10.4

Appendix 1: Federal and Provincial Regulations

<u>Methadone</u>

Federal Regulations

Methadone is a controlled substance that is regulated under the Controlled Drugs and Substances Act (S.C 1996, c.19) (CDSA), the Narcotic Control Regulations (C.R.C, c.1041) (NCR) and the Narcotics Safety and Awareness Act, 2010, S.O. 2010, c. 22.

Methadone is permitted to be prescribed in the same manner as other narcotics under the NCR. As such, pharmacists may sell or provide a narcotic, such as methadone, to a person if the pharmacist has a written order or prescription, signed and dated, by a practitioner. Practitioners and pharmacists must meet all other provisions of the NCR, as well as requirements set by their province or territory or the licensing authority governing their practice when dealing with controlled substances. Examples of such requirements include, but are not limited to, additional courses or training.

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Methadone must be dispensed according to the College's Opioid Policy, Centre for Addiction and Mental Health (CAMH) guidelines and the advice provided by the College of Physicians and Surgeons of Ontario (CPSO) to safeguard patients receiving high-risk medications.

Requirements for pharmacies include: informing the College within seven days of starting to dispense methadone; having copies of required reference materials available; adhering to the Opioid Policy; and ensuring that staff are trained. With regards to training, the designated manager and at least one staff pharmacist must complete mandatory education and training, which must be updated a minimum of every five years. The College also recommends that all pharmacies have their own supplementary written policies and procedures to ensure the requirements are consistently met.

<u>Cannabis</u>

Federal Cannabis Act Regulations

The regulations surrounding cannabis are contained in the Federal Government's Cannabis Act, which specifies the rules and standards related to the production, distribution, sale and possession of cannabis across Canada. All cannabis producers, for medical or recreational purposes, are required to obtain a licence issued by Health Canada, allowing for various activities with cannabis, including growing, selling, researching, and testing.

To obtain a licence from Health Canada, applicants must submit detailed and extensive information regarding the operations and logistics of their facility including, confirmation that their local government, fire authority, and police force have been notified about the proposed facility and its operations.

Licensing Requirements
Confirmation that local government, fire authority, and police force have been notified about
the proposed facility and its operations
Site that meets all licensing requirements (this includes provincial or territorial law and
municipal or local government laws, by-law and policies)
Site that meets all good production practice requirements including:
 Air filtration and ventilation systems that effectively prevent escape of odours
outdoors and maintains air quality indoors, as well as procedures for their continued
maintenance and upgrades as deemed necessary
 Appropriate and secure means of removing and disposing of cannabis waste and
materials
Site that adheres to physical security requirements including site design to prevent
unauthorized access, visual monitoring systems suited to locate both indoors and outdoors,
intrusion detection systems operating at all times to detect attempts at unauthorized access
or tampering with security systems
Documentation indicating the staff responsible for quality assurance meets technical
knowledge, training and experience requirements, as well as all required security clearances
Security screening

Although the Federal Government is responsible for cannabis production licensing, Health Canada licence holders are expected to comply with relevant municipal by-laws, noting that municipalities can still introduce policy or regulatory options to respond to local interests and concerns.

Applicants must also pay fees associated with the licence application and security screening as part of the process.