

Framework for FMRAC's Members on a Regulatory Approach to Physicians Who Prescribe Opioids

Purpose

The purpose of this Framework is to provide recommendations and propose minimum regulatory standards to FMRAC's members, i.e., the Medical Regulatory Authorities (MRAs) in Canada, to guide physicians who prescribe opioids to patients with pain and/or an opioid use disorder¹.

This Framework complements existing MRA policies and guidance to physicians and strives for pan-Canadian consistency in opioid prescribing. As FMRAC has no authority over its members, it is the discretion of the individual MRAs to adopt or adapt these recommendations as they deem appropriate and/or feasible.

Preamble

Prescription opioids can be effective for patients suffering from pain and/or an opioid use disorder. Physicians have a responsibility to manage their patients' pain and/or opioid use disorders, and this requires appropriate knowledge, skills and training. It also relies on open communication with patients, compassion and sound professional judgement, to ensure the effectiveness of the treatment plan, maintain the dignity of patients, as well as assure patient and public safety.

It is incumbent on MRAs to develop balanced approaches to support, guide and, where appropriate, identify and monitor physician opioid prescribing, to mitigate and safeguard against the risk of harm to patients.

Ethical, Professional and Legal Obligations

It is expected that all MRAs develop and implement policy that is informed by evidence and/or best practice and considers potential unintended consequences, including but not limited to stigmatizing patients and/or compromising either their health (e.g., rapid tapering or abruptly ceasing medications) or reasonable access to care. FMRAC believes that such policy must also articulate expectations that physicians comply with relevant legislation, including applicable human rights legislation, to ensure non-discrimination against any patient with pain and/or an opioid use disorder who requires opioids. It is also expected that all MRAs have clear policies for physicians on accepting new patients and terminating existing patients to ensure their decisions are fair and non-discriminatory to those currently using opioids for pain and/or those with an opioid use disorder.

MRA policies must also emphasize the ethical and professional obligations of physicians, as well as current regulatory policies and guidance in their jurisdiction, on matters including but not limited to:

¹ *Please note: This Framework does not apply to chronic pain in the context of active cancer pain, palliative and end of life care*

- the patient-physician relationship;
- accepting new patients;
- informed consent;
- medical records;
- privacy and confidentiality;
- follow-up with patients;
- expectations of ongoing competence, including when prescribing opioids for acute pain, chronic pain, an opioid use disorder and/or opioid agonist therapy;
- expectations of professionalism when collaborating with patients, colleagues, pharmacists and others involved in the provision of health care; and
- educational and/or clinical training requirements and, if applicable, requirements for evidence of their completion.

Principles

FMRAC also recommends that MRA guidance documents, policies and related communications materials address physicians' ethical and professional responsibilities to:

- strive to balance the needs of their patients with the potential harms of opioid prescribing to patients and the public;
- provide care that is culturally sensitive, supports open communication with patients and informed decision-making when initiating, tapering, and/or discontinuing opioids; and
- establish mutual and clear expectations with patients while remaining compassionate.

It is further recommended that these materials are regularly reviewed and updated to ensure they do not inadvertently stigmatize patients.

Recommendations Regarding Professional Guidance by MRAs

FMRAC also recommends that the following be adopted by all MRAs in their policies and professional guidance to physicians when prescribing opioids for acute pain, chronic pain, non-active cancer pain, opioid use disorders and/or opioid agonist therapy.

Physicians must:

1. First perform and document a relevant and appropriate clinical assessment based on the patient's presentation to ensure that an opioid prescription is the most appropriate course of action and will meet the patient's needs.
2. Inform patients about the potential benefits and harms of opioids, including but not limited to physical dependence, addiction, tolerance, withdrawal, overdose and death. Physicians must also address how to safely secure and store opioids and dispose of those unused, as well as review the potential consequences of diversion.
3. Collaborate and communicate, both verbally and in writing, with their patient's health care team and other providers, as appropriate.
4. Access provincial prescription monitoring programs when and where available.
5. Make evidence-informed decisions and document justification when varying from evidence-based guidelines and best practice for the management of pain, and/or an opioid use disorder.

Recommendations to the Medical Regulatory Authorities (MRAs)

FMRAC also recommends that all MRAs, where appropriate and/or feasible,:

1. advocate for and support the development and maintenance of pan-Canadian guidelines relating to pain management, opioid prescribing and opioid use disorder, as well as the management of chronic pain in specific and high risk populations, and encourage their application by physicians;
2. ensure prescribing standards are being maintained by collaborating with their respective Office of the Chief Medical Examiner/Coroner and other stakeholders to facilitate a process for the annual identification and review, by the respective MRA in their jurisdiction, all deaths attributed to prescription medications, including opioids;
3. collaborate with stakeholders to facilitate the development of a process for regularly sharing with opioid prescribers the outcomes and lessons learned from the review of all opioid-related deaths and serious medical complications;
4. encourage physicians to report adverse drug reactions to Health Canada and medication incidents to the appropriate body;
5. work with FMRAC, governments and other stakeholders to promote: i) the development of prescription monitoring programs in every province and territory; ii) the standardization of data elements and their collection; iii) recommendations on common quality indicators; and iv) data that are available and easily accessible by medical regulatory authorities and other stakeholders, and shareable across jurisdictions;
6. identify and monitor quality indicators relating to appropriate opioid prescribing;
7. collaborate with patients, including those with lived experience, and contribute to the work of these and other stakeholders (including pharmacy, nursing and dental regulators) on issues and/or activities relating to clinical and regulatory guidelines, education and mentorship opportunities, medication safety and surveillance;
8. encourage stakeholders to support the development of plain language patient information and resources, particularly for vulnerable populations, about opioids in general, as well as how to safely secure and store them, and dispose of those unused;
9. collaborate with regional health authorities, correctional services and primary care providers in the community to advocate for consistent policies and systems that facilitate reasonable access to appropriate and safe opioid treatment for pain and/or management of opioid use disorder, as well as non-pharmacological pain management options;
10. work with stakeholders to advocate for: i) patient access to the full continuum of opioid agonist therapy and evidence-based harm reduction interventions, particularly in rural and remote or underserved areas; ii) non-pharmacological pain management options to be more broadly accessible to and affordable by patients; and iii) the availability of culturally sensitive care;
11. provide on their websites, or facilitate easy access to, information about educational programs as well as mentorship opportunities relating to pain management and the and the management of opioid use disorders.