

1 **5221.6600 CHRONIC MANAGEMENT**

2
3 Subp. 3. Long term prescription of opioid analgesic medication. This subpart applies to the
4 use of oral, oral transmucosal, buccal, and transdermal opioid analgesic medications and does not
5 apply to the use of parenteral or intrathecal opioid analgesic medications. The choice of specific
6 opioid analgesic medication is governed by part 5221.6105 subpart 3. For purposes of this
7 subpart, “long-term prescription of opioid analgesic medication” means that:

- 8 (1) A health care provider documents a plan to initiate treatment for intractable pain by
9 prescribing opioid analgesic medication on a long-term basis; or
10 (2) A health care provider continues prescribing opioid analgesic medication for a patient
11 who has been taking opioid analgesic medication daily for three months.

12
13 A. Indications and documentation. Long-term prescription of opioid analgesic medication is
14 not indicated for treatment of workers’ compensation injuries unless the requirements in this
15 subpart are met. The prescribing health care provider shall document in the medical record the
16 patient selection criteria, the assessments performed, whether there are any potential
17 contraindications to the long-term prescription of opioid analgesics, the elements of the treatment
18 program, the written treatment agreement, an objective assessment of the success of the treatment
19 program, and the results of periodic monitoring.

20
21 B. Pain and function assessment tools. When a health care provider initiates a plan to treat
22 intractable pain by prescribing opioid analgesic medication on a long-term basis, or when a
23 health care provider continues prescribing opioid analgesic medication for a patient who has been
24 taking opioid analgesic medication daily for three months, the provider must assess the patient’s
25 level of pain and function using the following tools:

- 26 (1) A tool validated in the peer-reviewed scientific literature for the assessment of pain.
27 Examples are the Brief Pain Inventory, the Chronic Pain Grade, the Neuropathic Pain
28 Scale, the Visual Analog Scale, the Numeric Rating Scale, or the Verbal Descriptive
29 Scales; and
30 (2) A tool validated in the peer-reviewed scientific literature for the assessment of
31 function. Examples are the SF-36 Health Survey, the QuickDASH Outcome Measure,
32 the Quality of Life (QOL) Scale, the Oswestry Disability Index, the Neck Disability
33 Index, or the Short Musculoskeletal Function Assessment.

34 The results of these assessments provide the baseline for determining the success of the treatment
35 program as specified in item G, subitem (2).

36
37 C. Patient selection criteria. Patients may be considered for long-term prescription of oral
38 opioid analgesic medication if the prescribing health care provider determines that all of the
39 following criteria are met:

- 40 (1) The patient cannot maintain function at work, or in the activities of daily living,
41 without long-term use of opioid analgesic medication;
42 (2) The pain is not solely psychiatric in origin;
43 (3) All other reasonable medical treatment options have been exhausted as determined by
44 at least one health care provider specializing in either pain medicine or the treatment of
45 the area, system, or organ of the body identified as the source of the pain;

1 (4) The patient has a history of compliance with treatment and reliable use of prescription
2 medications;

3 (5) The patient does not have a current problem with substance abuse or substance
4 dependence as defined by the Diagnostic and Statistical Manual of Mental Disorders; and

5 (6) A urine drug screen confirms that the patient is not using any illegal substances.

6
7 **D. Potential contraindications.**

8 (1) Before beginning long-term prescription of opioid analgesic medication, the
9 prescribing health care provider must assess whether any of the following circumstances
10 in (a) to (g) are present and, if present, whether they constitute contraindications to the
11 ongoing prescription of opioid analgesic medication:

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

14 (b) The patient is pregnant or is planning to become pregnant during the period of
15 treatment with opioid analgesic medications;

16 (c) The patient has a history of substance abuse or substance dependence, as
17 defined by the most recent Diagnostic and Statistical Manual of Mental Disorders;

18 (d) The patient is a suicide risk;

19 (e) The patient has poor impulse control;

20 (f) The patient has an Axis I or Axis II psychiatric disorder; and

21 (g) The patient regularly engages in an activity that could be unsafe for a patient
22 taking opioid analgesic medications.

23
24 (2) The prescribing health care-provider may obtain an appropriate specialty consultation to
25 assist with the assessments in this item D or determine if the long-term prescription of opioid
26 analgesic medication is appropriate.

27
28 **E. Program of treatment.** Long-term prescription of opioid analgesic medication must be part of an
29 integrated program of treatment that includes all of the following elements, which must be
30 documented in the medical record:

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

36
37 (a) If the assessment shows the patient to be at high risk of dependence or abuse,
38 the provider must refer the patient to a pain medicine specialist or addiction
39 medicine specialist for a second opinion prior to initiating treatment with long-
40 term prescription of opioid analgesic medication.

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

44 (i) perform urine drug screening at least twice a year;

45 (ii) review the patient's prescription history in the Minnesota Prescription
46 Monitoring Program at each visit; and

1 (iii) see the patient in clinic for follow-up monthly for the first six months
2 of treatment and every three months thereafter.

3
4 (2) The patient and the prescribing health care provider must sign a formal written treatment
5 contract that meets the requirements of item F;

6
7 (3) All opioid analgesic medications must be used in fixed schedules of dosing and
8 prescribed in an amount sufficient to preclude exhaustion of a prescription on a weekend,
9 holiday, or vacation day when the prescribing health care provider is not available.

10
11 (4) Other treatment modalities are permitted in conjunction with long-term prescription of
12 opioid analgesic medication, to the extent indicated by parts 5221.6010 through 5221.6600;

13
14 (5) There must be a written plan for episodic pain due to the injury being treated, specifying
15 the modality or medication to be used, the frequency and scheduling of the modality or
16 dosing of medication, the duration of use, the circumstances for contacting the prescribing
17 health care provider, and treatment of possible side-effects of the medications.

18
19 (6) The patient must agree to inform the prescribing health care provider if opioid analgesic
20 medications are used by other health care providers in the treatment of other injuries or
21 conditions so that overall care can be properly coordinated. Examples of other acute medical
22 problems are dental procedures, acute trauma, surgery, or emergency medical treatment;

23
24 (7) The prescribing health care provider must discuss with the patient the risks associated
25 with the long-term prescription of opioid analgesic medication, the specific medications to be
26 used, and possible side effects;

27
28 (8) All medications and other treatment modalities for the condition arising as a result of the
29 work-related injury must be prescribed or provided on referral by the single health care
30 provider party to the written treatment agreement or by a proxy designated in the medical
31 record by the health care provider party to the written treatment agreement. The patient must
32 agree to inform the prescribing health care provider.

33
34 (9) All prescriptions for medications for the condition arising as a result of the work-related
35 injury must be filled at a single pharmacy, except that the health care provider who is party to
36 the contract or the designated proxy may authorize the use of a different pharmacy;

37
38 (9) The prescribing health care provider must note in the medical record the name of the drug
39 prescribed, the dose, the dosing schedule, the number of pills to be dispensed, and the
40 number of refills allowed, if any, for each opioid analgesic prescribed;

41
42 (10) A schedule of follow-up visits for monitoring the treatment must be established; and

43
44 (11) The prescribing health care provider must monitor the impact of long-term use of opioid
45 analgesic medications on the patient's ability to work function work and write appropriate
46 work restrictions; and

1
2 (12) If treatment with long-term opiates is discontinued, the prescribing health care provider
3 must prescribe an appropriate schedule of tapering doses and ancillary medications as needed
4 to minimize symptoms of withdrawal. The health care provider must offer alternative pain
5 management treatment or referral to another provider.

6
7 F. Written treatment contract. A patient receiving long-term prescription of opioid analgesic
8 medication must enter into a written treatment contract with the prescribing health care provider
9 as part of the integrated program of treatment. The written contract must be made part of the
10 patient's medical record. A copy of the contract must be provided to the patient. The prescribing
11 health care provider may discontinue treatment with opioid medication if the provider believes
12 that the patient has not complied with the terms of the contract. The contract must include the
13 following:

14
15 (1) The goals of treatment with long-term prescription of opioid analgesic medication; and
16 the program of treatment identified in items E, subitems 3, 6, 7, 8, 10, 11 and 12; and the
17 monitoring described in item G, subitems 5, 6 and 7;

18
19 (2) An agreement by the patient to comply with treatment prescribed in addition to the opioid
20 analgesic medication;

21
22 (3) An agreement by the patient that all prescriptions for medications for the condition
23 arising as a result of the work-related injury will be received only from the health care
24 provider party to the agreement or the designated proxy and that any opiates received from
25 any other health care providers for any other acute medical problems will be reported by the
26 patient as soon as possible. Examples of other acute medical problems are dental procedures,
27 acute trauma, surgery, or emergency medical treatment;

28
29 (4) An agreement by the patient that all prescriptions for medications for the condition
30 arising as a result of the work-related injury will be filled at a single pharmacy designated in
31 the agreement;

32
33 (4) An agreement by the patient that lost or stolen prescriptions or medications will not be
34 replaced only one replacement refill or prescription is permitted for lost or stolen medication
35 or prescription, but only the first time the employee alleges that the prescription or
36 medication was lost or stolen and only at the discretion of the prescribing health care
37 provider.

38
39 (5) An agreement by the patient that no prescriptions or medications will be renewed earlier
40 than scheduled;

41
42 (6) An agreement by the patient to notify all other health care providers of the treatment
43 agreement and its stipulations prior to receiving any prescription medications, and to notify
44 the prescribing health care provider party to the agreement of medications received from
45 other health care providers;

1 (7) An agreement by the prescribing health care provider that arrangements will be made
2 ahead of time to renew prescriptions when the prescribing health care provider is on vacation
3 or otherwise unavailable;

4
5 (8) An commitment agreement by the prescribing health care provider to be available or
6 provide coverage for episodic pain not responsive to planned interventions;

7
8 (9) A statement that the prescribing health care provider may discontinue treatment with
9 opioid analgesics in a medically appropriate manner if the patient does not comply with any
10 of the agreements set out in the written treatment agreement; but that if opioid analgesics are
11 discontinued the provider will offer alternative pain management treatment or referral to
12 another provider;

13
14 (10) An agreement by the patient to:

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

17 (b) abstain from all illegal drugs;

18 (c) cooperate with the assessments and urine drug testing requested by the
19 prescribing health care provider under item G;

20 (d) allow the prescribing health care provider to access the prescription
21 monitoring program under item G and contact any other health care provider
22 who treats the patient to discuss the patient's use of opioid medication; and

23 (e) cooperate with referrals to other providers, as requested by the prescribing
24 health care provider.

25
26 (11) The dated signatures of the patient and prescribing health care provider.

27
28 The commissioner shall develop a form for a model written contract addressing items (1) through
29 (11). If a prescribing health care provider uses the commissioner's form, then the contract shall be
30 deemed to meet the requirements of this item F once completed and made part of the patient's
31 medical record. The patient and prescribing health care provider must enter into a new written
32 contract whenever it is deemed necessary by the prescribing health care provider.

33
34 **G. Monitoring of long-term prescription of opioid analgesic medications.** Treatment that
35 includes long-term prescription of opioid analgesic medications must be monitored by the
36 prescribing health care provider who is party to the treatment agreement. Monitoring must be
37 documented in the medical record and must include:

38
39 (1) Regularly scheduled follow-up visits with the patient; at least quarterly in the first year of
40 treatment and no less than annually thereafter, except for patients taking more than 120
41 morphine-equivalent milligrams per day who must be seen at least every three months, and
42 except for patients at high risk of dependency or abuse under item E, subitem (1), who must
43 be seen every month for the first six months and every three months thereafter;

44
45 (2) At each follow-up visit, assessment of the success of the program treatment in meeting its
46 goals. For the program to be considered successful there must be an initial improvement in

1 both pain and function as measured by the tools selected by the treating physician at the
2 initiation of the program of treatment and this improvement must at least be maintained at
3 subsequent follow-up assessments;

4
5 (3) Assessment at each follow-up visit of possible side-effects of treatment, misuse of
6 medications, aberrant behaviors indicative of addiction, or contraindications to continuing
7 treatment;

8
9 (4) Assessment at each follow-up visit of adherence to the entire program of treatment;

10
11 (5) Review at least semi-annually the patient's prescription history in the Minnesota
12 Prescription Monitoring Program to validate correct medication usage, except for patients
13 taking more than 120 morphine-equivalent milligrams per day, and patients at high risk for
14 dependence or abuse under item E, subitem (1), whose prescription history must be reviewed
15 at every follow-up visit. If there is a pattern more than one instance of unreported opiate
16 prescriptions from other providers, the health care provider shall discontinue opioid
17 medications may be discontinued using an appropriate schedule of tapering dosages;

18
19 (6) Screening urine drug testing at the discretion of the treating physician except for patients
20 taking more than 120 morphine-equivalent milligrams per day, and patients at high risk for
21 dependence or abuse under item E, subitem (1), who must have a screening urine drug test at
22 least twice a year. A screening urine drug test is failed if the test is positive for illegal
23 substances or the test results are inconsistent with the opiate and dosage prescribed. If a
24 screening urine drug test is failed, the provider must follow-up with a confirmatory urine
25 drug test as soon as possible but no later than fourteen days after the failed test. If the
26 confirmatory urine drug test confirms the findings of the screening urine drug test, opioid
27 medications must be discontinued using an appropriate schedule of tapering dosages; and

28
29 (7) Referral to a pain medicine specialist for consultation under any of the following
30 circumstances:

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

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

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

36
37 H. A treating provider's failure to comply with any requirement of this subpart shall not be a basis to
38 deny payment for treatment with opioid analgesics unless the insurer has previously sent the provider
39 and the patient a copy of this subpart and has given the provider at least 30 days to initiate a plan to
40 come into compliance. The insurer is required to send the provider and patient the notice and provide
41 30 days to initiate a plan for compliance only once.

42
43 I. For patients who are being treated with long-term prescription of opioid analgesic medication on
44 the effective date of these rules, the treating health care provider must, within three months of receipt
45 of written notice of this rule from the insurer to the provider and patient:

- 1 (1) Assess the patient's current level of pain and function using tools validated in the peer-
2 reviewed scientific literature as required in item B above;
3 (2) Meet all of the requirements of item E (2) through (12);
4 (3) Complete a written agreement with the patient that complies with the requirements of
5 item F above; and
6 (4) Establish monitoring of the treatment that complies with the requirements of item G
7 above.

8
9 *Add the following definitions to Minn. R. 5221.6040:*

10
11 Subp. 2b. **Pain medicine specialist.** A pain medicine specialist is a health care provider with the
12 expertise and experience to assess chronic complex pain problems including the biological,
13 psychological, and social aspects of chronic pain; and who can coordinate a multi- or inter-
14 disciplinary approach to the management of such problems.

15
16 Subp. 6a **Confirmatory urine drug test.** For the purposes of 5221.6600 subpart 3, confirmatory
17 urine drug tests are urine drug tests in which a chain of custody is established and testing is
18 conducted in a laboratory meeting the accreditation standards of the College of American
19 Pathologists' Forensic Urine Drug Testing Accreditation Program using analytical procedure to
20 identify and quantify the presence of specific drug(s) or drug metabolite(s).

21
22 Subp. 8a. **Intractable pain.** Intractable pain is "a pain state in which the cause of the pain cannot
23 be removed or otherwise treated with the consent of the patient and in which, in the generally
24 accepted course of medical practice, no relief or cure of the cause of the pain is possible, or none
25 has been found after reasonable efforts" as defined in Minn. Stat. section 152.125.

26
27 Subp. 10a. **Modality.** A "modality" is a form of application or instance of employment of a
28 therapeutic agent or regimen. Modalities include injections and modalities defined as active
29 treatment in subpart 2 and passive treatment in subpart 12.

30
31 Subp. 10b. **Morphine-Equivalent Milligrams.** For the purposes of 5221.6600 subpart 3,
32 morphine-equivalent milligrams shall be determined using the following conversions. Morphine
33 30 milligrams orally is equivalent to:

- 34 Codeine 200 milligrams oral
35 Fentanyl transdermal 12.5 mcg/hr
36 Hydrocodone 30 milligrams oral
37 Hydromorphone 7.5 milligrams oral
38 Levorphanol 4 milligrams oral
39 Oxycodone 20 milligrams oral
40 Oxymorphone 10 milligrams oral

41
42 5221.6105 MEDICATIONS

43 Subpart 3 Opioid analgesics

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

3 (3) Continued prescription of oral opioid analgesics prescribed for more than 12
4 weeks after the injury may be for more than one month of medication per prescription
5 if there has been a clinical evaluation to confirm the need for an efficacy of the
6 prescription and a clinical evaluation at least every six months thereafter during
7 continued use of opiate analgesics and must be in compliance with all of the
8 requirements of 5221.6600 subpart 3.
9
10

**DRAFT PATIENT/PROVIDER CONTRACT
FOR DISCUSSION PURPOSES ONLY: 07/03/14**

Patient/Provider Contract for Long Term Treatment with Opioid Medication

Purpose of this contract and agreement to comply. This is a contract between _____ (name of patient) and _____ (name of health care provider"). Opiates (sometimes also called narcotics) are drugs that have a potential for abuse and addiction. I understand that this contract is essential to the trust and confidence needed in a patient-physician relationship and that my doctor's willingness to treat me is based on my compliance with the terms of this contract. In order to receive treatment with opioid medication from _____, I agree to comply with this contract. I understand that _____ may terminate treatment with opioid medication at any time that he or she believes that I am not complying with the terms of this contract.

Risks, side effects and benefits of opioid medication. I understand that the opioid medication is being prescribed to assist me in managing chronic pain that has not responded to other treatments. I am aware that use of this medication has certain risks associated with it such as sleepiness, constipation, nausea, itching, vomiting, dizziness, allergic reactions, slowing of reflexes, slowing of breathing rate, sleep apnea, physical dependence, tolerance, and addiction. The risks, side effects, and benefits have been explained to me. _____ has explained to me the problems that may occur if I drink alcohol or become pregnant while taking this medication.

Goal of treatment and risk of addiction. The medication must be both safe and effective. I understand that there is a risk that this medication may become addictive. The goal is to use the lowest dose that is both safe and effective in assisting me to function better. If my activity level or general function gets worse, the medication may be changed or discontinued.

Participation in other types of treatment. I will fully comply with other treatment recommendations and specialist consultations recommended by _____.

Keeping scheduled appointments. I agree to keep regularly scheduled appointments at the clinic and to participate as requested in the evaluation of the effectiveness of this treatment.

Only one health care provider to manage medication. All opioid and other controlled drugs for pain will be prescribed only by _____. When _____ is not available, _____ will manage my medications.

- I will not obtain opioids or other controlled drugs from other providers, unless I have another condition that requires the prescription of a controlled drug (narcotics, tranquilizers, barbiturates, or stimulants) or if I am hospitalized for any reason. In either of these situations, before opioids or other controlled drugs are prescribed or dispensed, I agree to tell the health care provider that I am being treated with long term opioids for chronic pain.
- I will keep _____ or the clinic informed about any new medical conditions that develop and all of the medications I receive from other providers.
- _____ agrees to be available or provide coverage for breakthrough pain or episodic pain not responsive to the planned treatments.

**DRAFT PATIENT/PROVIDER CONTRACT
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- I understand that I should check with my health care provider or my pharmacist before taking any other medications, including over the counter medications.

Taking medication exactly as prescribed: I will take my medications exactly as prescribed and will not change the medication dosage or schedule without _____'s approval. I understand that if I stop taking this medication without my health care provider's supervision, it may cause symptoms of withdrawal.

Refills. I am responsible for keeping track of my medication and planning ahead to arrange refills in a timely manner so that I will not run out of medication. I understand that I will be given enough medication to last for a fixed amount of time when used as prescribed. Refills will only be given during regular office hours. Refills will not be made at night, on weekends or on holidays. Prescriptions cannot be filled early.

Lost or stolen prescriptions or medications. If my prescriptions or medications are lost or stolen, they may not be replaced. I understand that my provider is only allowed to replace a lost or stolen prescription once.

Access to medication by others prohibited. I will not give, share, or sell my medication to anyone.

Monitoring by health care provider.

- I agree that _____ may contact any other health care provider with whom I treat to discuss my use of opioid medication.
- I agree that _____ will periodically access the Minnesota Prescription Monitoring Program database to review my prescription history.
- I agree to abstain from all illegal drugs and will provide urine specimens at the health care provider's request to monitor my compliance with treatment.

Discontinuance of medication. I understand that if my medication is stopped for any reason, _____ will taper me off the medication in a controlled fashion to avoid withdrawal symptoms and will offer alternative ways of treating my condition or referral to another provider.

Patient signature

Date signed: _____

Health care provider signature

Date signed: _____