAINTAIN	FACTORS TO ADDRESS
Internal Factors	**Strengths** Maintain, Build, Leverage What does a SIF do well?	**Weaknesses** Remedy, Stop In what ways are SIFs lacking?
External Factors	**Opportunities** Promising future factors to prioritize and optimize What external factors help facilitate a SIF's activities in Massachusetts?	**Threats** Negative future factors to counter What external factors hinder a SIF's activities Massachusetts?

SWOT Analysis

RESEARCH FACTORS			
INTERNAL			
Issue	**Strengths**	**Weaknesses**	**Analysis**
Overall	Rigorous, scientific evidence suggests that SIFs reduce harms associated with drug use and provide positive improvements to the local communities they serve.[54]	Despite a rigorous scientific evaluation of these SIFs, most studies were conducted in Vancouver, British Columbia, and Sydney, Australia.	Most of the research on SIFs has been conducted in two sites in Canada and Australia. Therefore, generalizing findings to the United States is not assured. However, the existing research is rigorous and has been endorsed by many experts as evidence that SIFs achieve positive outcomes.
Overdose-induced mortality and morbidity	No deaths by overdose have been reported in any of the studies cited. In Vancouver, researchers found a 35% decrease in the number of lethal overdoses after a SIF opened in that area.[55] Over 1,000 lethal overdoses avoided by the Vancouver SIF including 453 life-threatening and 2–12 lethal overdoses per year. Calls for ambulances related to overdoses were 68% lower during SIF operation in Sydney.[56]		SIFs have been shown to reduce overdose mortality by 35%. Given the rising rates of overdose mortality in the current opioid epidemic in Massachusetts, the MMS should advocate for a pilot SIF program in an effort to reduce these rates.

RESEARCH FACTORS *(continued)*			
INTERNAL			
Issue	**Strengths**	**Weaknesses**	**Analysis**
Access to addiction treatment programs	SIF attendance is associated with an increase in referral to an addiction treatment center, including a 30% increase in the rate of detoxification use, and an increase in initiation of methadone maintenance therapy.[57,58,59]		SIFs are associated with an increase in access to drug treatment. Therefore, the MMS should advocate for a pilot SIF program in Massachusetts to reduce rates of opioid use disorder and increase recovery among persons who inject drugs (PWIDs).
Impact of SIFs on injection behaviors and on reducing drug-related harms	Safer injection practices are known to reduce the risk of the transmission of HIV, HCV, as well as such conditions as cellulitis, osteomyelitis, MRSA, and endocarditis. Eight studies were examined. SIF use is independently associated with safe injection practices, including syringe sharing decreased with an estimated 69% reduced likelihood of syringe sharing; decreased reuse of syringes; increased use of sterile water; increased cooking/filtering of drugs; decreased public space injection; increased elimination of soiled materials; increased requests for education on safer injection practices by PWIDs; consistent SIF use was associated with fewer reports of rushed injections which are associated with non-sterile injection and an increased risk for overdose;[60] and an increase of alcohol swabbing of injection sites.[61] More than 30% of PWIDs reported that SIF nurses provided them with education on safer injection practices; 25% of the SIF users received care for injection-related cutaneous lesions.[62] The need for assistance with injection is a significant risk factor for HIV and HCV infection due to lack of knowledge regarding safe injection practices. More than 30% of PWIDs reported that SIF nurses provided them with education on safer injection practices.[63] SIF use was associated with increased condom use.		SIFs are associated with safer injection practices that lead to a reduction in serious illness and disease. Therefore, the MMS should advocate for a pilot SIF program in Massachusetts increase safer injection practices in an effort to decrease rates of diseases associated with injection drug use (IDU) in the Commonwealth.

RESEARCH FACTORS *(continued)*			
INTERNAL			
Issue	**Strengths**	**Weaknesses**	**Analysis**
Injection behaviors and their consequences	Regular SIF use was associated with reduction in syringe sharing, reduction in syringe reuse, reduction in public-space injection, fostering of the use of sterile syringe injection materials and the elimination of soiled materials, and increased requests from PWID for reduction on safer injection practices. Modeling studies (by Pinkerton et al., 2010, and Bayoumi et al., 2008 for example) also suggest HIV and HCV prevention benefits from SIFs.[64,65]	No direct finding that SIF use induced a decrease in viral transmission only indirect factors that can lead to transmission. The research did not examine rates of reductions in HIV and HCV pre- and post-SIF, only the reduction in risky behaviors that contribute to viral transmission. Direct reduction research is too difficult given other factors that can contribute to the decline in rates of viral transmission beyond SIFs. For example, one Vancouver research said he did not examine HIV incidence rates after the SIF opened because rates had become lower for a number of reasons.	Despite a lack of research on the direct impact SIFs have on viral transmission rates, as noted above, SIFs are associated with safer injection practices that lead to a reduction in serious illness and disease and demonstrate HIV and HCV prevention benefits. Therefore, the MMS should advocate for a pilot SIF program in Massachusetts to increase safer injection practices in an effort to decrease rates of diseases associated with IDU in the Commonwealth.
Nuisances induced by drug use in public spaces	Reduction in injection-related litter and dropped syringes and fewer complaints about public injecting by PWID.[66]	Some research noted little change in number of drug deals at SIFs. Reduction in public drug use could be related to other confounding factors including police surveillance and homeless programs in the area near the SIF.[67]	Research at the majority of SIFs demonstrates a reduction in public injecting and injection-related litter but some found little change in the number of drug deals in the surrounding area. However, research does show that SIFs do not increase the number of PWIDs or crime in the areas surrounding the SIF. The MMS should advocate for a pilot SIF program that includes a rigorous evaluation of the nuisances pre- and post-SIF. Piloting a SIF for a trial period would ensure that a SIF would only continue to operate if findings demonstrate a positive impact on the surrounding community.
Number of local PWID	No increase in the number of PWIDs, no decrease in those starting methadone maintenance therapy, and no increase in relapse rates 25 months after the SIF opened. While there have been concerns that SIFs encourage and foster drug use, there has been no increase in the number of people using drugs intravenously in localities where such facilities operate.[68]		Given that SIFs did not increase the number of PWIDs or crime in the areas surrounding the SIF, the MMS should advocate for a pilot SIF program in Massachusetts with an evaluation component that includes monitoring the impact on the local community including the number of PWIDs, crime, and violence.

RESEARCH FACTORS *(continued)*			
INTERNAL			
Issue	**Strengths**	**Weaknesses**	**Analysis**
Local drug-related crime, violence, and trafficking	No increase in crime related to drug consumption. Evaluation work undertaken in Vancouver revealed that the opening of the SIF Insite was not associated with increased crime or rates of initiation into injection drug use.[69,70] SIFs appear to shelter women who use the SIFs from the violence they are exposed to as part of their drug use. Specifically, qualitative research conducted by interviewing 25 women who used Insite found that the SIF worked to "mediate the adverse impacts of violence on women's risk environment and injection process," providing "refuge from the structural and interpersonal violence of the street," served "to facilitate the safe preparation and injection of drugs," and gave women "greater agency and control over resources in the process of drug consumption."[71]		
Medico-economic assessment of SIFs	Reduction in HIV and cost savings associated with those reductions. Local harm-reduction experts indicated that expanded services for Syringe Exchange Programs (SEPs) to include SIF services should not be too expensive.[72]	SIFs are estimated to cost $3 million by some estimates including Seattle's estimates for free-standing SIFs in that area. And some researchers believe the cost estimates modeled may be a bit high. However, most of the cost effectiveness analyses on SIFs have been focused on reduction in HIV infections, so other cost benefits may have been underexplored.	SIFs have been shown to be cost effective but some believe these estimates may be high and have not sufficiently explored outcomes beyond a reduction in HIV rates. However, a recent cost savings report demonstrated potential savings of $3.5 million per SIF in San Francisco beyond HIV rate reduction. Therefore, a pilot SIF program should include a strong cost-benefit analysis to determine if SIFs are an appropriate use of limited resources in Massachusetts. Massachusetts Law, Chapter 55, is a law that permits the linkage and analysis of state government data sets to better understand the opioid epidemic. Chapter 55 should be beneficial in allowing SIF evaluators to produce robust cost effectiveness research for an evaluation of a pilot SIF in Massachusetts.

RESEARCH FACTORS *(continued)*			
INTERNAL			
Issue	**Strengths**	**Weaknesses**	**Analysis**
Specific Cost Savings Examples: Bayoumi AM, Zaric GS. The cost-effectiveness of Vancouver's supervised injection facility. *CMAJ*. 2008;179(11):1143–1151. Pinkerton SD. Is Vancouver Canada's supervised injection facility cost-saving? *Addiction*. 2010;105: 1429–1436 Irwin A, Jozaghi E, Bluthenthal RN, Kral AH. A cost-benefit analysis of a potential supervised injection facility in San Francisco, California, USA. *Journal of Drug Issues*. 2016;1–21.	Cost savings over 10 years of Vancouver's SIF: • Decreased needle sharing as the only effect of the SIF equals a net savings of $14 million and 920 life-years. • Health effect of increased use of safe injection practices, the incremental net savings equals $20 million and the number of life-years gained to 1070. • When all three health benefits, decreased needle sharing, increased use of safe injection practices, and increased referral to methadone maintenance, the incremental net savings equals more than $18 million and the number of life-years gained 1175. It is estimated that Vancouver's SIF prevents 83.5 incident HIV infections per year for a cost saving of $17.6 million (Canadian) in lifetime HIV-related medical care costs which exceeds the SIF's operating costs of approximate, annual costs of $3 million. Researchers estimate that potential savings from averted HIV and hepatitis C virus (HCV) infections, reduced skin and soft tissue infection, averted overdose deaths, and increased medication-assisted treatment uptake for total annual net saving of $3.5 million for a single 13-booth SIF.[73]		

RESEARCH FACTORS *(continued)*			
INTERNAL			
Issue	**Strengths**	**Weaknesses**	**Analysis**
Opinion of PWID on SIFs	PWIDs report visiting the SIFs and 75% reported positive behavior changes as a result of visiting a SIF. PWIDs reported that the SIF "assessed, cared for and oriented them quickly, efficaciously, and without any judgment."[74]	Reasons that PWIDs gave for not visiting the SIFs were due to rules against sharing drugs and helping other PWIDs inject; presence of police in the area; length of wait times; suspension due to non-compliance; and distance from the SIF.	Given the feedback from PWIDs on SIFs, SIF planning should include barriers to use reported by existing SIF users in the design of a SIF pilot program in Massachusetts.
Opinions of local residents and local police	A majority of residents and business owners favor SIFs and also reported less drug use and syringe waste after SIF opened in Vancouver.[75,76,77]	Police in Ottawa and Toronto opposed SIFs. Despite the majority of Sydney residents and businesses being in favor of SIFs, the majority of residents and businesses surveyed reported that SIFs fostered a negative image of the area and drug use, attracted drug users and dealers, and increased crime and insecurity.	The opinions of local residents, police and businesses will be crucial in locating a SIF pilot in Massachusetts. Therefore, SIF planning and location siting should include advisory members representing the interests of the surrounding community and its members.
The Ethics of Randomized Control Trials (RCTs)		RCTs are not an ethical choice for evaluating SIFs based on the fact that too much evidence exists that SIFs reduce harm associated with drug use in marginalized PWIDs. Therefore, limiting the use of the SIF to those who agreed to participate in research is unethical.	Given that RCTs are not an ethical choice for evaluating SIFs, evaluators of a Massachusetts SIF should ensure that other methods for evaluating SIF outcomes are of the highest scientific standards. Experts from the Vancouver sites evaluation team should be consulted during the design of the SIF evaluation for a Massachusetts pilot program.

RESEARCH FACTORS *(continued)*			
EXTERNAL			
Issue	**Opportunity**	**Threat**	**Analysis**
Canada's Federal Government Treatment of Scientific Processes and Evidence		A conservative government with a political agenda based on a criminal justice approach to addiction likely interfered with the scientific process and research associated with the evaluation of a SIF in Vancouver.	The United States has a new president in 2017. Therefore, it is unknown whether or not the new administration will oppose SIFs in the way that Canada's government did. Also, federal officials should be consulted during the planning phase of any pilot SIF program in Massachusetts or in other U.S. states.
SPOT in Boston	Supportive Place for Observation and Treatment (SPOT) provides services to PWIDs in a geographic area where overdose rates are rising and emergency services are overburdened. SPOT has experience with and access to the marginalized patient populations engaged in harm reduction services. SPOT also has experienced staff and partners to provide the primary care, social and homeless services, drug treatment referrals, and a robust academic and medical community who can evaluate the pilot. Initial results from SPOT demonstrate positive findings in attracting and serving marginalized PWIDs in need of SIF services: 1,851 encounters, 330 unique visitors, 32% are women, 8.6% of SPOT users were connected directly into drug treatment from SPOT, including detoxification services, medication assisted treatment in the form of buprenorphine or methadone maintenance treatment; ~270 rapid response team consults; ~25 Naloxone administration; ~600 emergency department avoidances; 466 encounters with education.		SPOT in Boston is demonstrating positive results in reaching marginalized PWIDs in the Boston area. Given their success, SPOT may be considered a viable site for a pilot SIF program in Massachusetts. SPOT staff could offer valuable expertise in engaging marginalized PWIDs in Massachusetts.

ETHICAL FACTORS			
INTERNAL			
Issue	**Strengths**	**Weaknesses**	**Analysis**
Autonomy: **Patients should have the right to make autonomous decisions about their care; this principle is the basis for informed consent**[78]	SIFs respect the autonomy of PWIDs. SIFs remove stigma by removing paternalistic prohibition of drug use. Existing SIF evaluation models allow for voluntary participation of PWIDs in SIF research. Allowing PWIDs to continue to use, SIFs provide autonomy to PWIDs who want to reduce the harm of their drug use when they are not yet ready to stop injecting drugs. SIFs also add to the PWIDs autonomy by providing a safe place for them to be free to engage in their addiction without fear of violence or incarceration.	SIFs take away PWIDs autonomy as they condone the use of illegal drugs impeding PWIDs' full participation in society and are therefore a form of social control. SIFs fail to provide patients with access to the regular standard of care others (i.e., treatment to facilitate recovery and, ultimately, abstinence) are given. High-risk interventions like SIFs need to be evaluated. Allowing PWIDs to opt out of evaluation research might compromise the evaluation of SIFs.	The benefits of SIFs outlined in the research factors section demonstrate the benefits that SIFs provide to PWIDs and the communities where they live. SIFs provide medical care to a marginalized population giving them a gateway where one does not currently exist within the traditional health care system. Therefore, it seems likely that, from an ethically theoretical standpoint, the disadvantages do not outweigh the benefits. While SIFs are a high-level, high-risk intervention, the severity of the opioid epidemic in MA and the failure of existing efforts to curtail the harms associated with the epidemic in marginalized PWIDs thus far justify the implementation of a SIF in MA.
Beneficence: **Health care providers have a duty to help their patients and to take action to prevent and to remove harm from their patients' lives in an effort to ensure health and well-being.**	This keeps patients from harm, particularly in the form of death by overdose. Doctors have a duty to prevent harm from overdose and disease caused by unsafe injection practices. SIFs are a gateway to health care for marginalized PWIDs who may not otherwise have a way to access treatment. SIFs also provide PWIDs with a safe place to avoid isolation and the dangers of public injection including crime and violence.	The only way to actively ensure PWIDs do not suffer the consequences of drug addiction is to help them to stop using not continue to use "safely." Physicians are already able to provide treatment and reduce harm to PWIDs in health care environments other than SIFs including needle exchange programs.	

ETHICAL FACTORS *(continued)*			
INTERNAL			
Issue	**Strengths**	**Weaknesses**	**Analysis**
***Non-maleficence:* The duty of clinicians not to harm their patients; "do no harm." In contrast to beneficence, this is a negative duty (a duty not to act in a certain way).**[79]	PWIDs are already exposed to harm that can be reduced within a SIF. Designed for populations whose needs are not being met in other settings, SIFs remove harm but have been shown not to add harm in evaluation studies including evidence that they do not increase drug use or needle sharing. Providers working with PWIDs in a SIF are trained to work with the most vulnerable, at-risk populations and are well trained in not increasing harm but in reducing the harm that comes from public and unsafe injection practices.	SIFs allow injection drug use to continue, which is harmful to PWIDs. Physicians are obligated to do no harm. Other interventions are effective in combating the opioid epidemic without incurring the risks associated with injecting drugs. SIFs are staffed by PWIDs in recovery, which may be triggered to relapse by being exposed to injection drug use.	
***Justice:* Fairness and fair distribution of goods within society; "fair" distribution can be defined using a variety of metrics, including equality and health equity.**[80]	Resources should be allocated to SIFs as a proven, evidence-based intervention that reduces harm to a vulnerable population. SIFs improve fair distribution of resources to marginalized populations that cannot access more traditional health care services. SIFs provide PWIDs with a safe haven from crime, violence, and unsafe injection. Justice system is not undermined as the crime takes place during production and distribution.	SIFs are expensive and risky to implement. Resources could be put to better use with other interventions designed for all PWIDs. SIFs allow society to give up on PWIDs by giving them a space to continue harmful behaviors. SIFs offer less than the accepted standard of care setting up a system where different populations get different standards of care. SIFs break the law weakening our system of justice.	

ETHICAL FACTORS *(continued)*			
INTERNAL			
Issue	**Strengths**	**Weaknesses**	**Analysis**
Consequentialism: **The morality of an action depends exclusively on the net impact of the consequences of that action. In weighing the consequences of an action, all affected parties, including the agent, are given equal consideration; therefore, consequentialism is "agent-neutral."**[81]	SIFs ought to be implemented if the consequences of their implementation are positive overall. Harm reduction is demonstrably more effective than abstinence in promoting the health of PWIDs, the safety of local communities, and health care cost savings; therefore, harm reduction ought to replace strict prohibition of drug use.	The utilitarian framework depends on reliable information regarding the consequences of taking a given action. Therefore, SIFs must undergo rigorous scientific evaluations to determine if the ends justify the means. Abstinence is the only way we can be sure that PWIDs are no longer at risk for harm and that the community and health care system will benefit.	
Deontology: **The morality of an action is determined not by the consequences of that action, but rather, by whether that action is aligned with a moral rule. Different forms of deontology uphold different moral rules. The intentions of the moral agent in complying with moral rules are vital to determining the morality of an action.**[82]	The intentions behind creating a SIF are positive, in that SIFs are created out of a desire to promote the health of PWIDs. PWIDs have a right to receive treatment; given the present circumstances and available resources, SIFs are the most effective means of providing that treatment. By branding drug use as immoral, we are stigmatizing PWIDs and not promoting their health and treating their drug use as a disease putting them at more of a risk for harm.	Harm reduction aims to minimize negative consequences in a given situation, such as the opioid epidemic. However, the end does not justify the means. Only morally acceptable treatments should be used. SIFs do not meet the standard of care (i.e., treatment to facilitate recovery and, ultimately, abstinence); the creation of a SIF is morally unacceptable. Drug use is illegal because it is harmful to PWIDs and therefore ought to be universally prohibited as immoral.	
Informed Consent for Research Purposes	Best practices are currently in place in needle exchange programs in Boston and in the SIF in Vancouver, British Columbia, that will provide guidance to a SIF in Boston including allowing PWIDs to decline providing any identifying information when they use the facility and including PWIDs on a SIF advisory board and on the institutional review board (IRB).	In evaluating SIFs, those under the influence of controlled substances are unable to give consent.	Informed consent is a complex ethical issue when evaluating SIFs given that research subjects may be under the influence of a controlled substance. Therefore, informed consent models and IRB approval guidelines established by SIFs in Canada and at syringe exchange programs in Boston should serve as model principles for informed consent for a pilot SIF in Massachusetts. The rights of PWIDs should be respected and voluntary participation in research and evaluation of a pilot SIF should be assured.

EXPERT OPINIONS AND PERSPECTIVES ON THE ETHICS OF SIFS			
King County (Washington State) Heroin and Prescription Opiate Addiction Task Force	SIFs are an ethical response to reducing the harm from IDU.		Medical associations in Canada and Australia support SIFs from an ethical standpoint with little opposition from their members. These organizations have over a decade of experience in observing the societal and health outcomes associated with SIFs and remain supportive of the continuation and expansion of this harm reduction strategy in their countries. These examples are supportive of an ethical effort by the MMS to advocate for a pilot SIF program under the formation of a Massachusetts task force convened by a state authority, such as the Massachusetts Department of Public Health, to discuss the legal considerations and paths forward.
United States Medical Societies: **The American Medical Association and the medical societies and associations of the states of New York, Washington State, and California do not have policies on SIFs. However, all indicate that the issue of SIFs will be raised by their physician members in the coming year.**	Unknown	Unknown	

EXPERT OPINIONS AND PERSPECTIVES ON THE ETHICS OF SIFS *(continued)*			
Canadian Medical Society (CMA)	"The CMA fully supports harm reduction strategies as they aim to reduce mortality and morbidity even in the face of continued exposure to potentially harmful substances. Addiction is an illness, and harm reduction is a clinically mandated and ethical method of care and treatment. Physicians must treat patients as a matter of good medical practice and ethical obligation, whether the patient is believed to contribute to his or her injury or not. Section 31 of CMA's Code of Ethics provides that all physicians must 'recognize the responsibility of physicians to promote fair access to health care resources.'"	In August 2008, Tony Clement, Canada's federal health minister, addressed the Canadian Medical Association and questioned the medical ethics of supervised injection, stating, "The supervised injection site undercuts the ethic of medical practice and sets a debilitating example for all physicians and nurses … who might begin to question whether it's okay to allow someone to overdose under their care."[83]	
Australian Medical Association, Victoria (AMA Victoria)	On August 21, 2012, the AMA Victoria supported a trial of SIFs. AMA Victoria stated that SIFs "are in keeping with their policy position on blood borne viral infections which supports programs which protect against these infections including needle exchange programs and the availability and proper use of condoms."[84]		
Australian Medical Society, New South Wales (AMA NSW)	Supported making the SIF in Sydney NSW permanent based on positive outcomes.[85]		
Canadian Nurses Association (CNA)	According to the CNA, the health care benefits of SIFs have been confirmed. Therefore, refusing to provide PWIDs with evidence-based health care services with proven public health and safety benefits is unethical.		

EXPERT OPINIONS AND PERSPECTIVES ON THE ETHICS OF SIFS *(continued)*			
MMS Code of Ethics (adapted from the AMA's Code of Ethics)	In a Supreme Court case in British Columbia, the presiding judge defined the Vancouver SIF as health care: "While users do not use Insite directly to treat addiction, they receive services and assistance at Insite which reduces the risk of overdose that is a feature of their illness, they avoid risk of being infected or of infecting others by injection and they gain access to counselling and consultation that may lead to abstinence and rehabilitation. All of this is healthcare." (p. 51, para. 136)[86]	Some physicians may argue that supervising injections is not health care, although the other services provided may be considered health care including education on safer injection practices.	SIFs are in keeping with the MMS Code of Ethics whereby physicians are obligated to provide compassionate and respectful medical care to all people while respecting individual human dignity and rights. Therefore, it is reasonable for the MMS to advocate for a SIF pilot program in Massachusetts. In order to accomplish this, the MMS advocates for the formation of a Massachusetts task force convened by a state authority, such as the Massachusetts Department of Public Health, to discuss the legal considerations and paths forward. The state-led Task Force should include representation from state government (i.e., EOHHS, MassHealth, BRM, etc.), from related professional organizations (MMS, Massachusetts Hospital Association, Massachusetts Nurses Association, MASAM, etc.), and from patient and community organizations.
Principle I: A physician shall be dedicated to providing competent medical care, with compassion and respect for human dignity and rights.	Given that the services provided by a SIF are health care designed for PWIDs, a population of individuals who are often denied basic dignity and human rights because of their addiction, one could argue that support for SIFs to provide health care to this population are in line with this principle. SIFs in Vancouver have procedures for providing the voluntary testing of illegal drugs so physicians and their patients are both aware of the type and dose of drug the PWID is injecting.	Some physicians may argue that supervising injection of illegal drugs does not constitute competent medical care. Some may be concerned that physicians cannot truly know what types of substances are being injected and therefore cannot competently treat a PWID who is under the influence of an unknown substance.	
Principle III: A physician shall respect the law and also recognize a responsibility to seek changes in those requirements which are contrary to the best interest of the patient.	Given the evidence on SIFs indicating that SIFs are evidence-based health care that serve as a gateway to treatment for marginalized groups of PWIDs, one could also argue that physicians should follow the second section of this principle by seeking changes to the laws that are contrary to the best interests of the patient, in this case PWIDs who may benefit more from harm-reduction policies rather than abstinence-only policies.	The first section of this principle mandates physicians to obey the current laws against illegal drug use.	

EXPERT OPINIONS AND PERSPECTIVES ON THE ETHICS OF SIFS *(continued)*			
Principle IV: A physician shall respect the rights of patients, colleagues, and other health professionals, and shall safeguard patient confidences and privacy within the constraints of the law.	Given that SIFs are illegal under both federal and state law, it will be essential that physicians and other health care providers as well as all SIF staff members take special care in protecting the privacy and confidentiality of their patients who are at risk for incarceration and stigma if information on their drug use is released to the criminal justice system or the public.	SIFs could put physicians in a vulnerable position if mandated by law enforcement to release information on their patients who may be involved in the criminal justice system. Planned safeguards are essential to protect both patient and provider.	
Principle V: A physician shall continue to study, apply, and advance scientific knowledge, maintain a commitment to medical education, make relevant information available to patients, colleagues, and the public, obtain consultation, and use the talents of other health professionals when indicated.	A pilot SIF that includes a rigorous scientific evaluation is one way to ensure that physicians are advancing scientific knowledge in treating marginalized PWIDs. SIFs offer the opportunity for physicians to educate the public health community apprised of the latest controlled substances being used by those at risk for overdose death and infectious disease via voluntary testing of controlled substances used by PWIDs at the SIFs.		
Principle VI: A physician shall, in the provision of appropriate patient care, except in emergencies, be free to choose whom to serve, with whom to associate, and the environment in which to provide medical services.	Given that SIFs are designed to attract and provide services to a very specific population of marginalized, vulnerable PWIDs, physicians can choose not to participate in a SIF which allows for upholding this principle.		

EXPERT OPINIONS AND PERSPECTIVES ON THE ETHICS OF SIFS *(continued)*			
Principle VII: A physician shall recognize a responsibility to participate in activities contributing to the improvement of the community and the betterment of public health.	Given the positive outcomes associated with SIFs and outlined in detail in the research section of this report, SIFs uphold this principle as they contribute to the improvement of local communities and public health by reducing harms related to illegal drug use.		
Principle VIII: A physician shall, while caring for a patient, regard responsibility to the patient as paramount.	Research demonstrates that harm-reduction strategies, including SIFs, are one of the few evidence-based approaches to providing needed medical care and life-saving services to marginalized PWIDs disconnected from traditional health care systems and services. Therefore, SIFs provide physicians with the opportunity to put their responsibility to their patients as paramount and can focus on their immediate needs beyond abstinence-only solutions.	Some may argue that SIFs violate this principle by allowing physicians to supervise their patients while using potential dangerous substances that cause them harm, which might disregard what they view as their responsibility to the patients.	
Principle IX: A physician shall support access to medical care for all people.	SIFs provide medical care to marginalized PWIDs who are vulnerable to death by overdose and serious mental and physical harms associated with their drug addiction. Given how vulnerable and marginalized the PWIDs are that SIFs are designed to attract and treat, SIFs seem to be in keeping with this principle in that they are providing medical care to a group of patients who likely would not otherwise access medical care and drug treatment associated with their addiction.	Some physicians may be concerned that SIFs do not provide immediate drug treatment and health care as SIFs are a harm-reduction strategy that meets the PWIDs where they are, even if that means active injecting without a request for additional services that include treatment.	

LEGAL FACTORS			
EXTERNAL			
Issue	**Opportunity**	**Threat**	**Analysis**
State legislatures have the power to authorize SIFs as local governments have the power to protect public health.	Permits authorization by the Massachusetts legislature which would put the SIF on the strongest possible legal footing for any challenges by the federal government. Legitimizes the operation of the SIF. This is important as it decreases the chance of other Massachusetts governmental agencies from interfering with the SIF. Allows for the legislative process to deal with the issue of SIFs including the allowance for a wide group of stakeholders to weigh in on SIFs. Community members concerns can be heard and addressed and the public can be engaged on implementation.	Even if SIFs are legalized at the state level, they are not exempt from federal law. Therefore, the federal government could intervene and prosecute SIF users, staff, and operators. An exemption from federal law would be necessary to remove this threat. It is unclear how President Trump's administration will respond to these types of waivers. In seeking a federal waiver, Massachusetts would need to develop an expanded political base to maximize opportunities for success.	State-elected officials and government agencies have the power to legalize a pilot SIF program in Massachusetts. Therefore, the MMS could advocate for the formation of a task force convened by state officials to discuss the legal considerations and paths forward for a legally sanctioned pilot SIF program in Massachusetts. The state-led task force should consider partnering with other states or entities in seeking the federal waiver to expand the political base. The Board of Registration in Medicine (BRM) has authority to suspend and revoke medical licenses for physicians who practice medicine in violation of law or in deviation from good and acceptable medical practices. This provides further support for explicit clarification in statute that physicians' roles in SIFs are fully compliant with the law and have the state's endorsement that it is good medical practice and cannot be interpreted by the BRM as being medical practice that poses a threat to public health, safety, or welfare.

LEGAL FACTORS *(continued)*			
EXTERNAL			
Issue	**Opportunity**	**Threat**	**Analysis**
Existing Harm Reduction Efforts in Massachusetts	States a legal duty to protect and preserve the welfare of their citizens and the legal authority to perform this duty is known as "police power," which could be used to pass a law allowing SIFs as a law protecting the health of its citizens. Eliminates illegality of a SIF based on an opposing state law. Massachusetts has legalized several types of harm-reduction models including the introduction of pilot syringe exchange programs in 1993 and the sale of hypodermic syringes or needles in 2006. MA also passed laws and regulations promoting naloxone, a drug used to reverse opioid overdoses which have a similar harm-reduction component. In response to the city's increase in opioid overdoses, Boston Health Care for the Homeless Program (BHCHP) opened the SPOT offering medical monitoring to prevent fatal overdoses as well as health and social services, including primary care and drug treatment on demand for PWIDs who are over-sedated from the use of opioids and other substances.	Unlike other harm-reduction efforts in Massachusetts, SIFs are a form of harm reduction that is in direct opposition to federal and state laws that ban the consumption or possession of illegal drugs. Therefore, without a framework of legality at the state and federal levels, SIFs would be vulnerable to police interference and issues with funding while PWIDs and SIF staff could be vulnerable to arrest and incarceration.	Massachusetts' law includes several examples of successful harm-reduction strategies. Therefore, consistent with this trend, Massachusetts should consider a pilot SIF program.

LEGAL FACTORS *(continued)*			
EXTERNAL			
Issue	**Opportunity**	**Threat**	**Analysis**
MASSACHUSETTS LAW			
Being in the presence of heroin: Massachusetts General Laws, Controlled Substances Act, Chapter 94C, Section 35: "Any person who is knowingly present at a place where heroin is kept or deposited in violation of the provisions of this chapter, or any person who is in the company of a person, knowing that said person is in possession of heroin in violation of the provisions of this chapter, shall be punished by imprisonment for not more than one year or by a fine of not more than one thousand dollars, or both; provided, however, that the provisions of the third paragraph of section thirty-four relative to probation sealing of the records and repeated violations shall apply to him."	Amend Section 35 of Chapter 94C that makes it illegal to knowingly be present where heroin is kept or deposited to exclude physicians caring for patients at SIFs on the premise that this law was not designed to impede public health actions designed to prevent overdoses and reduce harm related to controlled substance use. Administrative action by the executive branch could authorize a SIF as a means to combat overdoses and other harms due to the opioid epidemic in Massachusetts.	Amend Section 35 of Chapter 94C: A bill was filed in the Massachusetts legislature in 2015 to amend this law to exclude physicians performing a public health service but it did not pass. There was no support that we know of other than co-sponsors for this bill. There is no testimony — written or oral — noted in our tracking system. Therefore, it is unlikely to pass without more support from legislators, voters, the criminal justice community, and other relevant stakeholders.[87] Administrative action by the executive branch could authorize a SIF. Among many opioid-related policy proposals discussed over the past year, there has not been any indications of support of this concept by the administration. As mentioned in previous sections, if SIFs are legalized at the state level, they are not exempt from federal law. Therefore, the federal government could intervene and prosecute SIF users, staff, and operators.	There is precedent for introduction of legislation in Massachusetts to allow for the legalization of being in the presence of heroin. However, given that this legislation did not pass, it is important that any efforts to advocate for the introduction of future legislation on this subject include support from a broader coalition. Toward that end, a task force of elected government officials and other stakeholders could be convened by a state authority, such as the Massachusetts Department of Public Health, to explore the feasibility of passage of this legislation.

LEGAL FACTORS *(continued)*			
EXTERNAL			
Issue	**Opportunity**	**Threat**	**Analysis**
MASSACHUSETTS LAW			
Possession of Heroin			
Massachusetts General Laws, Controlled Substances Act, Chapter 94C, Section 34: "No person knowingly or intentionally shall possess a controlled substance unless such substance was obtained directly, or pursuant to a valid prescription or order, from a practitioner while acting in the course of his professional practice, or except as otherwise authorized by the provisions of this chapter."	Amend Section 34 of Chapter 94C, which makes it illegal to knowingly possess a controlled substance, to exclude patients accessing services at SIFs. Massachusetts legislators could follow the lead of Maryland's House of Representatives and introduce legislation allowing PWIDs to use controlled substances at SIFs in the Commonwealth. Alternatively, legislation could decriminalize small amounts of heroin for PWIDs using SIF services mirroring state law on the decriminalized of small amounts of medical marijuana.	Amend Section 34 of Chapter 94C: Given the lack of support for legislation to amend legislation allowing physicians to be present where controlled substances are being used illegally (see Section 35 of Chapter 94C, it is unlikely that legislation allowing for patients to use controlled substances in a SIF would pass without more support from legislators, voters, the criminal justice community, and other relevant stakeholders. As mentioned in previous sections, if SIFs are legalized at the state level, they are not exempt from federal law. Therefore, the federal government could intervene and prosecute SIF users, staff, and operators.	The state-led task force examining the feasibility of SIFs in Massachusetts could explore the feasibility of decriminalizing small amounts of heroin for use only in a pilot SIF program.

LEGAL FACTORS *(continued)*			
EXTERNAL			
Issue	**Opportunity**	**Threat**	**Analysis**
FEDERAL LAW			
Controlled Substance Act: The Controlled Substance Act is a federal law that contains provisions that could be applied to challenge the legality of a state-authorized SIF. Section 844: This section prohibits drug possession and would, therefore, prohibit SIF clients from using drugs at the facility. Section 856: "The Crack House Statute," as this section is known, makes it illegal for anyone to "knowingly open or maintain . . . [or] manage or control any place . . . for the purpose of unlawfully . . . using a controlled substance." While proponents of SIFs could argue that Section 856 was not intended to interfere with state public health initiatives, there is no guarantee that the federal judiciary would agree.	Massachusetts could legalize SIFs at the state level as a public health approach to the epidemic of opioid disorder with the hope that the federal government would respect the states autonomy in dealing with this public health crisis. This tactic of state autonomy is in play in Massachusetts and other states in the case of medical and recreational marijuana laws. There is precedent for the federal government to selectively defer enforcement of drug laws in states where a drug may be legal for some purposes. The "Cole Memo" (see Appendix B) is a guidance put forward by the U.S. Department of Justice in August 2013 outlining the agency's perspective toward enforcement of federal marijuana laws. The memo outlines strong deference to states for enforcement of their marijuana laws, and provides priorities for circumstances that may warrant federal enforcement of federal marijuana laws such as the distribution to minors, sales to criminal enterprises, drugged driving, and possession and growing on federal lands. The Cole Memo could serve as a model of how the federal government could choose to selectively enforce conflicting federal law if the state chose to amend state law to allow for a SIF. The disadvantage to this route, however, is that this guidance can be appealed and amended at will, especially with a change in administration.	The change in administration in 2017 makes it unclear how the federal government will respond to legalization of SIFs by states.	There is precedent for the federal government to allow the states to legalize marijuana without federal interference and with explicit guidance (see Appendix B). Therefore, Massachusetts could work toward getting a federal exemption from the Controlled Substances Act to pilot a SIF program. The pilot SIF program should include a rigorous, scientific evaluation to demonstrate that exemption from federal law is beneficial.

LEGAL FACTORS *(continued)*			
EXTERNAL			
Issue	**Opportunity**	**Threat**	**Analysis**
Stigma Associated with Criminalization	Providing SIFs with an exemption to provide services to PWIDs can allow PWIDs to get the treatment they need and criminal justice system as criminalization perpetuates the stigma of addiction. Stigma of viewing addiction not as a disease but as a moral failing allows stigmatization to grow. Only removing the criminality of addiction will address stigma which is a documented barrier to reducing harm, including HIV and HCV, providing access to health care, drug treatment, and recovery services for PWIDs. Incarceration and the criminal justice system are also important issues to consider beyond public health and fatalities. Incarceration is a huge life disruptor, negatively impacts families and communities, and is a cost burden to society.	Criminalizing drug use acts as a deterrent to stop PWIDs from using drugs. Only abstinence will ensure that criminal actions and health outcomes associated with illegal drug use will end. The safety of our communities and the health of the public depend on getting PWIDs to stop using drugs, not providing them with a safe space to continue their addiction.	Given that stigma and criminalization have been identified in the literature as barriers to health care and treatment for PWIDs, the MMS advocates for a pilot SIF program to determine if the removal of stigma and criminalization will result in improved access to health care services and drug treatment as well as other public health and community benefits.
Risk: How much legal risk people are willing to take to address a public health crisis?	Given the current opioid epidemic and rising rates of deaths due to overdoses, there is greater justification for taking risk and piloting a SIF. It is unethical not to take the legal risk to save lives during a public health epidemic. This is happening in an underground SIFs currently operating in the United States.[88] The current federal and Massachusetts laws were not designed to prevent therapeutic interventions during a public health crisis. However, these SIFs are mostly staffed by lay persons, not health providers.	The risk to physicians, nurses, and other health care providers is too great to put their freedom and medical license on the line to supervise illegal drug injection in a SIF. We need to explore other methods for engaging this population in the health care system that does not condone illegal drug use.	The legal risk to physicians and health care providers is too great to risk piloting a SIF that is not legal in Massachusetts or is operating without exemptions from state and federal laws.

LEGAL FACTORS *(continued)*			
EXTERNAL			
Issue	**Opportunity**	**Threat**	**Analysis**
Professional Liability The MMS consulted with the Professional Liability Foundation Ltd. (PLF) on the liability issues associated with opening a pilot SIF in Massachusetts. The PLF "is a non-profit Massachusetts corporation established in 1995 aimed at improving the quality and affordability of patient health care by promoting reforms in the medical tort and professional liability insurance system, supporting legislation and/or administrative regulation consistent with its goals, and participating in litigation where necessary to express the views of its members." The members of the PLF represented by its advocacy voice include Baystate Health Inc., Boston Medical Center, Coverys, Lahey Health, Massachusetts Hospital Association, Massachusetts Medical Society, Reliant Medical Group, Risk Management Foundation of the Harvard Medical Institutions Inc., Southcoast Health System, Inc., Steward Health Care System, Tufts Medical Center, and UMass Memorial Health Care Inc.		The general consensus of the PLF board members when asked about SIFs from a professional liability perspective is that this is not an area where coverage is provided, although board members can see where it might meet a need. The major impediment is that supervising the injection of heroin would be an illegal activity under MA law and, hence, outside their written policies. Criminal activity is generally excluded from the specific terms of coverage. Additionally, there may be public policy issues where courts would not allow it. Second was the issue of exactly what the informed consent of the "patient" would be. The question is, what is the physician promising to do for the patient? There are instances where, once they have injected, users cannot be saved from death or serious injury. In these situations, the physician may be at risk for liability associated with these bad outcomes. Certifying and testing the drugs or recommending a dosage would be of questionable legality at a minimum. Also, PLF board members wondered if SIF "patients" can provide a valid waiver for care if the person is already under the influence of illegal drugs or impaired.	Overall, the PLF board members were consistent in their belief that SIFs are not a service that would currently be covered under existing professional liability policies and that development of such coverage would be extremely difficult, especially under the current Massachusetts laws.

LEGAL FACTORS *(continued)*			
EXTERNAL			
Issue	**Opportunity**	**Threat**	**Analysis**
Professional Licensure		Physicians must have insurance coverage for all medical activities as a condition of medical licensure in Massachusetts, or they must post a personal approved bond.	In the case of a SIF, the board might well not approve such a bond or the underlying activity.

POLITICAL FACTORS			
EXTERNAL			
Issue	**Opportunity**	**Threat**	**Analysis**
GLOBALLY			
	Approximately 100 SIFs are currently operating in at least 66 cities around the world in nine countries (Switzerland, Germany, the Netherlands, Norway, Luxembourg, Spain, Denmark, Australia, and Canada) beginning in 1986.[89] The Iranian Drug Control Headquarters approved plans to open pilot SIFs in the Kerman and Khuzestan provinces.[90]	Select government officials have pushed back on SIFs in Canada and Australia.	SIFs have been operating across the world for decades. Given the increasing public health epidemic of opioid addiction, now may be the right time to introduce pilot SIF programs in the United States.

POLITICAL FACTORS *(continued)*			
EXTERNAL			
Issue	**Opportunity**	**Threat**	**Analysis**
CANADA			
The first North American supervised injection site, Insite, opened in Vancouver, British Columbia, in 2003.[91]	*Vancouver SIF support includes the following:* • Current and former mayors of Vancouver • Business owners including the Chinatown Merchants Association and the president of the Chinese Canadian National Council • Vancouver Police Department • Supreme Court of Canada In September 2016, Canada's current Health Minister Jane Philpott asked federal officials to make it easier for communities to approve and set up safe injection sites because of what she calls a public health emergency: "I've made it very clear to my department that there should be no unnecessary barriers for communities who want to open supervised consumption sites," Philpott said during a question period in the House of Commons. "They are working with communities that are interested in this." In July 2016, the City Council of Toronto, Ontario, approved the implementation of three SIFs for the downtown area of Toronto.	*Vancouver SIF opposition includes:* • Former Federal Health Minister Tony Clement • Ontario Association of Chiefs of Police • Royal Mountain Canadian Police	Given the support from local business owners and police, the Vancouver SIF shows the benefits to the community of a pilot SIF in Massachusetts. Threats from the federal minister and police force and Canada serve to demonstrate the need for incorporating federal stakeholders in the design and implementation of SIFs in the United States. Overall the Canadian government is very supportive of SIFs and they will likely increase in number across Canada. Given Canada's success in North America, this may be an excellent opportunity for the United States to continue that growth here. However, given the push back the Insite received from lawmakers and other stakeholders, Massachusetts should include a multi-stakeholder approach to designing and implementing a SIF.

POLITICAL FACTORS *(continued)*			
EXTERNAL			
Issue	**Opportunity**	**Threat**	**Analysis**
UNITED STATES			
Surgeon General's Report, *Facing Addiction in America (2016)*	Highlights and supports harm reduction strategies: "Harm reduction programs provide public health-oriented, evidence-based, and cost-effective services to prevent and reduce substance use–related risks among those actively using substances, and substantial evidence supports their effectiveness. These programs work with populations who may not be ready to stop substance use — offering individuals strategies to reduce risks while still using substances, and substantial evidence supports their effectiveness."	SIFs are not mentioned as a type of harm-reduction strategy.	Given that the surgeon general recognizes that harm-reduction strategies are effective in addressing addiction in the United States, now is the time to advocate for all types of harm reduction strategies serving all segments of the population, including marginalized PWIDs.
SYRINGE EXCHANGE PROGRAMS (SEPS)			
Reframe SIFs as a response to the issue of a public health crisis to remove it from the political realm. *For example:* SEPs can be a political model for SIFs. SEPs are a reducing harms model associated with IDUs that were highly controversial because they were thought to encourage drug use by providing PWIDs with clean needles to inject illegal drugs.	Under political pressure, then Indiana Governor (now Vice President) Pence, eventually agreed to partially lift the ban on SEPs after an HIV outbreak in his state caused by PWIDs sharing contaminated needles. Gregorio Millett, director of public policy at amfAR (the Foundation for AIDS Research, an advocacy and research group) noted, "We must give Governor Pence credit for finally doing the right thing in the end," but noted that the HIV outbreak was "entirely preventable."[92] Several experts note that converting existing SEPs into SIFs would leverage resources, staff, and trust models.	Despite signing a pledge to fight the growing opioid crisis in his home state, Vice President Pence delayed lifting the ban on SEPs when he was governor of Indiana, which may have contributed to an outbreak in HIV in rural Scott County where 20 new cases were diagnosed per week.[93]	It may not be enough to reframe SIFs as a public health crisis. Therefore, it is important that a state authority convene a multi-stakeholder group of experts that includes politicians and government officials at the local, state, and federal levels to explore this issue and ensure it gets the political and public support needed.

POLITICAL FACTORS *(continued)*			
EXTERNAL			
Issue	**Opportunity**	**Threat**	**Analysis**
American Public Health Association (APHA)	APHA supports SIFs with the following statement: "Investigating (and, if results are favorable, implementing) new innovative agonist and partial agonist replacement treatments and medically supervised injection facilities, which have demonstrated their safety and efficacy in several countries around the world but have not yet been attempted in the United States."[94]		Massachusetts should consider the expertise of the United States' national public health organization which supports the exploration of SIFs as part of a comprehensive approach to the public health crisis of opioid addiction.
Underground SIFs operating in the United States	At least one underground SIF is operating in an undisclosed city in the United States. Research is underway and preliminary studies demonstrate positive outcomes. Publication of these findings will allow local politicians and the public to see the positive benefits of SIFs elsewhere in the United States. Providing a legal exemption for a SIF in the United States would allow underground SIFs to provide a better level of care because they could use trained physicians, nurses, and other health care professionals to deliver health care services to PWIDs rather than untrained non-medical volunteers or personnel. Prior to legalization, underground SEPs existed as SIFs do today without notice despite fears that they would increase IDU and public nuisance issues.	Given that underground U.S. SIFs break federal and state laws, they are operated by staff members who are not physicians or health care providers due to a fear that these providers will put their license to practice in jeopardy for providing health care to PWIDs operating at an illegal SIF. Politicians opposed to harm reduction strategies and SIFs may call for a crackdown on underground SIFs operating in the United States just as a member of Congress threatened to pull federal funding from San Francisco's public health department back in 2007 when they gathered stakeholders together for a meeting to discuss SIFs to address rising rates of HIV among PWIDs.	The fact that underground SIFs are operating in the United States speaks to the need for this service. The fact that these SIFs are unregulated and staff by non-professionals is concerning and calls for a pathway forward in making SIFs legal so that PWIDs using these sites have the highest standard of care from physicians, nurses, and other health care providers who are legally authorized to work in these settings.

POLITICAL FACTORS *(continued)*			
EXTERNAL			
Issue	**Opportunity**	**Threat**	**Analysis**
United States Communities	In September 2016, King County (Seattle, Washington area) Task Force on Heroin and Prescription Opiate Addiction, convened by the mayor of Seattle, recommended two SIFs open in Seattle and just outside the city. The sheriff of Seattle supports the recommendation. In September 2016, the New York City Council, with support from Mayor Bill de Blasio, allocated $100,000 to the city's health department to study SIFs. And the mayor of Ithaca, NY, supports SIFs as well. To educate the public on what SIFs are, San Francisco has been holding public education gatherings that include pop-up SIF models they can enter and videos providing information on SIFs.	San Francisco Mayor Ed Lee is opposed to SIFs.	A growing number of U.S. cities are exploring SIFs to address the growing opioid crises in their cities and communities. Massachusetts, as a model for health care reform and a leader in addressing the opioid epidemic, should consider a pilot SIF as well.
MASSACHUSETTS			
Massachusetts Department of Public Health (MA DPH)	The MA DPH's "An Assessment of Opioid-Related Deaths in Massachusetts" (2013–2014) states that "Harm reduction strategies and other interventions that address Heroin, Fentanyl, and polysubstance use should be increased, expanded, and enhanced to reduce opioid-related deaths." (page 9)[95] SIFs are a harm-reduction strategy that is proven to reduce opioid-related deaths by preventing opioid overdose mortalities.	Unfortunately, the MA DPH does not specifically mention SIFs, only "harm reduction strategies."	Although the Massachusetts DPH has not explicitly recommended SIFs, the agency has a long history of providing harm-reduction services to citizens in the Commonwealth. Therefore, this agency has the expertise to convene and direct a task force to explore a pilot SIF program in Massachusetts.

POLITICAL FACTORS *(continued)*			
EXTERNAL			
Issue	**Opportunity**	**Threat**	**Analysis**
MASSACHUSETTS			
Massachusetts State Legislature	The state legislature explains that likely route would be a statutory fix to heroin laws, which would require bill sponsors, and support of leadership to make it a priority. Ultimately, the bill would need the support of the governor or the ability to overturn veto.		Leaders from the state legislature and leaders from other relevant government agencies should be included on the state-led task force convened to examine the implementation of a SIF pilot program in Massachusetts.
Other Massachusetts Government Agencies	Agencies, such as the Board of Registration in Medicine (BRM) and the attorney general's office, would need to be at least politically neutral to not derail effort.		
City of Boston Mayor's Office of Recovery Services	The Mayor's Office of Recovery Services is glad the MMS is conducting a study on the feasibility of SIFs. SIFs are one type of harm-reduction strategy they are exploring among many others. They asked us to share our study with them so it can inform their position on SIFs. The office also indicated that "everything is on the table" as they continue to develop strategies to address the opioid crisis in Boston.	Although the mayor's office is open to exploring all options in addressing the opioid crisis in Boston, they have no position on SIFs.	It is an encouraging sign that the Mayor's Office of Recovery Service approves of the MMS's study of SIFs and is open to consider different options in addressing the epidemic. Now may be an ideal time for Massachusetts to consider a pilot SIF in Boston.
Mayor of Boston, Martin Walsh	Mayor Walsh has not weighed in on SIFs. However, he did weigh in on SPOT when it opened: "I'm up for trying anything when it comes to addiction and active using," Walsh said. "If we can help some folks — homeless folks in particular — we should try anything."		Given the mayor's support of SPOT, Massachusetts should consider expanding SPOT's services to include a pilot SIF.

POLITICAL FACTORS *(continued)*			
EXTERNAL			
Issue	**Opportunity**	**Threat**	**Analysis**
MASSACHUSETTS			
Massachusetts Governor Charlie Baker	Governor Baker has not weighed in on SIFs in Massachusetts. However, he did weigh in another harm reduction strategy, SPOT. "I have tremendous faith in them," Baker said, "and think because they are on the ground and because they are closer, most of the time, than practically anybody else who's working with the homeless population, they tend to be a pretty good bellwether about good ideas."		Given that the governor is open to SPOT and is on board with BHCHP's recommendations for serving the homeless population, a pilot SIF should be considered as an extension of BHCHP's existing SEP and SPOT services by the task force planning a SIF in Massachusetts. The governor's office should also be part of the multi-stakeholder task force involved in the planning of a SIF.
Boston Community Support SPOT staff conducted an online survey of community members living within a 500-meter radius of SPOT pre- and post-SPOT opening	Prior to SPOT's opening 47.5% (N=201) of survey respondents indicated that SIF is a good idea. Post-SPOT that percentage increased to 50.4% (N=141). The majority of respondents believe that drug use is a serious problem in the area around SPOT.	Half of respondents in the area do not support SIFs and many may believe that their area of Boston's South End has its fair share of harm-reduction services for marginalized PWIDs.	Public support for a SIF is crucial to piloting a SIF in Massachusetts. Therefore, public opinion education and outreach will be crucial prior to developing a pilot SIF in Boston or anywhere else in Massachusetts. A less residential area may need to be considered in order to get local community approval.
Local Media	The *Boston Globe* editorial board endorsed SIFs in 2015.[96]		Given that the one of the major newspapers in Boston is supporting SIFs locally, it is likely that the idea of SIFs is gaining more mainstream acceptance and should be a type of harm reduction strategy examined in Massachusetts.

POLITICAL FACTORS *(continued)*			
EXTERNAL			
Issue	**Opportunity**	**Threat**	**Analysis**
MASSACHUSETTS			
Local Police	The former police chief of Gloucester, Massachusetts, instituted a policy where PWIDs and drug users should not be arrested and should instead be offered treatment. This is a sea change in moving from the criminalization of drug use to seeing drug use as a disease in need of treatment, an important tenet of the harm-reduction philosophy. Other police departments have followed suit.[97]	Getting treatment for PWIDs who want treatment is very different from police condoning the injection of illegal substances. The Boston Police Department does not oppose SPOT but did weigh in on SIFs, which it is opposed to: "Although they have no concerns about the program's (SPOT) 'safe room' as planned. They would not support allowing injections inside. 'We can't allow the illicit distribution or sale or transfer of narcotics to be happening and not take action against that,' says Lt. Detective Michael McCarthy, a spokesman for Boston's police department."[98]	Given the police department's opposition to SIFs in Boston, any task force working on implementing a pilot SIF in Massachusetts should include police representation.
MEDICAL ASSOCIATIONS			
MMS Policy	MMS strategic priorities for 2015–2016 were "to improve health care quality, access, and equity for patients, while delivering cost-effective care and promoting a sound public health system for the Commonwealth"[99] as policy that supports the study of the feasibility of a SIF for the Commonwealth.	The MMS does not have existing policy on SIFs.	

POLITICAL FACTORS *(continued)*			
EXTERNAL			
Issue	**Opportunity**	**Threat**	**Analysis**
MEDICAL ASSOCIATIONS			
MMS Policy on Drug Addiction The MMS will work with other appropriate public and private entities to increase access to services for opiate treatment. The MMS will work with physicians, including those specializing in addictions, to develop ways to increase access to opiate treatment. The MMS supports efforts to educate physicians about newly available treatment options for addicted patients in primary care and other settings and, in particular, encourage further education around the pharmacologic potential for improved treatment.[100]	SIFs are shown to increase access to opiate treatment and other forms of drug treatment for marginalized PWIDs. SIFs are a type of treatment many physicians are unaware of in Massachusetts despite being available in other countries.		Given that the MMS's policy supports increasing access to services for opiate treatment and educating physicians on available treatment for addicted patients, SIFs are likely in keeping with MMS policy on drug addiction related to increasing access to drug treatment.
AMA Policy	Syringe and Needle Exchange Programs H-95.958 "Our AMA: (1) encourages all communities to establish needle exchange programs and physicians to refer their patients to such programs; (2) will initiate and support legislation providing funding for needle exchange programs for injecting drug users; and (3) strongly encourages state medical associations to initiate state legislation modifying drug paraphernalia laws so that injection drug users can purchase and possess needles and syringes without a prescription and needle exchange program employees are protected from prosecution for disseminating syringes."[101]	The AMA does not have current policy on SIFs.	

POLITICAL FACTORS *(continued)*			
EXTERNAL			
Issue	**Opportunity**	**Threat**	**Analysis**
MEDICAL ASSOCIATIONS			
Other Medical Societies	Although medical societies in the United States have not weighed in on SIFs, medical societies and associations in the states of Washington and New York will likely have resolutions introduced on SIFs in the near future, according to staff.[102]		

APPENDIX B: James M. Cole Memo

U.S. Department of Justice

Office of the Deputy Attorney General

The Deputy Attorney General

Washington, D.C. 20530

August 29, 2013

MEMORANDUM FOR ALL UNITED STATES ATTORNEYS

FROM: James M. Cole
Deputy Attorney General

SUBJECT: Guidance Regarding Marijuana Enforcement

In October 2009 and June 2011, the Department issued guidance to federal prosecutors concerning marijuana enforcement under the Controlled Substances Act (CSA). This memorandum updates that guidance in light of state ballot initiatives that legalize under state law the possession of small amounts of marijuana and provide for the regulation of marijuana production, processing, and sale. The guidance set forth herein applies to all federal enforcement activity, including civil enforcement and criminal investigations and prosecutions, concerning marijuana in all states.

As the Department noted in its previous guidance, Congress has determined that marijuana is a dangerous drug and that the illegal distribution and sale of marijuana is a serious crime that provides a significant source of revenue to large-scale criminal enterprises, gangs, and cartels. The Department of Justice is committed to enforcement of the CSA consistent with those determinations. The Department is also committed to using its limited investigative and prosecutorial resources to address the most significant threats in the most effective, consistent, and rational way. In furtherance of those objectives, as several states enacted laws relating to the use of marijuana for medical purposes, the Department in recent years has focused its efforts on certain enforcement priorities that are particularly important to the federal government:

- Preventing the distribution of marijuana to minors;
- Preventing revenue from the sale of marijuana from going to criminal enterprises, gangs, and cartels;
- Preventing the diversion of marijuana from states where it is legal under state law in some form to other states;
- Preventing state-authorized marijuana activity from being used as a cover or pretext for the trafficking of other illegal drugs or other illegal activity;

- Preventing violence and the use of firearms in the cultivation and distribution of marijuana;
- Preventing drugged driving and the exacerbation of other adverse public health consequences associated with marijuana use;
- Preventing the growing of marijuana on public lands and the attendant public safety and environmental dangers posed by marijuana production on public lands; and
- Preventing marijuana possession or use on federal property.

These priorities will continue to guide the Department's enforcement of the CSA against marijuana-related conduct. Thus, this memorandum serves as guidance to Department attorneys and law enforcement to focus their enforcement resources and efforts, including prosecution, on persons or organizations whose conduct interferes with any one or more of these priorities, regardless of state law.[1]

Outside of these enforcement priorities, the federal government has traditionally relied on states and local law enforcement agencies to address marijuana activity through enforcement of their own narcotics laws. For example, the Department of Justice has not historically devoted resources to prosecuting individuals whose conduct is limited to possession of small amounts of marijuana for personal use on private property. Instead, the Department has left such lower-level or localized activity to state and local authorities and has stepped in to enforce the CSA only when the use, possession, cultivation, or distribution of marijuana has threatened to cause one of the harms identified above.

The enactment of state laws that endeavor to authorize marijuana production, distribution, and possession by establishing a regulatory scheme for these purposes affects this traditional joint federal-state approach to narcotics enforcement. The Department's guidance in this memorandum rests on its expectation that states and local governments that have enacted laws authorizing marijuana-related conduct will implement strong and effective regulatory and enforcement systems that will address the threat those state laws could pose to public safety, public health, and other law enforcement interests. A system adequate to that task must not only contain robust controls and procedures on paper; it must also be effective in practice. Jurisdictions that have implemented systems that provide for regulation of marijuana activity

[1] These enforcement priorities are listed in general terms; each encompasses a variety of conduct that may merit civil or criminal enforcement of the CSA. By way of example only, the Department's interest in preventing the distribution of marijuana to minors would call for enforcement not just when an individual or entity sells or transfers marijuana to a minor, but also when marijuana trafficking takes place near an area associated with minors; when marijuana or marijuana-infused products are marketed in a manner to appeal to minors; or when marijuana is being diverted, directly or indirectly, and purposefully or otherwise, to minors.

must provide the necessary resources and demonstrate the willingness to enforce their laws and regulations in a manner that ensures they do not undermine federal enforcement priorities.

In jurisdictions that have enacted laws legalizing marijuana in some form and that have also implemented strong and effective regulatory and enforcement systems to control the cultivation, distribution, sale, and possession of marijuana, conduct in compliance with those laws and regulations is less likely to threaten the federal priorities set forth above. Indeed, a robust system may affirmatively address those priorities by, for example, implementing effective measures to prevent diversion of marijuana outside of the regulated system and to other states, prohibiting access to marijuana by minors, and replacing an illicit marijuana trade that funds criminal enterprises with a tightly regulated market in which revenues are tracked and accounted for. In those circumstances, consistent with the traditional allocation of federal-state efforts in this area, enforcement of state law by state and local law enforcement and regulatory bodies should remain the primary means of addressing marijuana-related activity. If state enforcement efforts are not sufficiently robust to protect against the harms set forth above, the federal government may seek to challenge the regulatory structure itself in addition to continuing to bring individual enforcement actions, including criminal prosecutions, focused on those harms.

The Department's previous memoranda specifically addressed the exercise of prosecutorial discretion in states with laws authorizing marijuana cultivation and distribution for medical use. In those contexts, the Department advised that it likely was not an efficient use of federal resources to focus enforcement efforts on seriously ill individuals, or on their individual caregivers. In doing so, the previous guidance drew a distinction between the seriously ill and their caregivers, on the one hand, and large-scale, for-profit commercial enterprises, on the other, and advised that the latter continued to be appropriate targets for federal enforcement and prosecution. In drawing this distinction, the Department relied on the common-sense judgment that the size of a marijuana operation was a reasonable proxy for assessing whether marijuana trafficking implicates the federal enforcement priorities set forth above.

As explained above, however, both the existence of a strong and effective state regulatory system, and an operation's compliance with such a system, may allay the threat that an operation's size poses to federal enforcement interests. Accordingly, in exercising prosecutorial discretion, prosecutors should not consider the size or commercial nature of a marijuana operation alone as a proxy for assessing whether marijuana trafficking implicates the Department's enforcement priorities listed above. Rather, prosecutors should continue to review marijuana cases on a case-by-case basis and weigh all available information and evidence, including, but not limited to, whether the operation is demonstrably in compliance with a strong and effective state regulatory system. A marijuana operation's large scale or for-profit nature may be a relevant consideration for assessing the extent to which it undermines a particular federal enforcement priority. The primary question in all cases – and in all jurisdictions – should be whether the conduct at issue implicates one or more of the enforcement priorities listed above.

As with the Department's previous statements on this subject, this memorandum is intended solely as a guide to the exercise of investigative and prosecutorial discretion. This memorandum does not alter in any way the Department's authority to enforce federal law, including federal laws relating to marijuana, regardless of state law. Neither the guidance herein nor any state or local law provides a legal defense to a violation of federal law, including any civil or criminal violation of the CSA. Even in jurisdictions with strong and effective regulatory systems, evidence that particular conduct threatens federal priorities will subject that person or entity to federal enforcement action, based on the circumstances. This memorandum is not intended to, does not, and may not be relied upon to create any rights, substantive or procedural, enforceable at law by any party in any matter civil or criminal. It applies prospectively to the exercise of prosecutorial discretion in future cases and does not provide defendants or subjects of enforcement action with a basis for reconsideration of any pending civil action or criminal prosecution. Finally, nothing herein precludes investigation or prosecution, even in the absence of any one of the factors listed above, in particular circumstances where investigation and prosecution otherwise serves an important federal interest.

cc: Mythili Raman
Acting Assistant Attorney General, Criminal Division

Loretta E. Lynch
United States Attorney
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