Department of Labor and Industry

Adopted Permanent Rules Establishing Criteria for Long-Term Treatment with Opioid Analgesic Medication for Workers' Compensation Injuries

5221.6040 DEFINITIONS.

[For text of subps 1 to ~~8~~ 7, see M.R.]

Subp. 7a. **Illegal substance.** "Illegal substance" means a drug or other substance that is illegal under state or federal controlled substances law, but does not include a patient's use of medical cannabis permitted under Minnesota Statutes, sections 152.22 to 152.37.

[For text of subp 8, see M.R.]

Subp. 8a. **Intractable pain.** "Intractable pain" is as defined in Minnesota Statutes, section 152.125.

Subp. 8b. **Medical contraindication.** "Medical contraindication" means a condition that makes the use of a particular treatment or medication inadvisable because of an increased risk of harm to the patient.

[For text of subps 9 and 10, see M.R.]

Subp. 10a. **Modality.** A "modality" is the application or use of a therapeutic agent or regimen. Examples include the active treatment modalities described in subpart 2, the passive treatment modalities described in subpart 12, and the injection modalities described in subpart 13.

Subp. 10b. **Morphine-equivalent milligrams.** For purposes of part 5221.6110, subpart 8, morphine-equivalent milligrams shall be determined using the following conversions. Morphine 30 milligrams orally is equivalent to:

A. codeine 200 milligrams oral;

B. fentanyl transdermal 12.5 mcg/hr;

C. hydrocodone 30 milligrams oral;

D. hydromorphone 7.5 milligrams oral;

E. levorphanol 4 milligrams oral;

F. oxycodone 20 milligrams oral; and

G. oxymorphone 10 milligrams oral.

[For text of subp 11, see M.R.]

Subp. 11a. **Pain medicine specialist.** A "pain medicine specialist" is a health care provider with at least five years of experience in the assessment and treatment of chronic complex pain problems for more than one patient; or who has completed fellowship training in pain management.

[For text of subps 12 and 13, see M.R.]

5221.6105 MEDICATIONS.

[For text of subps 1 and 2, see M.R.]

Subp. 3. **Opioid analgesics.** An opioid is any agent that binds to opioid receptors. There are three broad classes of opioids: opium alkaloids, such as morphine and codeine; semisynthetic opioids such as heroin and oxycodone; and fully synthetic opioids such as meperidine and methadone. Opioid analgesics include codeine, hydrocodone, levorphanol, methadone, morphine, hydromorphone, and oxycodone.

[For text of items A and B, see M.R.]

C. A course of oral opioid analgesics or combination of an oral opioid and a nonopioid analgesic is limited as provided in subitems (1) to (3).

[For text of subitems (1) and (2), see M.R.]

(3) Continued prescription of oral opioid analgesics for more than 12 weeks may be for more than one month of medication and must comply with all of the requirements of part 5221.6110.

[For text of items D to F, see M.R.]

[For text of subp 4, see M.R.]

5221.6110 LONG-TERM TREATMENT WITH OPIOID ANALGESIC MEDICATION.

Subpart 1. **Application.** This part applies to the use of oral, oral transmucosal, buccal, and transdermal opioid analgesic medications and does not apply to the use of parenteral or intrathecal opioid analgesic medications. The choice of specific opioid analgesic medication is governed by part 5221.6105, subpart 3. For purposes of this part, "long-term treatment with opioid analgesic medication" means that:

A. a health care provider documents a plan to initiate treatment for intractable pain by prescribing opioid analgesic medication to be taken daily for at least 90 days; or

B. a health care provider continues prescribing opioid analgesic medication for a patient who has been prescribed opioid analgesic medication to be taken daily for at least 90 days.

Subp. 2. **Indications and documentation.** Long-term treatment with opioid analgesic medication is not indicated for treatment of workers' compensation injuries unless the requirements in this part are met. The prescribing health care provider must document in the medical record the patient selection criteria, the assessments performed, whether there are any potential contraindications to the long-term prescription of opioid analgesics, the elements of the treatment program, the written treatment contract, an objective assessment of the success of the treatment program, and the results of periodic monitoring and testing.

Subp. 3. **Pain and function assessment tools.** When a health care provider initiates a plan for long-term treatment with opioid analgesic medication, the provider must assess the patient's level of pain and function using the following tools:

A. a tool validated in peer-reviewed scientific literature for the assessment of pain. Examples are the Brief Pain Inventory, the Chronic Pain Grade, the Neuropathic Pain Scale, the Visual Analog Scale, the Numeric Rating Scale, or the Verbal Descriptive Scales; and

B. a tool validated in peer-reviewed scientific literature for the assessment of function. Examples are the SF-36 Health Survey, the QuickDASH Outcome Measure, the Quality of Life (QOL) Scale, the Oswestry Disability Index, the Neck Disability Index, or the Short Musculoskeletal Function Assessment.

The results of these assessments provide the baseline for determining the success of the treatment program as specified in subpart 8, item B.

Subp. 4. **Patient selection criteria.** Before initiating a plan for long-term treatment with opioid analgesic medication, the prescribing health care provider must determine that all of the following criteria are met:

A. the patient cannot maintain function at work, or in the activities of daily living, without long-term use of opioid analgesic medication;

B. the patient does not have a Somatic Symptom Disorder as defined in the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5);

C. all other reasonable medical treatment options have been exhausted as determined by either a pain medicine specialist or a health care provider specializing in the treatment of the area, system, or organ of the body identified as the source of the pain;

D. the patient does not have a history of failing to comply with treatment or failing to take medication as prescribed;

E. the patient does not have a current Substance Use Disorder as defined in the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5); and

F. a qualitative urine drug test confirms that the patient is not using any illegal substances.

Subp. 5. **Potential contraindications.** Items A and B apply to potential contraindications.

A. Before beginning long-term treatment with opioid analgesic medication, the prescribing health care provider must assess whether any of the following circumstances are present and, if present, whether they constitute contraindications to the long-term treatment with opioid analgesic medication:

(1) the patient has a history of respiratory depression, or a condition that can cause respiratory depression when taking opioid analgesic medications;

(2) the patient is pregnant or is planning to become pregnant during the period of treatment with opioid analgesic medications;

(3) the patient has a Substance Use Disorder in remission as defined in the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5);

(4) the patient has another mental disorder referenced in the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5);

(5) the patient is a suicide risk;

(6) the patient has poor impulse control; and

(7) the patient regularly engages in an activity that could be unsafe for a patient taking opioid analgesic medications.

B. The prescribing health care provider may obtain an appropriate specialty consultation to assist with the assessments in this subpart or determine if the long-term prescription of opioid analgesic medication is appropriate.

Subp. 6. **Opioid risk assessment; program of treatment.**

A. Long-term treatment with opioid analgesic medication must be part of an integrated program of treatment that complies with this subpart and that is documented in the medical record.

B. The health care provider must complete an opioid risk assessment using a tool validated in the peer-reviewed scientific literature. Examples of this type of assessment tool are the Opioid Risk Tool; the Diagnosis, Intractability, Risk, Efficacy Scale (DIRE); and the Screener and Opioid Assessment for Patients with Pain - Revised (SOAPP-R). The provider must disclose the results of the assessment to the patient.

(1) If the assessment shows the patient to be at high risk of dependence or abuse, the provider must refer the patient to a pain medicine specialist or addiction medicine specialist for a second opinion before initiating long-term treatment with opioid analgesic medication.

(2) Following the second opinion, if long-term treatment with opioid analgesic medication is initiated in a patient at high risk, the prescribing provider must:

(a) perform urine drug testing at least twice a year;

(b) review the patient's prescription history in the Minnesota prescription monitoring program at each visit; and

(c) see the patient in clinic for follow-up every month for the first six months of treatment and every three months thereafter.

C. The patient and the prescribing health care provider must sign a formal written treatment contract that meets the requirements of subpart 7.

D. All opioid analgesic medications must be used in fixed schedules of dosing and prescribed in an amount sufficient to preclude exhaustion of a prescription on a weekend, holiday, or vacation day when the prescribing health care provider is not available.

E. Other treatment modalities are permitted in conjunction with long-term treatment with opioid analgesic medication, to the extent indicated by parts 5221.6010 to 5221.6600.

F. The prescribing health care provider must have a written plan for treatment of episodic pain due to the injury being treated, specifying the modality or medication to be used, the frequency and scheduling of the modality or dosing of medication, the duration of use, the circumstances for contacting the prescribing health care provider, and treatment of possible side effects of the medications.

G. All prescriptions for long-term treatment with opioid analgesic medication must be written only by the prescribing health care provider or the designated proxy. The patient must agree to inform the prescribing health care provider if short-term treatment with opioid analgesic medications or other controlled drugs is prescribed by other health care providers in the treatment of acute injuries or conditions so that overall care can be properly coordinated. Examples of acute medical problems are dental procedures, acute trauma, surgery, or emergency medical treatment. The patient must also agree to inform the prescribing health care provider of any use of medical cannabis permitted under Minnesota Statutes, sections 152.22 to 152.37.

H. The prescribing health care provider must discuss with the patient the risks associated with the long-term treatment with opioid analgesic medication, the specific medications to be used, and possible side effects.

I. All medications and other treatment modalities for the work-related injury must be prescribed or provided on referral by the single health care provider party to the

written treatment contract or by a proxy designated in the medical record by the health care provider party to the written treatment contract.

J. The prescribing health care provider must document in the medical record the name of the drug prescribed, the dose, the dosing schedule, the amount to be dispensed, and the number of refills allowed, if any, for each opioid analgesic prescribed.

K. The prescribing health care provider must establish a schedule of follow-up visits for monitoring the treatment.

L. The prescribing health care provider must provide written reports of work ability or restrictions as required by part 5221.0410, subpart 6.

M. If long-term treatment with opioid analgesic medication is discontinued, the prescribing health care provider must prescribe a schedule of tapering dosages and ancillary medications as needed to minimize symptoms of withdrawal, taking into account the type, dose, and duration of the opioid medication being discontinued. The health care provider must offer alternative pain management treatment or referral to another provider.

Subp. 7. **Written treatment contract.** A patient receiving long-term treatment with opioid analgesic medication must enter into a written treatment contract with the prescribing health care provider as part of the integrated program of treatment. The written contract must be made part of the patient's medical record. A copy of the contract must be provided to the patient. Except when discontinuance is required by subpart 8, items E and F, the prescribing health care provider has discretion to discontinue treatment with opioid analgesic medication if the provider believes that the patient has not complied with the terms of the contract. Discontinuance must be according to a tapering schedule as described in subpart 6, item M. The contract must include the following:

A. the goals of long-term treatment with opioid analgesic medication; the program of treatment identified in subpart 6, items D, G, H, I, K, L, and M; and the monitoring described in subpart 8, items E, F, and G;

B. an agreement by the patient to comply with treatment prescribed in addition to the opioid analgesic medication;

C. an agreement by the patient that only one replacement refill or prescription is permitted in the event of lost or stolen medication or prescription, but only the first time the patient alleges that the prescription or medication was lost or stolen and only at the discretion of the prescribing health care provider;

D. an agreement by the patient that prescriptions or medications will not be renewed earlier than scheduled;

E. an agreement by the patient to notify all other health care providers of the treatment contract and its stipulations before receiving any prescription medications and to notify the prescribing health care provider party to the contract of medications received from other health care providers;

F. an agreement by the prescribing health care provider that arrangements must be made ahead of time to renew prescriptions when the prescribing health care provider is on vacation or otherwise unavailable;

G. an agreement by the prescribing health care provider to be available or provide coverage for episodic pain not responsive to planned interventions;

H. a statement that, except for the required discontinuance provided in subpart 8, items E and F, the prescribing health care provider has discretion to discontinue treatment with opioid analgesics using a schedule of tapering dosages if the patient does not comply with any of the agreements set out in the written treatment contract; and that if opioid analgesics are discontinued the provider must offer alternative pain management treatment or referral to another provider;

I. an agreement by the patient to:

(1) follow a schedule of regular visits recommended by the prescribing health care provider and take the opioid medication exactly as prescribed;

(2) abstain from all illegal ~~drugs~~ substances;

(3) cooperate with the assessments and urine drug testing requested by the prescribing health care provider;

(4) allow the prescribing health care provider to access the prescription monitoring program and contact any other health care provider who treats or has treated the patient to discuss the patient's use of opioid medication; and

(5) cooperate with referrals to other providers, as requested by the prescribing health care provider; and

J. the dated signatures of the patient and prescribing health care provider.

The commissioner shall develop a form for a model written contract addressing items A to J. If a prescribing health care provider uses the commissioner's form, then the contract shall be deemed to meet the requirements of this subpart once completed and made part of the patient's medical record. The patient and prescribing health care provider must enter into a new written contract whenever it is deemed necessary by the prescribing health care provider.

Subp. 8. **Monitoring long-term treatment with opioid analgesic medications.** The prescribing health care provider who is party to the treatment contract must monitor treatment that includes long-term prescription of opioid analgesic medications. The prescribing health care provider must document the monitoring in the medical record. Monitoring must include everything in items A to G.

A. The prescribing health care provider must schedule regular follow-up visits with the patient. Visits must be at least quarterly in the first year of treatment and no less than annually thereafter, except for patients taking more than 120 morphine-equivalent

milligrams per day who must be seen at least every three months, and except for patients at high risk of dependency or abuse under subpart 6, item B, who must be seen every month for the first six months and every three months thereafter.

B. At each follow-up visit, the prescribing health care provider must assess the success of the program treatment in meeting its goals. The prescribing health care provider must assess pain and function at each follow-up visit, using the same tools chosen for the initial assessment in subpart 3. The program is considered successful if there is improvement in both pain and function within six months after long-term treatment with opioid analgesic medication is initiated, and this improvement is at least maintained at subsequent follow-up assessments.

C. At each follow-up visit, the prescribing health care provider must assess the possible side effects of treatment, misuse of medications, aberrant behaviors indicative of addiction, or contraindications to continuing treatment.

D. At each follow-up visit, the prescribing health care provider must assess the patient's adherence to the entire program of treatment.

E. At least semiannually, the prescribing health care provider must review the patient's prescription history in the Minnesota prescription monitoring program to validate correct medication usage, except that the prescription history must be reviewed at every follow-up visit for each patient who is taking more than 120 morphine-equivalent milligrams per day or is at high risk for dependence or abuse under subpart 6, item B. If there is more than one instance of unreported opiate prescriptions from other providers, the health care provider must discontinue opioid medications using a schedule of tapering dosages as described in subpart 6, item M.

F. The prescribing health care provider has discretion to order urine drug testing as part of a patient's monitoring, except that monitoring must include urine drug testing at

least twice per year for each patient who is taking more than 120 morphine-equivalent milligrams per day or is at high risk for dependence or abuse under subpart 6, item B.

(1) Urine drug testing protocol is within the discretion of the prescribing provider. After all tests requested by the prescribing provider are completed, urine drug testing is failed if it shows the presence of an illegal ~~substances~~ substance or if the results are inconsistent with the opiate and dosage prescribed. If the urine drug testing is failed, opioid medications must be discontinued using a schedule of tapering dosages as described in subpart 6, item M.

(2) If a urine sample is sent to a laboratory for testing, the employer or insurer may designate the laboratory so long as it is accredited by the College of American Pathologists under the Forensic Urine Drug Testing Program.

G. The prescribing health care provider must provide a referral to a pain medicine specialist for consultation under any of the following circumstances:

(1) there is a sudden or progressive increase in the dosage of opioid analgesic required;

(2) the goals of the treatment program are not met; or

(3) the patient requires more than 120 morphine-equivalent milligrams per day to meet or maintain the program's treatment goals.

Subp. 9. **Notice and plan for compliance.** A prescribing provider's failure to comply with any requirement of this part is not a basis to deny payment for treatment with opioid analgesics unless the insurer has previously sent the provider and the patient a copy of this part and has given the provider at least 30 days to initiate a plan to come into compliance. The insurer is required to send the provider and patient the notice and provide 30 days to initiate a plan for compliance only once.

Subp. 10. **Patients currently receiving treatment.** For a patient who is receiving long-term treatment with opioid analgesic medication on the effective date of this part, the prescribing health care provider must, within three months of receipt of written notice of this part from the insurer to the provider and patient:

A. assess the patient's current level of pain and function using tools validated in peer-reviewed scientific literature as required in subpart 3;

B. meet all of the requirements of subpart 6, items C to M;

C. complete a written contract with the patient that complies with the requirements of subpart 7; and

D. establish monitoring of the treatment that complies with the requirements of subpart 8.

Subp. 11. **Incorporation by reference.** The Diagnostic and Statistical Manual of Mental Disorders, fifth edition (DSM-5), copyrighted by the American Psychiatric Association, is incorporated by reference. It is not subject to frequent change, although the American Psychiatric Association publishes DSM-5 errata and coding updates. DSM-5 is published by American Psychiatric Publishing, Inc. (APPI), and may be purchased from them by calling 800-368-5777 or by ordering online at the APPI Web site. It is also available from other bookstores and online retailers. It is available through the Minitex interlibrary loan system.