This document is a conceptual rules draft, designed for discussion purposes only, and is subject to further revision

RULES FOR COMPREHENSIVE OPIOID ANALGESIC PRESCRIBING

Proposed SECTION 1
Opioid Prescribing —Intent

Pursuant to ESHB 1427, chapter 297, sections 2 through 8, Laws of 2017 and Executive Order 16-09, the Dental Quality Assurance Commission, the Nursing Care Quality Assurance Commission, the Medical Quality Assurance Commission, the Board of Osteopathic Medicine and Surgery, and the Board of Podiatric Medicine and Surgery have worked together to adopt shared professional practice requirements expected of all healthcare practitioners who prescribe opioid analgesics.

The diagnosis and treatment of pain is integral to the practice of (medicine/nursing/osteopathic medicine and surgery/dentistry/podiatric medicine and surgery).
Practitioners should not prescribe opioid analgesics by default. Opioid analgesics may be essential in the treatment of acute or subacute pain due to trauma or surgery; however, use for acute or subacute pain can raise the risk of addiction. Use for chronic pain carries significant patient risk.

Proposed SECTION 2
Scope and Applicability

The variety and complexity of human conditions make it impossible to address in rule all the situations the practitioner must consider when treating a patient. As with all health professions regulations, these rules are intended to set minimum standards for professional conduct; these rules do not encompass all of the guidelines recommended by the agency medical directors' group, the Bree collaborative, centers for disease control guidelines, or other agencies or organizations.

Where these rules do not address specific issues, the (board/commission) will govern based on nationally accepted and evidence-based standard of care and will refer to current clinical practice guidelines and expert review in considering cases involving management of pain. The practitioner should obtain sufficient education and training on current clinical practice guidelines, on an ongoing basis, to ensure competency in safe prescribing of opioids and other analgesics.

These rules establish legal standards for practitioners prescribing opioid analgesics under the (board's/commission's) jurisdiction. Compliance with applicable state or federal law is required. These rules do not establish a legal standard of care outside the context of the (board's/commission's) jurisdiction.

Proposed **SECTION 3**
Definitions

The definitions in this section apply throughout sections 4 through section X unless the context clearly requires otherwise.

- "Acute pain" means the normal, predicted physiological response to a noxious chemical, thermal, or mechanical stimulus and typically is associated with invasive procedures, trauma, and disease.
- "Addiction" means a primary, chronic, neurobiologic disease with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include: impaired control over drug use, craving, compulsive use, or continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.
- “Biological specimen testing” means tests including but not limited to urine, hair or other biological samples for various drugs and metabolites to provide objective documentation of adherence to an opioid treatment plan as well as aid in the diagnosis and treatment of addiction or substance abuse disorders
- "Chronic pain” means pain caused by various diseases or abnormal conditions that continue longer than twelve weeks.
- “Clinically meaningful improvement in function” means a measurable improvement in function of at least thirty percent as compared to the start of treatment or in response to a dose change. A decrease in pain intensity in the absence of improved function is not considered clinically meaningful improvement in function.
- "Comorbidity" means a preexisting or coexisting physical or psychiatric disease or condition.
- “Functional examination” means an examination used to describe an individual’s ability to perform key daily activities and to evaluate changes in the activities of everyday life. It encompasses physical, social, and psychological domains.
- “High-risk” means a patient at increased propensity for misuse, abuse, stockpiling, diversion, addiction, overdose, or other aberrant behaviors as determined by the patient’s history and/or the risk assessment tool chosen by the provider.
- "Hospice care" means a model of care that focuses on relieving symptoms and supporting patients with a life expectancy of six months or less. Hospice involves an interdisciplinary approach to provide health care, pain management, and emotional and spiritual support. The emphasis is on comfort, quality of life, and patient and family support. Hospice can be provided in the patient's home as well as freestanding hospice facilities, hospitals, nursing homes, or other long-term care facilities.
- “Hospital” means any institution, place, building, or agency licensed by the department under chapter 70.41 RCW to provide accommodations, facilities, and services over a continuous period of twenty-four hours or more, for observation, diagnosis, or care of two or more individuals not related to the operator who are suffering from illness, injury, deformity, or abnormality, or from any other condition for which obstetrical, medical, or surgical services would be appropriate for care or diagnosis.

- "Inpatient" means a person who has been admitted to a hospital for more than twenty-four hours.
- "Morphine equivalent dose" means a conversion of various opioids to a morphine equivalent dose by the use of accepted conversion tables.
- "Opioid analgesic" means a drug that is used to alleviate moderate to severe pain that is either an opiate (derived from the opium poppy) or opiate-like (synthetic drugs). Examples include morphine, codeine, fentanyl, meperidine, and methadone.
- "Opioid naïve" means a patient who has not used opioids for more than seven consecutive days during the previous thirty days.
- "Palliative care" means care that improves the quality of life of patients facing life-threatening illness. With palliative care particular attention is given to the prevention, assessment, and treatment of pain and other symptoms, and to the provision of psychological, spiritual, and emotional support.
- "Pain" means an unpleasant sensory or emotional experience associated with actual or potential tissue damage, or described in terms of such damage.
- "Pain management clinic" means a publicly or privately owned facility for which a majority of patients are receiving chronic pain treatment which may include opioid analgesics or other care provided by multiple available disciplines or treatment modalities.
- "Perioperative pain" means acute pain that occurs as the result of surgery for which opioid analgesics may be prescribed.
- "PMP" means the Washington prescription monitoring program authorized under chapter 70.225 RCW.
- "Practitioner" means an advanced registered nurse practitioner licensed under chapter 18.79 RCW, a dentist licensed under chapter 18.32 RCW, a physician licensed under chapter 18.71, 18.57, or 18.22 RCW, or a physician assistant licensed under chapter 18.71A or 18.57A RCW.
- "Risk assessment tools" means utilizing a tool appropriate for the patient, such as but not limited to, the Screener and Opioid Assessment for Patients with Pain, Opioid Risk Tool, or Screening, Brief Intervention and Referral to Treatment, which are designed for predicting the likelihood that a patient will abuse or misuse a prescribed controlled substance based on past behavior, genetic predispositions, social or environmental factors, or other risks.
- "Subacute pain" means the symptom or illness has passed the acute episode, but is not yet chronic.

***Proposed* SECTION 4**
Exclusions

Practitioners treating the following patients are exempt from these requirements:

- Active cancer treatment patients;
- Hospice care patients;
- Inpatient hospital patients; or

- Palliative care patients.

***Proposed* SECTION 5**
Mandatory Prescription Monitoring Program Review

Prior to writing any prescription for opioid analgesics or sedative hypnotics, the practitioner shall review the Washington state PMP to ensure the patient's controlled substance history is consistent with the prescribing record and self-report.

If the patient is prescribed a drug by another prescriber which could interact with opioid analgesics (e.g. benzodiazepines, sedative-hypnotics, anxiolytics, or CNS depressants) or other opioid analgesics, the practitioner shall consult with the other practitioner. If the other practitioner is not available, the practitioner will document attempts to contact in the patient's healthcare record.

If the practitioner identifies aberrancies in the PMP, the practitioner shall consider tapering based on the requirements of these rules. The practitioner shall document completion of these requirements in the patient's healthcare records.

***Proposed* SECTION 6**
Informed Consent
Prior to writing a prescription for an opioid analgesic for the first time during a course of treatment to any patient, and at least annually thereafter, practitioners shall provide patient education and informed consent as follows:

- The practitioner shall have an in-person discussion with the patient regarding potential side effects; risks of using illicit opioid analgesics or synthetic opioids (e.g. fentanyl and fentanyl analogs); risks of dependence and overdose; tolerance; alternative treatments; appropriate tapering; illegality of sharing; accidental exposure, especially in children; safe storage; proper disposal to prevent non-medical use of medications; and potential fatal overdose when combining with alcohol or other psychoactive medication. In addition, the practitioner will discuss neonatal opioid withdrawal syndrome as appropriate.
- The practitioner shall receive a signed informed consent form from the patient which includes all of the topics described above.
- The practitioner shall receive a signed informed consent form from the patient which includes all of the topics described above written in a fifth-grade reading level or lower.
- If the patient is a minor or lacks legal competence, the in-person discussion shall take place between the prescriber, the patient, and the patient's parent, guardian, or legal representative, unless otherwise provided for by law.
- The practitioner shall document completion of these requirements in the patient's healthcare records.

***Proposed* SECTION 7**
Naloxone for High Risk Patients

The practitioner should consider issuing a prescription for naloxone for any patient when the doses are in excess of 120 MED, there are risk factors for overdose, or the patient is also prescribed concomitant benzodiazepines, sedative-hypnotics, anxiolytics, or CNS depressants.

***Proposed* SECTION 8**
Perioperative Pain

The practitioner shall comply with the following requirements when performing a surgical procedure on a patient. The practitioner shall document completion of these requirements in the patient's healthcare records.

- The practitioner shall conduct a thorough preoperative evaluation to include:
    - Assessment of patient's risk for potential postoperative opioid over-sedation, respiratory depression, or difficult postoperative pain control. The surgical practitioner shall share the results with the entire perioperative team.
    - Development of a coordinated treatment plan, including a timeline for tapering perioperative opioids. The coordinated treatment plan will identify the surgical practitioner responsible for managing postoperative pain as follows:
        - If a patient is opioid naïve, the surgeon will manage any opioid analgesics prescribed during the acute episode.
        - If a patient is receiving chronic pain treatment, the surgeon shall consult with the outpatient prescriber and develop a plan for transition of pain care back to the outpatient prescriber.
- The surgical practitioner should avoid new prescriptions of benzodiazepines, sedative-hypnotics, anxiolytics, or CNS depressants.
- During the postoperative period, the surgical practitioner shall reserve the use of opioid analgesics for moderate to severe acute pain.
- After discharge, the surgical practitioner shall follow through with the agreed upon preoperative plan to taper the patient off opioids prescribed for surgery and comply with the requirements for acute pain identified in Section 8. The surgical practitioner shall be responsible for pain treatment during the course of recovery, unless coordination of care has been made with the outpatient prescriber.

***Proposed* SECTION 9**
Patient evaluation and treatment plan

Prior to writing a prescription for acute pain, subacute pain, or chronic pain, the practitioner shall obtain, evaluate, and document the patient's health history and physical examination in the healthcare record.

- The initial patient evaluation shall include:
    - Physical examination;
    - The nature and intensity of the pain;

  - The effect of the pain on physical and psychological function;
  - Medications including indication(s), date, type, dosage, and quantity prescribed; and
  - A risk screening of the patient for potential comorbidities and risk factors using an appropriate risk assessment tool.
- The practitioner should not prescribe opioid analgesics to a patient if the patient has the following contraindications:
  - Significant respiratory depression, acute or severe asthma in an unmonitored setting or in the absence of resuscitative equipment, non or suspected paralytic ileus or hypersensititivity;
  - Current substance use disorder as defined by the current Diagnostic and Statistical Manual of Mental Disorders, except for tobacco, or past opioid use disorder; or
  - Pattern of aberrant behavior.
- The practitioner should use caution and monitor more frequently when prescribing opioid analgesics to a patient if the patient has the following risk factors:
  - Mental health disorder as defined by the current Diagnostic and Statistical Manual of Manual Disorders;
  - Family or personal history of substance use disorder;
  - History of sexual or physical abuse;
  - Medical condition that could increase sensitivity to opioid-related side effects, (e.g. impaired respiratory function, sleep apnea, high fall risk, altered drug metabolism, impaired renal, hepatic or cardiac function); or
  - Current use of benzodiazepines, sedative hypnotics, anxiolytics, or CNS depressants.
- Subsequent patient evaluations shall include:
  - Using validated tools to document clinically meaningful improvement in function and pain;
  - Checking the PMP;
  - Conducting a re-examination for patients who do not follow the normal course of recovery; and
  - Administering a fluid drug screen at the frequency determined by the patient's risk category.
- The healthcare record shall be maintained in an accessible manner, readily available for review, and include:
  - Any available diagnostic, therapeutic, and laboratory results;
  - Any available consultations;
  - An appropriate pain treatment plan and consideration of non-pharmacological modalities and non-opioid therapy;
  - Documentation of the presence of one or more recognized indications for the use of pain medication;
  - Documentation of any medications prescribed;
  - Documentation from the PMP;
  - Results of periodic reviews;

- Any consequences for failed biological tests or other aberrancies;
- Any written agreements for treatment between the patient and the practitioner;
- The practitioner's instructions to the patient; and,
- Objectives that will be used to determine treatment success, including, at a minimum:
    - Any change in pain relief;
    - Any change in physical and psychosocial function;
    - Additional diagnostic evaluations or other planned treatments.

Proposed **SECTION 10**
Acute Pain Episode-0 - 6 weeks

The practitioner shall comply with the following requirements when prescribing opioid analgesics for acute pain. An acute pain episode is generally no more than six weeks. The practitioner shall document completion of these requirements in the patient's healthcare records.

- The practitioner shall consider prescribing non-opioid analgesics as the FIRST line of pain control in patients, unless not clinically appropriate. Examples of such treatments may include, but are not limited to acetaminophen, acupuncture, chiropractic, cognitive behavior therapy, nonsteroidal anti-inflammatory drugs (NSAIDS), osteopathic manipulative treatment, physical therapy, and sleep hygiene.
- The practitioner should prescribe for effective pain control and no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed. If prescribing beyond these recommended limits, clinical documentation is required.
- The practitioner should re-evaluate a patient who does not follow the normal course of recovery.
- The practitioner should taper opioids by six weeks if clinically meaningful improvement in function and pain has not occurred.
- Long-acting opioids are not indicated for acute pain (except in post-operative situations). Should a provider need to use a long-acting opioid for acute pain for a specific reason, that reason must be justified in the patient's health record.

Proposed **SECTION 11**
Practitioner requirements to treat subacute and chronic pain

If the practitioner chooses to treat patients for subacute or chronic pain, the practitioner must meet one or more of the following qualifications:

- The practitioner has successfully completed, within the last two years, a minimum of twelve continuing education hours on chronic pain management with at least two of these hours dedicated to addiction; or
- The practitioner has a minimum three years of clinical experience in a chronic pain management setting, and at least thirty percent of his or her current practice is the direct provision of pain management care.

***Proposed* SECTION 12**
Written agreement – Subacute and chronic pain

The prescribing practitioner shall use a written agreement for treatment with the patient outlining patient responsibilities if the patient is subacute and high-risk or is receiving chronic pain treatment. This written agreement shall be written in a fifth-grade reading level or lower and shall include:

- The patient's agreement to provide biological samples for screening when requested by the practitioner;
- The patient's agreement to take medications at the dose and frequency prescribed with a specific protocol for lost, stolen, or destroyed prescriptions and early refills;
- Reasons for which drug therapy may be discontinued (e.g., violation of agreement);
- All chronic pain management prescriptions should be provided by a single prescriber or multidisciplinary pain clinic and dispensed by a single pharmacy or pharmacy system;
- The patient's agreement to not abuse alcohol or use other medically unauthorized substances;
- A written authorization for:
    - The practitioner to release the agreement for treatment to local emergency departments, urgent care facilities, and pharmacies; and
    - Other practitioners to report violations of the agreement back to the practitioner;
- A written authorization that the practitioner may notify the proper authorities if the practitioner has reason to believe the patient has engaged in illegal drug activity;
- Acknowledgement that the practitioner will check the PMP to ensure patient is not engaged in aberrant behavior (e.g. doctor shopping or overuse of emergency room)
- Acknowledgment that a violation of the agreement may result in a tapering or discontinuation of the prescription;
- Acknowledgment that it is the patient's responsibility to safeguard all medications and keep them in a secure location; and
- Acknowledgment that if the patient violates the terms of the agreement, the violation and the practitioner's response to the violation will be documented, as well as the rationale for changes in the treatment plan.

***Proposed* Section 13**
Subacute Pain Episode 6 – 12 weeks

The practitioner shall comply with the following requirements when prescribing opioid analgesics for subacute pain. A subacute pain episode is generally for more than six weeks but no greater than twelve weeks. The practitioner shall document completion of these requirements in the patient’s healthcare records.

- The practitioner should have observed a patient with clinically meaningful improvement in function and pain to have a legitimate basis to continue prescribing opioid analgesics beyond the acute pain episode.
- Prior to prescribing opioid analgesics for subacute pain, the practitioner shall complete the following:
    - Evaluate function and pain using validated instruments to determine whether continued opioid therapy is warranted;
    - Screen the patient for depression and for anxiety. If comorbid mental health conditions exist, the practitioner will refer them to a behavior health provider; and
    - Screen the patient for opioid misuse risk and review the patient's health records to verify the risk assessment tool results.
- When prescribing to a patient during the subacute phase, the practitioner shall monitor for opioid-related adverse outcomes (e.g. central sleep apnea, endocrine dysfunction, opioid-induced hyperalgesia, opioid use disorder, or signs of acute toxicity).
- When prescribing to a patient during the subacute phase, the practitioner should prescribe opioids in multiples of seven day supply to reduce the chance of a patient running out of opioid analgesics on a weekend.
- The practitioner shall not prescribe opioids if results of a confirmed biological specimen testing indicate the presence of cocaine, amphetamines, non-prescribed controlled substances, or alcohol.
- If a patient is prescribed opioid analgesics and benzodiazepines or sedative-hypnotics, the practitioner must ensure these drugs can be co-prescribed safely or should consider tapering. The practitioner should not issue new prescriptions for benzodiazepines and sedative-hypnotics.

Proposed **SECTION 14**
Chronic Pain Treatment – greater than 12 weeks

Chronic pain treatment should be a deliberate decision that takes into considerations the risks and benefits of chronic pain treatment for the patient. The practitioner shall comply with the following requirements, in addition to the requirements identified in Section 13, when providing chronic pain treatment for a patient. Chronic pain treatment is for pain lasting greater than twelve weeks. The practitioner shall document completion of these requirements in the patient's healthcare records.

- The practitioner should only prescribe chronic pain treatment if there is sustained clinically meaningful improvement in function and no serious adverse outcome or contraindications.
- The practitioner shall periodically review the course of treatment for chronic pain, the patient's state of health, and any new information about the etiology of the pain. Generally, periodic reviews shall take place at least every six months. However, for treatment of stable patients with chronic pain involving nonescalating daily dosages of forty MED or less, periodic reviews shall take place at least annually.
- During the periodic review, the practitioner shall determine:

  - Patient's compliance with any medication treatment plan;
  - Whether there is sustained meaningful improvement in function and no serious adverse outcome or contraindications; and
  - Whether continuation or modification of medications for pain management treatment is necessary based on the practitioner's evaluation of progress towards treatment objectives.
- The practitioner shall assess the appropriateness of continued use of the current treatment plan if the patient's progress or compliance with current treatment plan is unsatisfactory. The practitioner shall consider tapering, changing, or discontinuing treatment when:
  - There is evidence of significant adverse effects;
  - Other treatment modalities are indicated; or
  - There is evidence of abuse, misuse, stockpiling, addiction, or diversion.
- The practitioner shall periodically reassess the need for continued opioid treatment, tapering when possible, as part of the comprehensive pain care plan. A second opinion or consultation may be useful in making that decision.
- The practitioner shall increase the frequency of periodic review of high-risk patients on opioids to monthly visits, unless the patient has demonstrated no aberrancy for a period of twelve months.

Proposed **SECTION 15**
Long-acting opioids, including methadone.

The practitioner shall only prescribe long-acting opioids, including methadone, if the practitioner is knowledgeable of methadone's non-linear pharmacokinetics, unpredictable clearance, multiple drug-to-drug interactions and additional monitoring requirements. Prior to prescribing long-acting opioids, the practitioner shall complete an educational program compliant with the ER/LA Opioid Analgesic REMS Educational requirements issued by the U.S. Food and Drug Administration.

Proposed **SECTION 16**
Consultation—Recommendations and requirements.
Prior to prescribing a dosage amount that meets or exceeds one hundred twenty milligrams MED (orally) to a chronic pain patient, the practitioner shall consult a pain management specialist, unless the consultation is exempted under Section 17 or Section 18. Great caution should be used when prescribing opioids to children with chronic pain treatment and appropriate referrals to a specialist is encouraged.

- The mandatory consultation shall consist of at least one of the following:
  - An office visit with the patient and the pain management specialist;
  - A telephone consultation between the pain management specialist and the practitioner;
  - An electronic consultation between the pain management specialist and the practitioner; or

  - An audio-visual evaluation conducted by the pain management specialist remotely.
- The practitioner shall document each mandatory consultation with the pain management specialist. Any written record of the consultation by the pain management specialist shall be maintained as a patient record by the specialist. If the specialist provides a written record of the consultation to the practitioner, the practitioner shall maintain it as part of the patient record.

Proposed **SECTION 17**
Consultation—Exemptions for exigent and special circumstances.

The practitioner is not required to consult with a pain management specialist as described in Section 16 when they have documented adherence to all standards of practice as defined in Section 1 through Section X and when any one or more of the following conditions apply:

- The patient is following a tapering schedule;
- The patient requires treatment for acute pain which may or may not include hospitalization, requiring a temporary escalation in opioid dosage, with expected return to or below their baseline dosage level; or
- The practitioner documents reasonable attempts to obtain a consultation with a pain management specialist and the circumstances justifying prescribing above one hundred twenty milligrams MED per day without first obtaining a consultation; or
- The practitioner documents the patient's pain and function is stable and the patient is on a nonescalating dosage of opioids.

Proposed **SECTION 18**
Pain Management Specialist
A pain management specialist shall meet one or more of the following qualifications:

- If a physician or osteopathic physician:
  - Board certified or board eligible by an American Board of Medical Specialties-approved board (ABMS) or by the American Osteopathic Association (AOA) in physical medicine and rehabilitation, rehabilitation medicine, neurology, rheumatology, or anesthesiology; or
  - Has a subspecialty certificate in pain medicine by an ABMS-approved board; or
  - Has a certification of added qualification in pain management by the AOA; or
  - A minimum of three years of clinical experience in a chronic pain management care setting; and
    - Successful completion of a minimum of at least eighteen continuing education hours in pain management during the past two years for allopathic practitioners or three years for osteopathic practitioners; and
    - At least thirty percent of the practitioner's or osteopathic practitioner's current practice is the direct provision of pain management care or is in a multidisciplinary pain clinic.
- If a dentist: Board certified or board eligible in oral medicine or orofacial pain by the American Board of Oral Medicine or the American Board of Orofacial Pain.

- If an advanced registered nurse practitioner (ARNP):
  - A minimum of three years of clinical experience in a chronic pain management care setting;
  - Credentialed in pain management by the Washington state nursing care quality assurance commission-approved national professional association, pain association, or other credentialing entity;
  - Successful completion of a minimum of at least eighteen continuing education hours in pain management during the past two years; and
  - At least thirty percent of the ARNP's current practice is the direct provision of pain management care or is in a multidisciplinary pain clinic.
- If a podiatric practitioner:
  - Board certified or board eligible in a specialty that includes a focus on pain management by the American Board of Podiatric Surgery, the American Board of Podiatric Orthopedics and Primary Podiatric Medicine, or other accredited certifying board as approved by the Washington state podiatric medical board; or
  - A minimum of three years of clinical experience in a chronic pain management care setting; and
  - Credentialed in pain management by the Washington state podiatric medical board-approved national professional association, pain association, or other credentialing entity; and
  - Successful completion of a minimum of at least eighteen hours of continuing education in pain management during the past two years, and at least thirty percent of the podiatric practitioner's current practice is the direct provision of pain management care.

***Proposed* SECTION 19**
Special Populations

Place Holder – while this topic was discussed at the November 15 stakeholder meeting, further input is needed from the task force on the identification of rules for special populations.

***Proposed* SECTION 20**
Tapering

Place Holder

***Proposed* SECTION 21**
Termination of Care

Place Holder

***Proposed* SECTION 22**
Opioid Use Disorder

Place Holder