



# Northeastern University

## School of Law

### MEMORANDUM

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FROM: Leo Beletsky, Commissioner  
TO: Massachusetts Harm Reduction Commission  
DATE: January 11, 2019  
RE: Follow-up to January 9, 2019 meeting

Dear Colleagues:

In follow-up to the January 9, 2019 meeting, I am writing to respond to three issues raised by members of the Commission. Below, I have outlined the questions presented with responses that include references to the attached materials.

**1. What are the legal considerations in creating and operating an SCF under federal and state law?**

These considerations have been previously outlined in *Beletsky et al (2009)*, and were more recently detailed in the legal analysis commissioned by New York City (*NYC SCF Report (2017)*, Appendix F, pp. 130-147). Although the latter analysis specifically addresses New York State law, insights drawn regarding state supervised consumption facility (SCF) authorization provisions and federal-state dynamics would apply. In my view, any state legislation to implement SCFs would need address three general domains:

- a. Safe harbor provisions/carveouts from state criminal law relating to drug possession and other provisions reasonably related to the operations of SCF;
- b. Civil and professional liability and forfeiture provisions to minimize risk for professionals, property operators, and volunteers; and
- c. Technical elements of SCF approval and operations, including regulatory authority, minimum standards, state and local licensing requirements, funding, coordination with other sectors such as law enforcement, and other related issues.

Our Commonwealth and/or individual jurisdictions may consider commissioning additional analyses to chart a path for supervised consumption services under Massachusetts law.

## 2. What is the evidence on injectable opioid agonist therapy (iOAT), as an alternative/ancillary to existing OAT options (oral methadone and buprenorphine)

True to the imperative to “meet people where they are at,” a number of countries offer iOAT as a maintenance treatment option for people who inject opioids. Most commonly, these clinics use pharmaceutical-grade heroin (A.K.A. diacetylmorphine) as the maintenance agent. (Historical Note: numerous such heroin maintenance clinics operated in the United States in early 1900s, but were subsequently shuttered as the result of the Harrison Narcotics Act of 1914). The evidence base on heroin maintenance is extensive. *Strang et al. (2015)* systematically reviewed data from six robust trials comparing injectable heroin to oral methadone, finding that it is superior to methadone for the specific patient populations studied. Research has also found heroin iOAT to confer ancillary benefits, including reduced criminal justice involvement compared to methadone.

There is a considerable regulatory and financial burden involved in administering heroin iOAT. To reduce such barriers, researchers have also studied a similar, but much cheaper and more widely-available opioid—hydromorphone (A.K.A. Dilaudid)—as an iOAT option. *Oviedo-Joekes et al. (2016)* conducted a robust clinical trial that compared diacetylmorphine and hydromorphone iOAT in Canada. They found no appreciable difference across a range of health and adherence outcomes.

Given comparable effectiveness, hydromorphone would be a logistically-superior option as an iOAT medication in the US context. This is because hydromorphone is a Schedule II opioid (contrasted with diacetylmorphine, which is Schedule I). Hydromorphone is already widely used for pain treatment. Current federal law does not currently authorize the prescription of hydromorphone for opioid maintenance treatment. Nevertheless, it is estimated that up to 90% of individuals who inject drugs *also* suffer from chronic and/or acute physical pain. This means that hydromorphone could be deployed to reduce drug injection-related harms through some combination of the following channels:

- A. Utilization of injectable hydromorphone as iOAT as a DEA/NIDA authorized research trial (see item 2 below) or by exploring other channels of legal flexibility or federal law enforcement discretion; and/or
- B. Utilization of injectable hydromorphone for the purpose of pain treatment among people who inject drugs, making it unnecessary to seek approval of a novel purpose

The bottom line is that providing iOAT creates an important *legal* paradigm shift from the traditional SCF model to a supervised consumption venue that is squarely medical. Clients of such facilities consume prescribed, medical-grade drugs in compliance with applicable laws and without triggering concerns about criminal provisions like the “Crack House Statute.” Finally, the traditional and the prescription SCF model are not mutually-exclusive, as the same venue could conceivably house both.

**3. What is the legal and administrative framework for the creation and opening of supervised consumption facilities (SCFs) under federal research exemption mechanisms?**

The federal Controlled Substances Act and other federal law creates a framework for conducting human subjects research involving scheduled drugs, including Schedule I (e.g. heroin). This means that administrators (and participants) of the research receive special exemptions and permissions for possession, supply chain management, distribution and other activities involving these drugs as they pertain to the research protocol. This process involves both National Institutes of Drug Abuse (NIDA) and Drug Enforcement Administration (DEA) approval, as well as compliance with other federal and state requirements. It is possible that an SCF could come under such a research exemption, as outlined in the *NYC SCF Report* (pp. 145-146). This would be a novel use of this mechanism, since the drugs consumed on premises as part of the study would be pre-obtained, rather than provided by research study personnel. Approval for studies involving Schedule I substances takes a considerable period of time—typically several years.

Sincerely,

A handwritten signature in black ink, appearing to read "Leo Beletsky". The signature is fluid and cursive, with a long, sweeping underline that extends downwards and to the right.

Leo Beletsky, JD/MPH  
Associate Professor of Law and Health Sciences  
Director, Health in Justice Action Lab  
Northeastern University