College of Physicians and Surgeons of British Columbia

Professional Standards and Guidelines

Safe Prescribing of Drugs with Potential for Misuse/Diversion

Preamble

This document establishes both professional standards as well as guidelines of the Board of the College of Physicians and Surgeons of British Columbia.

A **standard** reflects the minimum standard of professional behaviour and ethical conduct on a specific topic or issue expected by the College of all physicians in British Columbia. Standards also reflect relevant legal requirements and are enforceable under the *Health Professions Act*, RSBC 1996, c.183 (*HPA*) and College Bylaws under the *HPA*.

A **guideline** reflects a recommended course of action established based on the values, principles and duties of the medical profession. Physicians may exercise reasonable discretion in their decision to act on the guidance provided, but should support a decision to follow a different action with a comprehensively documented rationale.

College's Position

The public health crisis of prescription drug misuse has developed in part due to the prescribing of physicians. The profession has a collective ethical responsibility to mitigate its contribution to the problem of prescription drug misuse, particularly the over-prescribing of opioids, sedatives and stimulants.

The College acknowledges the appropriate role of pharmacotherapy in the context of active cancer, palliative, nursing home and end-of-life care. These standards may not apply to the treatment of patients in these situations.

Every physician is professionally responsible for the prescription that they provide to a patient.

Long-term opioid treatment (LTOT) refers to the prescribing of daily opioid medications on a continuous, and not as-required, schedule.

Standards

Physicians **must**:

1. Review patients' current medications (using PharmaNet profiles when access is available) before prescribing opioids, sedatives or stimulants.
2. Base long-term treatment with medications with known risks, including opioids, sedatives and stimulants, upon a clinical diagnosis and objective evidence. Continuing to prescribe medication solely on the basis that they have been previously prescribed is not acceptable.
3. Document discussion with patients that non-pharmacologic therapy and non-opioid analgesics are preferred for chronic non-cancer pain (CNCP) and that potential benefit of LTOT is modest and risk significant.
4. Advise patients that LTOT is not indicated for certain medical conditions including headache disorders, fibromyalgia and axial low back pain.
5. Always prescribe the lowest effective dosage of opioid medication. Doses >50 morphine milligram equivalents (MME) per day warrant careful reassessment and documentation. Doses >90 MME per day warrant substantive evidence of exceptional need and benefit. (This advice excludes treatment with methadone.)
6. When treating patients with acute pain conditions, prescribe only immediate release opioids in quantities that the patient will need before community follow-up will be resumed (three to seven days is often adequate).
7. When discharging patients from acute-care settings, or post-operatively, prescribe only the quantities of opioids, sedatives or stimulants that the patient will need before community follow-up will be resumed.
8. Base decisions to prescribe long-term psychoactive medications, including LTOT, on well-documented, comprehensive initial assessments and frequent (at least every three months) reassessments. These assessments and reassessments must include documented history and physical examination of the patient. There must also be documentation that the patient has been screened regularly for the presence or emergence of mental health and substance use disorders and risk factors and advised about safety-sensitive occupational risks, child care responsibilities and driving.
9. Document the offer of a take-home naloxone prescription to all patients who are at risk of respiratory depression as a consequence of receiving opioid medications.
10. Document having directed and regularly reminded patients for whom they are prescribing LTOT to abstain from alcohol and non-prescription sedatives.
11. Order at least annual random urine drug testing (rUDT) and/or random pill counts for all adult patients on long-term opioids, benzodiazepines, sedative hypnotics or stimulants.

Further, physicians **must not**:

12. Prescribe benzodiazepines or sedative hypnotics to patients on LTOT, other than as a documented taper.
13. Prescribe combinations of:
    - opioids with benzodiazepines and/or sedative hypnotics

- stimulants with benzodiazepines and/or sedative hypnotics

14. Provide prescriptions allowing dispenses of opioids, sedatives and stimulants, which exceed a three-month supply or 250 tablets, whichever is less.
15. Initiate treatment with drugs with a high risk-profile such as methadone and fentanyl without relevant training and experience.

Guidelines

1. Physicians who prescribe opioids, sedatives or stimulants will be expected in the future to have PharmaNet access in all clinical locations and to use it appropriately. In situations where PharmaNet access is not currently available, physicians are expected to consult colleagues, including pharmacists and prescribe only necessary medications until the patient's dispensing history is available. (Walk-in, urgent care, multi-physician clinics and methadone clinics must have on-site access to PharmaNet.)
2. If starting opioid therapy for chronic non-cancer pain (CNCP) physicians should prescribe immediate release (IR) opioids only. Extended release (ER) and long-acting (LA) preparations should not be prescribed for an opioid-naïve patient and should be reserved for patients experiencing severe continuous pain.
3. LTOT should always be described as a trial, to be discontinued if functional improvement cannot be objectively demonstrated or harms emerge. When patients have been on LTOT for long periods of time, physicians should perform a comprehensive assessment of the benefits versus the harms of the treatment. Where benefits do not outweigh harms, patients should be empathetically advised that the medication will be tapered to a lower dose or to discontinuation. It is rarely appropriate to abruptly discontinue LTOT and opioid tapering protocols should be slow enough to minimize symptoms of withdrawal (a 10% dose reduction every one to two weeks is considered reasonable).
4. LTOT is generally not appropriate for high-risk groups, including patients with addiction, major psychiatric illness or personality disorders, young people, and those with functional somatic syndromes. When patient assessment or reassessment reveals a diagnosis of a substance use disorder or other mental health diagnosis physicians should consider consultation with a physician with experience in addiction medicine and/or a psychiatrist regarding appropriate management.
5. The prevalence of an opioid use disorder may be as high as 26% among primary care patients receiving opioids for CNCP. Patients with a diagnosis of an opioid use disorder should be offered treatment including medication assisted treatment with methadone or buprenorphine, as well as abstinence-based treatment where appropriate.
6. Other concurrent medical conditions which should be carefully considered in the context of decisions to prescribe or continue LTOT include obesity, congestive heart failure, sleep apnea, chronic lung disease and renal or hepatic insufficiency. Elderly patients are more likely to suffer from these concurrent diagnoses and to be taking multiple medications and suffer from cognitive impairment all of which significantly increase risk.
7. When providing prescriptions for opioids, sedatives or stimulants, consider the possibility that other household members (including young children) might accidentally

or deliberately take those medications. Prescription medications, especially opioids, should be securely stored, preferably locked, and unused medications disposed of at a pharmacy.

8. Tolerance to benzodiazepines and sedative hypnotics may develop quickly. They should be prescribed for short-term use only and not in doses that exceed the manufacturer‘s recommended maximum.
9. It is recommended that all emergency rooms, urgent care and multi-physician clinics have a consistent policy around the prescribing (and dispensing) of opioids, sedatives and stimulants.
10. Assessing risks of misuse or diversion based only on patient assessment and self-report without objective contextual information is difficult. Supervised urine drug testing (UDT) may be performed in the office as point-of-care testing or sent to the laboratory, but physicians should understand the results and limitations of the test they are using. Even when risks seem low, random urine drug testing (rUDT) and/or random pill counts can provide important information. The requirement for UDT should be discussed non-judgmentally at the initiation of the treatment relationship, in order to minimize the perception of stigmatization. (Supervised UDT urine drug testing means a reasonable level of supervision but not necessarily witnessed provision of the sample. Random UDT using a 24-hour phone call protocol is more informative than predictable UDT at the time of a scheduled office visit. Random pill counts are a non-intrusive method of assessing patient compliance.)
11. The advice to avoid concurrent prescribing of opioids and sedative hypnotics such as benzodiazepines is based on the significantly increased risk of overdose death in this patient population. However, physicians should be aware that other central nervous system (CNS) depressants (including muscle relaxants, anticonvulsants, sedating antidepressants, antipsychotics, some over-the-counter medications and alcohol) may also potentiate CNS and respiratory depression. If LTOT is clinically appropriate, benzodiazepines should be tapered and discontinued. Benzodiazepine tapering should be gradual because of the significant risks of benzodiazepine withdrawal.

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Questions and Answers

Safe Prescribing of Drugs with Potential for Misuse/Diversion

The following attempts to address some of the questions raised by the profession.

Why is the College's professional standard described as legally enforceable?

The newly revised professional standard evolved from a previous version developed in 2012 by the College's Prescription Review Program called *Prescribing Principles*, which, as a "guideline," did not prevent an increasing toll of prescription drug misuse and overdose deaths in this province. Additionally, clinical guidelines developed by the National Opioid Use Guideline Group (NOUGG) in 2010, an initiative sponsored by this and other Canadian medical regulatory authorities, have also apparently not been effective in preventing the increasing reliance of prescribers on long-term opioid treatment for chronic non-cancer pain. The current document comprises 15 standards, which are enforceable under the *Health Professions Act* thereby making them more authoritative, and an additional 11 guidelines, which outline a recommended course of action.

Do physicians have to stop prescribing drugs with potential for misuse/diversion?

No, each of these classes of prescription medication is indicated for some patients. The key message contained in the standard is that physicians should more carefully consider both starting these medications and/or continuing them for long-term use because of the risks involved both for the individual patient and the public at large. That is not to say that no patients should be prescribed these medications. The decision to prescribe however, even when the patients have been "inherited" from another physician or are legacy patients who have been on the medication for many years, should be based on documented and careful patient assessment and treatment rationale. It is unacceptable to refuse to treat patients solely on the basis of their long-term medications or medical diagnosis. The newly revised standard does not support inappropriate withdrawal of long-term prescription medications. It endorses an empathetic discussion of benefits versus harms of long-term prescription medications with patients. Where tapering to a lower dose or to discontinuation is the clinically appropriate course, physicians are advised to taper slowly to minimize physical and psychological withdrawal.

Do all patients need to receive less than 90 mg MEDD?

Standard #5 requires documentation of the rationale for all prescriptions of opioid medication, and avoidance of higher doses unless there is clinical indication for this. Physicians must critically analyze medication regimens for chronic non-cancer pain and other complex patients, and exercise judicious, safe prescribing. Risks associated with concurrent medical conditions (e.g. sleep apnea, chronic lung disease, cognitive impairment, etc.) must be carefully reassessed at intervals. Some physicians may have misinterpreted the document as a standard of dosage alone when it was intended to be a standard of documentation of thoughtful prescribing. It does not say that a physician must not prescribe >90 MME per day (or MEDD). It states that if prescribing greater than 90 mg MEDD, physicians must carefully document the rationale for their decision, and must frequently reassess the dose.

Why does this standard speak to 90 mg MEDD when the previous NOUGG guidelines referred to 200 mg MEDD as being the "watchful dose"?

The literature review that preceded the 2010 NOUGG guidelines began in 2008. Current medical evidence, as reviewed most recently in the March 2016 US Centers for Disease Control and Prevention's (CDC) *Guidelines for Prescribing Opioids for Chronic Pain*, has identified the lack of evidence for supporting high-dose opioid use in chronic non-cancer pain. The College is aware that the NOUGG guidelines are also currently under review and a new version is expected in 2017. It is expected the new NOUGG guidelines will reference a lower "watchful dose" than it did in 2010.

Does the 90 mg MEDD include methadone?

No. The College recognizes that the morphine equivalent for doses of methadone in patients with chronic non-cancer pain and/or opioid use disorder can be significantly higher than 90 mg MEDD.

What if the patient is on opioids and benzodiazepines? The standards say that benzodiazepines can only be prescribed as a taper.

Benzodiazepines should not be prescribed as an ongoing prescription if the patient is also on long-term opioid treatment (LTOT). This does not refer to patients who intermittently use an opioid medication. There is no clinical data to support this long-term combination, and coroners' data shows it to be unsafe. Physicians should discuss these issues with their patient and suggest a choice for monotherapy. If and when tapering opioids, and more especially benzodiazepines, physicians should do so slowly to minimize withdrawal discomfort and psychological distress. And, they should develop a treatment plan and reasonable timeline for the taper, including the pharmacist when appropriate. Blister packing can be a very useful strategy in this context.

Why did the College include stimulants in a professional standard about opioids?

The professional standard is not intended to address only opioids, or benzodiazepines, or stimulants. The College knows from both clinicians and law enforcement that these three groups of prescription medications are the most widely misused and diverted. Although it has not been possible to avoid reference to patients with chronic non-cancer pain, the standard is not focused on a single group of patients or a single diagnosis.

Standard #14 states that physicians must prescribe "a one-month supply or 250 tablets, whichever is less." Does that mean that patients on a once- or twice-daily medication can only be prescribed dispenses of 30 to 60 tablets?

The College has reviewed this specific statement and recognizes that it may be too restrictive. The standard will be edited to read "a three-month supply or 250 tablets, whichever is less."

Does the standard apply to palliative care patients?

No. As stated in the standard: The College acknowledges the appropriate role of pharmacotherapy in the context of active cancer, palliative, and end-of-life care.

Standard # 4 says not for headache, fibromyalgia or back pain. Why?

To clarify, this refers to LTOT, not intermittent or PRN use of opioids. There is not good medical evidence to support continuous daily opioid treatment of these conditions.

What other resources can physicians offer their patients with chronic pain?

Medication is just one part of the treatment plan for most chronic and nonmalignant pain conditions.

Patients may access:

- chronic pain self-management workshops for patients from Self-Management BC: www.selfmanagementbc.ca
- resources from PainBC: www.painbc.ca

The College encourages physicians not to write off the option of offering physical or exercise therapy to patients who do not have the coverage or personal resources for physiotherapy or rehabilitation programs. Physicians can prescribe simple exercise regimes and monitor functional improvement where other resources are not available. Additionally, patients who do not have access to psychologists may still benefit from advice from their physician about cognitive behavioural therapy.

Patients with acute pain need enough medication to bridge them to community follow-up. What if three to seven days is not enough?

Short-term prescriptions should be enough to get patients with acute pain to their regular prescriber. Large quantities are never advisable. The duplicate prescription can be written for a total quantity, but specify part fills. For example, "*Total quantity 300 tablets. Dispense 100 tablets every two weeks*." Dispensing smaller volumes is one way to foster compliance, prevent diversion and potential overdose, and prevent wastage. Patients should be directed to take unused medication to the pharmacy for safe disposal.

Is it appropriate for patients who have been on long-term opioid therapy for many years to be told by a physician that their prescriptions will be stopped immediately?

The only situation in which this approach might be considered appropriate is if the patient's urine drug testing (with laboratory confirmation of the optimal sample by gas chromatography-mass spectrometry, particularly for semi-synthetic and synthetic opioids) showed no evidence at all of the opioid being prescribed. In all other cases, this approach might be considered clinically inappropriate. The College would encourage any patient or physician aware of such a case to contact the College.