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LABOR & INDUSTRY

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March 12, 2015

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Re: In The Matter of the Proposed Permanent Rules of the Department of Labor and Industry governing Long-Term Treatment with Opioid Analgesic Medication for Workers' Compensation Injuries; *Minnesota Rules*, Parts 5221.6040, 5221.6105, and 5221.6110; Revisor's ID Number 04229.

Dear Librarian:

The Minnesota Department of Labor and Industry intends to adopt rules governing Long-Term Treatment with Opioid Analgesic Medication for Workers' Compensation Injuries. We plan to publish Dual Notice in the Monday, March 16, 2015 State Register.

The Department has prepared a Statement of Need and Reasonableness. As required by Minnesota Statutes, sections 14.131 and 14.23, the Department is sending the Library an electronic copy of the Statement of Need and Reasonableness at the same time we are mailing our Notice of Intent to Adopt Rules.

If you have questions, please contact me at 651-284-5006.

Yours very truly,

Kathryn Berger

Kathryn Berger,
General Counsel
Minnesota Department of Labor and Industry

Enclosure: Statement of Need and Reasonableness

Minnesota Department of Labor and Industry

STATEMENT OF NEED AND REASONABLENESS

Proposed Permanent Rules Governing Long-Term Treatment with Opioid Analgesic Medication for Workers' Compensation Injuries; *Minnesota Rules*, Parts 5221.6040, 5221.6105, and 5221.6110; RD-4229.

ALTERNATIVE FORMAT

Upon request, this Statement of Need and Reasonableness can be made available in an alternative format, such as large print, Braille, or audio recording. To make a request, contact the agency contact person, Kathryn Berger, at the Department of Labor and Industry in any of the following ways:

- by mail at 443 Lafayette Road North, St. Paul, MN 55155;
- by phone at 651-284-5006;
- by FAX at 651-284-5725; or
- by email at dli.rules@state.mn.us

STATUTORY AUTHORITY AND INTRODUCTION

Statutory Authority

In 1992 the legislature enacted Minnesota Statutes, § 176.83, subdivision 5, which granted the commissioner of the Department of Labor and Industry ("Department") the authority to promulgate emergency and permanent rules establishing standards and procedures for treatment of workers' compensation injuries. In consultation with the Medical Services Review Board ("MSRB"), as required by statute, the Department adopted "treatment parameter" rules, codified in Minn. R. 5221.6010 to 5221.6600.

Minnesota Statutes § 176.83, subd. 5, paragraph (b) was most recently amended, effective October 1, 2013, to add clause (7), which requires the commissioner to adopt rules including "criteria for the long-term use of opioids or other scheduled medications to alleviate intractable pain and improve function, including the use of written contracts between the injured worker and the health care provider who prescribes the medication."[1] These proposed rules are in response to this amendment.

> The current Minn. Stat. § 176.83, subdivision 5 states:
>
> **Treatment standards for medical services.**
> (a) In consultation with the Medical Services Review Board or the rehabilitation review panel, the commissioner shall adopt rules establishing

[1] 2013 Minn. Laws; chapter 70, article 2, secs. 11 and 14; https://www.revisor.leg.state.mn.us/laws/?doctype=Chapter&year=2013&type=0&id=70.

standards and procedures for health care provider treatment. The rules shall apply uniformly to all providers including those providing managed care under section 176.1351. The rules shall be used to determine whether a provider of health care services and rehabilitation services, including a provider of medical, chiropractic, podiatric, surgical, hospital, or other services, is performing procedures or providing services at a level or with a frequency that is excessive, unnecessary, or inappropriate under section 176.135, subdivision1, based upon accepted medical standards for quality health care and accepted rehabilitation standards.

(b) The rules shall include, but are not limited to, the following:

(1) criteria for diagnosis and treatment of the most common work-related injuries including, but not limited to, low back injuries and upper extremity repetitive trauma injuries;

(2) criteria for surgical procedures including, but not limited to, diagnosis, prior conservative treatment, supporting diagnostic imaging and testing, and anticipated outcome criteria;

(3) criteria for use of appliances, adaptive equipment, and use of health clubs or other exercise facilities;

(4) criteria for diagnostic imaging procedures;

(5) criteria for inpatient hospitalization;

(6) criteria for treatment of intractable pain; and

(7) criteria for the long-term use of opioids or other scheduled medications to alleviate intractable pain and improve function, including the use of written contracts between the injured worker and the health care provider who prescribes the medication. [*Emphasis added*]

(c) If it is determined by the payer that the level, frequency, or cost of a procedure or service of a provider is excessive, unnecessary, or inappropriate according to the standards established by the rules, the provider shall not be paid for the procedure, service, or cost by an insurer, self-insurer, or group self-insurer, and the provider shall not be reimbursed or attempt to collect reimbursement for the procedure, service, or cost from any other source, including the employee, another insurer, the special compensation fund, or any government program unless the commissioner or compensation judge determines at a hearing or administrative conference that the level, frequency, or cost was not excessive under the rules in which case the insurer, self-insurer, or group self-insurer shall make the payment deemed reasonable.

(d) A rehabilitation provider who is determined by the rehabilitation review panel board, after hearing, to be consistently performing procedures or providing services at an excessive level or cost may be prohibited from receiving any further reimbursement for procedures or services provided

> under this chapter. A prohibition imposed on a provider under this subdivision may be grounds for revocation or suspension of the provider's license or certificate of registration to provide health care or rehabilitation service in Minnesota by the appropriate licensing or certifying body. The commissioner and Medical Services Review Board shall review excessive, inappropriate, or unnecessary health care provider treatment under section 176.103.

Additional authority for the rules is in Minn. Stat. § 176.103, subd. 2, which states that the commissioner, in consultation with the MSRB, "shall adopt rules defining standards of treatment, including inappropriate, unnecessary or excessive treatment and the sanctions to be imposed for inappropriate, unnecessary or excessive treatment."[2] The MSRB was established by Minn. Stat. § 176.103 in 1983, and advises the Department about workers' compensation medical issues and is a liaison between the Department and the medical-provider community.[3] As discussed later in this Statement of Need and Reasonableness (SONAR), the Department has extensively consulted with the MSRB in the development of the proposed rules.[4]

Finally, Minn. Stat. § 176.83, subds. 3 and 4, also authorize these proposed rules. Subdivision 3 authorizes the commissioner to adopt rules, specifically, "[r]ules establishing standards for reviewing and evaluating the clinical consequences of services provided . . . to an employee by health care providers." Subdivision 4 authorizes the commissioner to adopt "[r]ules establishing standards and procedures for determining whether or not charges for health services or rehabilitation services rendered under this chapter are excessive."

Therefore, the Department has the necessary statutory authority to adopt the proposed amendments to the treatment parameter rules.[5]

Jacka v. Coca-Cola

The Department adopted permanent treatment parameter rules effective on January 4, 1995. In *Jacka v. Coca-Cola Bottling Co.*, 580 N.W.2d 27 (Minn. 1998), the Minnesota Supreme Court upheld the permanent treatment parameter rules. The Court found that the permanent treatment parameter rules did not exceed the Department's rulemaking authority and did not violate the due process clause of the United States and Minnesota constitutions. Specifically, the Court

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[2] The rules governing the sanctioning process are in Minn. R. part 5221.8900.

[3] Under Minn. Stat. § 176.103, the MSRB is composed of the commissioner or commissioner's designee as an ex officio member, two chiropractic representatives, one hospital representative, one physical therapist, one registered nurse, one occupational therapist, six physicians of different specialties, one employee representative and one employer or insurer representative. A list of current MSRB members is at www.dli.mn.gov/PDF/msrb/msrbmembers.pdf. MSRB members serve four-year terms, which may be renewed. Previous years' membership lists are available from the agency contact person.

[4] The MSRB addressed the proposed rules at meetings between 2006 and 2014. These MSRB meeting minutes are online at http://www.dli.mn.gov/PDF/docket/5221_6020_8900TrtmPar_2.pdf.

[5] Minnesota Statutes, § 14.125 requires an agency to publish a notice of intent to adopt rules or a notice of hearing within 18 months of the effective date of the law authorizing or requiring rules to be adopted, amended, or repealed. The effective date of the statutory authority to adopt these rules was October 1, 2013. Minn. Laws; chapter 70, article 2, secs. 11 and 14; https://www.revisor.leg.state.mn.us/laws/?doctype=Chapter&year=2013&type=0&id=70.

determined that the rules did not place absolute limits on the duration of treatment, that the rule allowing departures (Minn. R. 5221.6050, subp. 8) did not state that it provides the exclusive means of departing from the rules, and that the legislature had clarified "how the rules should interact with the compensation judge's role" in the 1995 amendments. The court stated:

> In summary, we hold that the permanent treatment parameter rules adopted by D.O.L.I. are flexible and yielding and, therefore, ensure that reasonably priced, appropriate medical care will not be denied simply because of a time-line or rigid categories. At the same time, the rules are substantial enough to establish standards and procedures based on good medical practice that can be used to regulate provider abuses and reduce litigation over compensable treatment. We recognize, as the broader medical community has done, that rules establishing standards and procedures for managed care do not have to be at odds with the purpose of restoring the employee to good health. We conclude that these rules have struck the right balance between flexibility and substance and should have the respect, force and effect accorded other properly promulgated administrative rules."[6]

Organization of the rules

The treatment parameter rules are intended to be used as strategies for managing patient care in workers' compensation according to accepted medical standards for quality health care. They reflect general strategies applicable to all patients as well as specific strategies for patients with certain conditions or circumstances. The parameters assist health care providers in decision making and to improve the quality of health care while at the same time making it more efficient and cost-effective. They optimize outcomes for injured workers while reasonably containing costs for employers and insurers by ensuring that treatment of the injury meets accepted medical standards.

These proposed rule amendments reorganize and clarify the existing rules related to long term use of opioid (narcotic) medications. To better understand the proposed rule amendments, it is helpful to know how the amendments fit with the other treatment parameter rule parts.[7,8,9] The rule

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[6] *Jacka v. Coca-Cola Bottling Co.*, 580 N.W.2d 27, 36. The court also stated that "in recognition of the fact that the treatment parameters cannot anticipate every exceptional circumstance, we acknowledge that a compensation judge may depart from the rules in those rare cases in which departure is necessary to obtain proper treatment." *Id.*at 35-36.

[7] Because not all treatment parameter rule parts are being amended at this time, additional background about other treatment parameter rule parts is in the 1994 Statement of Need and Reasonableness. The 1994 Statement of Need and Reasonableness is available from the Department contact person by phone at 651-284-5006 or by email at dli.rules@state.mn.us, or on the Revisor's website at www.leg.mn/archive/sonar/SONAR-02317.pdf.

[8] The treatment parameter rules governing medications, medical imaging, functional capacity evaluations, passive care and complex regional pain syndrome were amended in 2010.35 SR 138. The rule amendments and SONAR are at: https://www.revisor.mn.gov/rules/rule_display.php?id=R-03721&keyword_set%5B%5D=document&keyword_set%5B%5D=title&keyword_set%5B%5D=action&keyword_set%5B%5D=revisor&keyword_set%5B%5D=lrl&keyword_set%5B%5D=oah&keyword_set%5B%5D=ag&rule_id=5221&ruletype%5B%5D=Permanent

[9] The treatment parameters governing spinal cord stimulators and intrathecal drug delivery systems were amended in September, 2013. 39 SR 286; http://www.comm.media.state.mn.us/bookstore/stateregister/39_09.pdf . The SONAR for these rules is at http://www.dli.mn.gov/PDF/docket/5221_6020_8900TrtmPar_3.pdf.

content and organization provides a progression of appropriate treatment that begins with the least invasive treatment options and progresses only as necessary. Here is a brief summary of the treatment parameters rule parts:

- Part 5221.6020 states the purpose and application of these rules. These rules establish parameters for reasonably required treatment of employees with compensable workers' compensation injuries to prevent excessive services. No amendments are proposed to this part in this proceeding.

- Part 5221.6030 incorporates by reference the International Classification of Diseases diagnostic coding manual referred to throughout the treatment parameters.[10] No amendments are proposed to this part in this proceeding.

- Part 5221.6040 provides definitions of terms used throughout the parameters. New definitions for "intractable pain," "modality," "morphine equivalent milligrams," and "pain medicine specialist" are proposed.

- Part 5221.6050 provides general treatment parameters, including bases for departure from the parameters.[11] No amendments are proposed to this part in this proceeding.

- Part 5221.6100 identifies general principles that must be adhered to when ordering medical imaging studies. No amendments are proposed to this part in this proceeding.

- Part 5221.6105 governs the use of medications in the treatment of workers' compensation injuries. This part is proposed to be amended to ensure coordination with the proposed rules governing long-term use of opioids.

- Part 5221.6110 is the proposed new part governing long-term treatment with opioid analgesic medication.

- Part 5221.6200 (low back pain); 5221.6205 (neck pain); and 5221.6210 (thoracic back pain) provide parameters for the diagnosis and treatment of back and neck injuries.[12] Generally, the first five subparts in each of these rule parts address diagnostic procedures, general treatment parameters, passive treatment modalities, active treatment modalities and therapeutic injections. In particular, subpart 2(B) identifies three treatment phases: the first phase is initial nonsurgical care, which may include any combination of passive, active, injection and medication treatment modalities; the second phase is surgical evaluation for patients with persistent symptoms following initial nonsurgical

[10] Minn. R. 5221.6030 provides in part: "The ICD-9-CM diagnostic codes referenced in parts 5221.6010 to 5221.6600 are contained in the fourth edition of the International Classification of Diseases, Clinical Modification, 1994, and corresponding annual updates. For information see www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/. The Department intends to update ICD-9 to ICD-10 in a subsequent rule proceeding when ICD-10 is required for federal programs, as authorized by Minn. Stat. § 176.135, subd.7 (b) and (c).

[11] See footnote 28 for the full departure rule language.

[12] Because of the close similarities among these three rule parts, they are described together here.

management; a patient cannot proceed to phase two until all appropriate nonsurgical options have been exhausted.[13] The third phase is chronic management, when the injured worker is not a candidate for surgery or when there has not been complete resolution of symptoms following surgery. No amendments are proposed to these parts in this proceeding.

- Part 5221.6300 addresses diagnosis and treatment of upper extremity disorders. No amendments are proposed to this part in this proceeding.

- Part 5221.6305 describes parameters for complex regional pain syndrome and related conditions (a.k.a. reflex sympathetic dystrophy and causalgia), which is a complication of injuries to upper and lower extremities. No amendments are proposed to this part in this proceeding.

- Part 5221.6400 provides parameters for inpatient hospitalization. No amendments are proposed to this part in this proceeding.

- Part 5221.6500 provides parameters for surgical procedures. No amendments are proposed to this part in this proceeding.

- Part 5221.6600 provides parameters for the third phase of treatment, chronic management. No amendments are proposed to this part in this proceeding.

REGULATORY ANALYSIS

Minnesota Statutes, section 14.131, sets out eight factors for a regulatory analysis that must be included in the Statement of Need and Reasonableness ("SONAR"). Paragraphs (1) through (8) identify these factors and the agency's response.

(1) A description of the classes of persons who probably will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule.

The proposed rule amendments will likely affect injured workers and health care providers who treat injured workers with workers' compensation claims with long-term treatment with opioid analgesic medication, including physicians and advanced-practice health care providers with prescribing authority, such as nurse practitioners and physician assistants. Additionally, the amendments will likely affect workers' compensation employers and insurers who pay for workers' compensation medical treatment, and certified workers' compensation managed care plans established under Minn. Stat. § 176.1351.

[13]See, for example, Minn. R. 5221.6200, subp. 2(B); https://www.revisor.mn.gov/rules/?id=5221.6200

All of the named classes of persons will benefit from the rules because they reflect the current accepted standards of medical care. This should reduce costs and disputes related to whether long-term treatment with opioids is reasonable and necessary. Because the proposed amendments reflect the current standard of medical care, additional cost is not anticipated. There may be reduced revenue for providers who do not currently comply with the current accepted standards but that cannot reasonably be measured because there are too many unknown variables. For example, the Board of Medical Practice regularly issues orders to physicians who have inappropriately prescribed narcotics, but only after receiving a complaint. We do not know how many health care providers do not currently adhere to the current accepted standards of care reflected in the proposed rules, the extent to which each health care provider delivers nonstandard care, the number of injured workers treated by those providers and the extent to which insurers are currently paying for nonstandard treatment. The potential costs or savings to payers will depend on the same variables. There may be savings to the extent payers no longer pay for nonstandard care based on the rule. However, there may be additional costs to the extent payers were previously denying payment for care that is consistent with the current accepted standards of medical care.

(2) The probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

A state agency may be affected by implementation and enforcement of the proposed rules to the extent a state agency is an affected party as described above. For example, a state agency may be a an employer of an injured worker; the Department of Administration pays claims of injured state workers; the University of Minnesota pays claims of injured university employees; and the Department of Labor and Industry's Special Compensation Fund pays for medical services in claims where the employer was uninsured.

No additional costs to this Department or any other agency are anticipated for the implementation and enforcement of the proposed rules because the proposed rules incorporate current accepted medical standards, which payers must already use to determine whether treatment of a work-related injury is appropriate and therefore compensable. The proposed rules should reduce litigation, but even if they don't, the number of disputes is not anticipated to significantly impact the workers' compensation dispute resolution system. Therefore, there should be no additional costs to other agencies, such as Minnesota Department of Administration and the Office of Administrative Hearings (which conducts proceedings and issues decisions in workers' compensation disputes). There is no anticipated effect on state revenues.

(3) A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

The purpose of the treatment parameters is stated in Minn. Stat. § 176.83, subd. 5 (a) and (c):

> (a) In consultation with the Medical Services Review Board or the rehabilitation review panel, the commissioner shall adopt rules establishing standards and procedures for health care provider treatment. . . . The rules shall be used to determine whether a provider of health care services and rehabilitation services,

including a provider of medical, chiropractic, podiatric, surgical, hospital, or other services, is performing procedures or providing services at a level or with a frequency that is excessive, unnecessary, or inappropriate under section 176.135, subdivision 1, based upon accepted medical standards for quality health care and accepted rehabilitation standards."

. . . . (c) If it is determined by the payer that the level, frequency, or cost of a procedure or service of a provider is excessive, unnecessary, or inappropriate according to the standards established by the rules, the provider shall not be paid for the procedure, service, or cost . . . . unless the commissioner or compensation judge determines at a hearing or administrative conference that the level, frequency, or cost was not excessive under the rules in which case the insurer, self-insurer, or group self-insurer shall make the payment deemed reasonable.

Finally, Minn. Stat. § 176.83, subd. 5 (b) (7) provides that the rules for long-term use of opioids should be used to alleviate intractable pain and improve function for injured workers. Following extensive consultation with the MSRB and the Department's medical consultant,[14] the proposed rules update the treatment parameters to reflect current accepted medical standards for providing quality, cost effective health care to cure and relieve injured workers of the effects of their injuries, including alleviating intractable pain and improving function, as required by statute.[15] As a consequence, no less-costly or less-intrusive method for achieving this purpose has been identified.

(4) A description of any alternative methods for achieving the purpose of the proposed rule that were seriously considered by the agency and the reasons why they were rejected in favor of the proposed rule.

As noted above, under Minnesota Statutes, section 176.83, subdivision 5, the purpose of the proposed rule amendments is to update the treatment parameters to reflect current accepted medical standards for providing quality and cost effective health care to relieve injured workers with intractable pain from their injuries and improve their function. The Department reviewed many source materials,[16] including those recommended in orders issued by the Board of Medical Practice related to long-term use of opioid medication and the documents described on pages 14 to 19 of this Statement of Need and Reasonableness. Notice of availability of the draft rules was provided in the Request for Comments published on November 12, 2013. As they were revised, the draft rules were made available on the Department's web site and at MSRB meetings. At its meetings, the MSRB extensively discussed each of the proposed rules and comments submitted by interested persons to assist the Department determine the current accepted medical standards upon which the amendments are based, as more fully discussed later in this SONAR. The Department

[14] The Department's medical consultant, Dr. William Lohman, M.D., is the Department's medical liaison with the MSRB and advises the Department on workers' compensation medical issues, the workers' compensation treatment parameters and on the continuum of care of injured workers. Minn. Stat. § 176.103, subd. 1. https://www.revisor.mn.gov/statutes/?id=176.103

[15] Minnesota Statutes, § 176.83.

[16] These source materials are identified in the bibliography attached as Appendix A. These materials are available for review on the Department's rule docket page at http://www.dli.mn.gov/PDF/docket/5221_6020_8900TrtmPar_2.pdf, or at the Department.

seriously considered comments received and incorporated the recommendations made by the MSRB in response to the comments. The Department is not proposing any amendments that were not supported by the medical literature and the MSRB. A compilation of comments discussed by the MSRB and its responses shows the thorough consideration of the issues by the MSRB.[17]

(5) The probable costs of complying with the proposed rule, including the portion of the total costs that will be borne by identifiable categories of affected parties, such as separate classes of governmental units, businesses, or individuals.

The proposed rules reflect current accepted medical standards for quality and cost-effective health care as supported by the medical literature and recommended by the MSRB. There is no cost of compliance for providers because the rules do not require providers to spend money to comply. The proposed rules may reduce or increase revenue for providers, depending on the variables discussed under regulatory analysis #1 and whether the providers currently meet the standards of practice for long-term treatment with opioid analgesic medication. The rules may require additional payment by insurers that are not currently paying for accepted medical treatment, and save costs for insurers who are currently paying for treatment that does not meet the standards. The rules should reduce costs for providers, injured workers, and workers' compensation payers to the extent that they reduce litigation and inappropriate denials of treatment, but the level of assessment required of providers may increase costs for those who are currently not providing that level of assessment. The cost analysis would be no different for governmental units because governmental units either act in the capacity of an employer, insurer or provider.

Although specialty consultations required or permitted by the rules could increase payer costs, they will not be required in every case, and in some cases the prescribing health care provider may perform the assessment if he or she specializes in pain medicine or treatment of the condition causing the pain. Additionally, these specialty assessments could save costs by better patient selection or ensuring a more effective treatment plan with the long-term use of opioids. Additional savings may be realized by the avoidance of disputes. Finally, because the rules incorporate the current standard of care, consultations by specialists are likely already being performed in some workers' compensation claims involving long-term treatment with opioids. For these reasons, the specialty consultation provisions are not likely to increase costs for payers.

Some providers may argue that the extensive level of required assessments is a source of potential cost. The listed peer-reviewed assessment tools are available free online, and are administered on paper to the injured worker to assess the patient's level of pain, function and opioid risk. The provider must also assess whether there are any contraindications to the treatment, the success of the treatment in meeting the goals at follow-up visits, possible side effects of treatment, misuse of medications, aberrant behaviors indicative of addiction, contraindications to continuing treatment; and adherence to the entire program of treatment. The provider must review at least semiannually the patient's prescription history in the Minnesota prescription monitoring program to validate

[17] The MSRB minutes reflect its consideration of comments and corresponding recommendations. The minutes are linked on the docket page for these proposed rules at http://www.dli.mn.gov/PDF/docket/5221_6020_8900TrtmPar_2.pdf

correct medication usage. Providers must also enter into a contract with patients reflecting obligations of both parties. These requirements reflect the standard of care for long-term use of prescription opioids and are critically important to ensure that the treatment is safe and effective.

Whether the proposed rules will increase costs for a specific provider will depend on the provider's current practice and level of expertise. Because this is an area of medicine that requires significant skill and expertise, providers who do not routinely prescribe long-term opioids consistent with these standards may decide it is more cost-effective to refer patients to providers who have the expertise. Other providers may decide to develop the expertise. Again, however, the rules do not require any provider to develop this expertise or treat with long-term opiates and do not require providers to spend money to comply with the rules. For providers who choose to provide this treatment, the additional attention to the injured worker will allow the provider to bill a higher level of office visit, resulting in a higher level of reimbursement. Therefore there is no actual cost of compliance for providers.

The Department solicited input on the cost of complying with the proposed amendments (and the other regulatory analysis questions) from members of the Medical Services Review Board and from members of the Workers' Compensation Insurers Task Force.[18] The Department has not received responses to either inquiry, which also suggests that costs of compliance cannot be readily identified.

(6) The probable costs or consequences of not adopting the proposed rule, including those costs or consequences borne by identifiable categories of affected parties, such as separate classes of government units, businesses, or individuals.

The probable costs or consequences of not adopting the proposed rules are that injured workers may receive treatment with long-term opioids that is not consistent with current accepted medical standards of practice for quality health care. The rules require a rigorous treatment plan and a contract between the patient and the prescribing provider for assessment and monitoring of the long-term treatment with opioid medication. Without this the consequences to the patient can be serious, including failure to adequately treat pain and improve function, or even devastating, such as addiction or death.[19] Additionally, without the rules payers might pay for treatment that does not meet current treatment standards or may deny payment for treatment that does meet the standards, resulting in inadequate treatment for the injured worker and workers' compensation medical disputes.[20]

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[18] The Workers' Compensation Insurers' Task Force ("WCITF") is an ad hoc committee of representatives of workers' compensation payers, including insurance companies, and employers who self-insure for their workers' compensation coverage (including government entities). The WCITF meets up to four times a year to facilitate the exchange of information about current workers' compensation issues between payers and with the Department. A list of WCITF members is at http://www.dli.mn.gov/Wcitf.asp

[19] See, for example, the case of *Bowman vs. A & M Moving & Storage Co.* (8-14-13; WCCA; No. WC13-5551), in which the employee's death from Oxycodone toxicity was determined to be causally related to his work injury. The decision does not state whether any of the safeguards required by the rule were used.

[20] See also, *Brunkhorst v. Andrews Knitting Mills* (9-25-14; WCCA; No. WC14-5683), in which the Workers' Compensation Court of Appeals found that substantial evidence supported the compensation judge's determination that the narcotic medications

(7) An assessment of any differences between the proposed rule and existing federal regulations and a specific analysis of the need for and reasonableness of each difference.

There are no federal regulations governing Minnesota workers' compensation treatment. The federal Controlled Substances Act (CSA) and corresponding federal regulations regulate drugs, including opioids. The U. S. Drug Enforcement Administration (DEA) describes the CSA as follows:

> Under the framework of the CSA, all controlled substance transactions take place within a "closed system" of distribution established by Congress. Within the "closed system" all legitimate handlers of controlled substances – manufacturers, distributors, physicians, pharmacies, and others, must be registered with DEA (unless exempt) and maintain strict accounting for all controlled substance transactions. . . . Federal controlled substance laws are designed to function in tandem with state controlled substance laws. DEA works in cooperation with state professional licensing boards and state and local law enforcement officials to make certain that pharmaceutical controlled substances are prescribed, administered, and dispensed for a legitimate medical purpose in the usual course of professional practice. Within this framework, the majority of investigations into possible violations of controlled substance laws are carried out by state authorities. DEA focuses its investigations on cases involving violators of the highest level or most significant impact.[21]

Thus, the CSA classifies controlled substances into one of five "schedules," depending on the potential for abuse, potential for psychological or physical dependence and the extent to which there is a currently accepted medical use for the drug.[22] Schedule I contains illegal drugs, which cannot be legally prescribed. Schedules II –V all include narcotic drugs that may be prescribed under these proposed rules.[23]

The CSA and federal regulations govern pharmacy registration, recordkeeping, security, inventory, theft or loss, online pharmacies, and distribution, transfer and disposal of controlled substances.[24] In addition, the CSA and corresponding regulations govern who may issue prescriptions, the purpose of the prescriptions, electronic prescriptions, refills, practitioner and mid-level practitioner registration, and requirements for prescription of schedule II and III controlled substances.[25] State law may include additional requirements where federal law allows discretion.[26]

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prescribed over a twelve year period did not significantly improve the employee's discomfort or function and were not reasonable and necessary to treat her work injury.

[21] Drug Enforcement Administration Pharmacist's Manual, 2010 edition, Preface, p. 3. http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf.

[22] 21 U.S.C. 812(b). http://www.gpo.gov/fdsys/pkg/USCODE-2013-title21/html/USCODE-2013-title21-chap13-subchapI-partB-sec812.htm

[23] Effective October 6, 2014, the DEA reclassified hydrocodone combination products from Schedule III to the more restrictive Schedule II category. The DEA Pharmacist's Manual still reflects the old classification. https://www.federalregister.gov/articles/2014/08/22/2014-19922/schedules-of-controlled-substances-rescheduling-of-hydrocodone-combination-products-from-schedule

[24] http://www.deadiversion.usdoj.gov/21cfr/cfr/index.html

[25] http://www.deadiversion.usdoj.gov/21cfr/cfr/2106cfrt.htm

[26] See, Minn. Stat. chapter 152.11 and 152.12. https://www.revisor.mn.gov/statutes/?id=152

The proposed rules do not conflict with or differ from any federal or state law. They do not govern pharmacies, or how or by whom prescriptions are written because those are regulated by the laws cited above. Instead, they describe the assessment, treatment plan and monitoring of injured workers who are prescribed opioids on a long term basis. The prescribing provider and pharmacies are still required to comply with applicable federal and state laws governing opioid medication. For example, under the federal regulations, depending on the medication prescribed, the provider may be prohibited from refilling prescriptions beyond a certain number of days. The proposed workers' compensation rules, in part 5221.6110, subp. 8 (A), require a minimum number of visits with and evaluation by the prescribing provider for any workers' compensation patient receiving an opiate medication. However, the rules do not prohibit more visits if required by federal law when, for example, Schedule II opioids are prescribed.[27]

(8) An assessment of the cumulative effect of the rule with other federal and state regulations related to the specific purpose of the rule. . . . '[C]umulative effect' means the impact that results from incremental impact of the proposed rule in addition to other rules, regardless of what state or federal agency has adopted the other rules. Cumulative effects can result from individually minor but collectively significant rules adopted over a period of time.

There are no cumulative effects of the rule with other federal regulations as there are no federal regulations related to the specific purpose of the rule. The specific purpose of the rules is to comply with the legislature's requirement that the Department promulgate treatment parameter rules governing the long-term treatment with opioid medication to relieve intractable pain and improve the function of injured workers according to accepted medical standards for quality health care. There are no other state regulations related to this specific purpose. The Board of Medical Practice (BMP) has not promulgated rules governing the long-term prescription of opioid medication, but it does investigate complaints against health care providers alleging improper prescription practices and issue orders and corrective action plans where appropriate. The Department has reviewed recent orders and corrective action plans provided to the Department by the BMP and the materials cited by the BMP in the corrective action plans. The proposed rules are consistent with the BMP's approach. And, as noted above, the proposed rules complement state and federal laws governing controlled substances but do not replace or conflict with those other laws.

PERFORMANCE-BASED RULES

Minnesota Statutes, section 14.002 and 14.131, require that the SONAR describe how the agency, in developing the rules, considered and implemented performance-based standards that emphasize superior achievement in meeting the agency's regulatory objectives and maximum flexibility for the regulated party and the agency in meeting those goals.

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[27] See, for example, 21 CFR 1306.12 (b), which prohibits refills beyond a 90-day supply of a Schedule II controlled substance. However, paragraph (b) states: "Nothing in this paragraph (b) shall be construed as mandating or encouraging individual practitioners to issue multiple prescriptions or to see their patients only once every 90 days when prescribing Schedule II controlled substances. Rather, individual practitioners must determine on their own, based on sound medical judgment, and in accordance with established medical standards, whether it is appropriate to issue multiple prescriptions and how often to see their patients when doing so." http://www.deadiversion.usdoj.gov/21cfr/cfr/1306/1306_12.htm

According to Minnesota Statutes, section 176.83, subdivision 5: "The rules shall be used to determine whether a provider of health care services . . . . is performing procedures or providing services at a level or with a frequency that is excessive, unnecessary, or inappropriate under section 176.135, subdivision 1, based upon accepted medical standards for quality health care and accepted rehabilitation standards." The 2013 Legislature further required that the proposed rules govern long-term treatment with opioid medication to relieve intractable pain and improve function of injured workers according to accepted medical standards for quality health care. As is evident by these requirements, the treatment parameters are performance-based rules that provide health care providers with flexibility to determine what treatment to provide based on the provider's assessment of the unique needs of each injured worker within the guidelines set forth in the treatment parameters. They do not rigidly proscribe or prescribe specific treatment, but rather reflect the acceptable standards of quality health care for each individual patient as described by the medical literature referenced in Appendix A, the standards discussed on pages 17-25, and the Medical Services Review Board.

The bases for departing from the parameters also apply to the proposed amendments.[28] As stated by the Minnesota Supreme Court in *Jacka*, ". . . the treatment parameters are flexible and yielding and, therefore, ensure that reasonably priced, appropriate medical care will not be denied simply because of a time-line or rigid categories. At the same time, the rules are substantial enough to establish standards and procedures based on good medical practice that can be used to regulate provider abuses and reduce litigation over compensable treatment." *Jacka v. Coca Cola Bottling Co.*, 580 N.W.2d 27, 36 (Minn. 1998).

ADDITIONAL NOTICE

Minnesota Statutes, section 14.131 and 14.23, require that the SONAR contain a description of the Department's efforts to provide additional notice to persons who may be affected by the proposed rules or explain why these efforts were not made. This Additional Notice Plan was reviewed by the Office of Administrative Hearings and approved on February 26, 2015.

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[28] Minn. R. 5221.6050, Subp. 8. Departures from parameters. A departure from a parameter that limits the duration or type of treatment in parts 5221.6050 to 5221.6600 may be appropriate in any one of the circumstances specified in items A to E. The health care provider must provide prior notification of the departure as required by subpart 9. A. Where there is a documented medical complication. B. Where previous treatment did not meet the accepted standard of practice and the requirements of parts 5221.6050 to 5221.6600 for the health care provider who ordered the treatment. C. Where the treatment is necessary to assist the employee in the initial return to work where the employee's work activities place stress on the part of the body affected by the work injury. The health care provider must document in the medical record the specific work activities that place stress on the affected body part, the details of the treatment plan and treatment delivered on each visit, the employee's response to the treatment, and efforts to promote employee independence in the employee's own care to the extent possible so that prolonged or repeated use of health care providers and medical facilities is minimized. D. Where the treatment continues to meet two of the following three criteria, as documented in the medical record: (1) the employee's subjective complaints of pain are progressively improving as evidenced by documentation in the medical record of decreased distribution, frequency, or intensity of symptoms; (2) the employee's objective clinical findings are progressively improving, as evidenced by documentation in the medical record of resolution or objectively measured improvement in physical signs of injury; and (3) the employee's functional status, especially vocational activity, is objectively improving as evidenced by documentation in the medical record, or successive reports of work ability, of less restrictive limitations on activity. E. Where there is an incapacitating exacerbation of the employee's condition. However, additional treatment for the incapacitating exacerbation may not exceed, and must comply with, the parameters in parts 5221.6050 to 5221.6600.

The Department has identified persons and organizations that represent those most likely to be affected by or interested in the rule amendments. The Dual Notice of Intent to Adopt Rules and proposed rules will be mailed or emailed to all of the following:

1. The members of the Workers' Compensation Advisory Council (WCAC) established pursuant to Minn. Stat. § 175.007, which consists of labor, employer, and legislative representatives, and persons who have requested to receive notice of WCAC meetings.[29]

2. Members of the Workers' Compensation Insurers Task Force (WCITF), an ad hoc group of workers' compensation payers who meet at the Department of Labor and Industry several times a year to learn about and discuss workers' compensation issues with the Department. The WCITF consists of 19 representatives of workers' compensation insurers, self-insured employers, and third-party administrators. Persons who have requested to receive notice of the WCTIF meetings will also be provided with the Notice.[30]

3. Members of the Workers' Compensation Medical Services Review Board, which consists of persons representing health care providers, labor and payers, as specified in Minnesota Statutes, section 176.103; and persons who have requested to receive notice of MSRB meetings.[31]

4. Persons and organizations who have requested to be on the electronic mailing list for *CompAct*, the Department's quarterly workers' compensation publication.[32]

5. Persons and organizations who are on the Department's email list for health care providers.[33]

6. Persons and organizations who are on the Department's email list for workers' compensation adjusters.[34]

7. Attorneys on the Office of Administrative Hearing's email list for workers' compensation attorneys.

8 The Minnesota Medical Association, the Minnesota Chiropractic Association, the Minnesota Nurses Association, the Minnesota Board of Nursing, the Minnesota Psychological Association, the Minnesota Psychiatric Society, the Minnesota Board of Medical Practice; Minnesota Nurse Practitioners organization; the Minnesota APRN

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[29] WCAC membership can be viewed at: http://www.dli.mn.gov/PDF/wcac/wcacmembers.pdf . Notice of WCAC meetings is currently sent to approximately 181 persons (including members).
[30] WCITF membership can be viewed at: http://www.dli.mn.gov/Wcitf.asp. Notice of WCITF meetings is currently sent to 45 persons (including members).
[31] MSRB membership can be viewed at: http://www.dli.mn.gov/Msrb.asp. Notice of MSRB meetings is currently sent to 69 persons (including members).
[32] There are currently 1605 persons and organizations on the DLI *CompAct* email list.
[33] There are currently 693 persons on the DLI email list for health care providers.
[34] There are currently 1877 persons on the DLI email list for adjusters.

Coalition (Advanced Practice Registered Nurses), and the Minnesota Academy of Physician Assistants.

9. Twenty-seven pain medicine specialists in Minnesota who are diplomats of the American Board of Pain Medicine and thirty-five Minnesota clinics that self-identify as specializing in the treatment of pain.

10. The Minnesota Employers Workers Compensation Alliance (originally called the Minnesota Self-Insurer's Association), the Insurance Federation of Minnesota, and the Minnesota Assigned Risk Plan Administrator (Affinity Insurance Services, Inc.).

11. The three workers' compensation managed care plans certified under Minnesota Statutes, section 176.1351: CorVel, GENEX Services, Inc., and HealthPartners.

12. The League of Minnesota Cities, the Association of Minnesota Counties, the University of Minnesota workers' compensation department, and the Minnesota Department of Administration.

13. Those who have commented on the draft amendments since the Request for Comment was published on November 12, 2013.

The Department will also place the Dual Notice of Intent to Adopt the proposed rules, the proposed rule amendments, and this Statement of Need and Reasonableness on the Department's rule docket Web site at http://www.dli.mn.gov/PDF/docket/5221_6020_8900TrtmPar_2.pdf. The Department's Notice Plan also includes giving notice required by statute. The proposed rules and Notice of Intent to Adopt will be mailed or emailed to everyone who has registered to be on the Department's rulemaking mailing lists under Minnesota Statutes, section 14.14, subdivision 1a. Notice will also be given to the Legislature as required by Minnesota Statutes, section 14.116.

CONSULT WITH MMB ON LOCAL GOVERNMENT IMPACT

Minnesota Statutes, section 14.131 requires the agency to consult with the Commissioner of Minnesota Management and Budget to help evaluate the fiscal impact and benefits of proposed rules on local governments. As required, the Department has consulted with the Commissioner of Minnesota Management and Budget. The Department sent a letter to the Executive Budget Officer dated January 9, 2015, requesting help evaluating the fiscal impact and fiscal benefits of the proposed rule on units of local government. In a letter dated February 16, 2015, Executive Budget Officer Betsy Hammer opined that there does not appear to be significant costs to local units of government as a result of the proposed rule.

DETERMINATION ABOUT RULES REQUIRING LOCAL IMPLEMENTATION

Under Minnesota Statutes, section 14.128, agencies must determine if a town, county, or home rule charter or statutory city will be required to adopt or amend an ordinance or other

regulation to comply with a proposed agency rule. The Department has determined that no local government will be required to adopt or amend an ordinance or other regulation to comply with the proposed amendments because local governments are required to comply with the workers compensation law as set forth in Minnesota Statutes, chapter 176, including the treatment parameters adopted under Minnesota Statutes, section 176.83, subdivision 5.[35] Therefore, no ordinance or regulation is required to implement these rules.

COST OF COMPLYING FOR SMALL BUSINESS OR CITY

Agency Determination of Cost

As required by Minnesota Statutes, section 14.127, the Department has considered whether the cost of complying with the proposed rules in the first year after the rules take effect will exceed $25,000 for any small business or small city.[36] The Department has determined that the cost of complying with the proposed rules in the first year after the rules take effect will not exceed $25,000 for any small business or small city.

Small businesses potentially affected by the proposed rules would most likely be small health care provider offices. As discussed above in the regulatory analysis section, the proposed rules do not require small-business health care providers to provide any particular treatment or spend money to comply. Moreover, providers can bill for a higher level of office visit to reflect additional time spent and assessment of the injured worker, so there is no direct cost of compliance; the proposed rules describe the accepted medical practice to ensure safe and effective treatment and payment by workers' compensation insurers and self-insured employers. Since workers' compensation health care is a relatively small percentage (approximately 1.4%) of the cost of general medical care and long-term treatment of injured workers with opioids is a small percentage of this, it is unlikely that the proposed rules will result in reduction in revenue of greater than $25,000 in the first year for any small-business health care provider who is currently providing nonstandard treatment.[37]

Small cities may also be affected as employers of injured workers. However, small cities typically do not pay workers' compensation claims directly. Furthermore, any additional costs as a result of the amendments would likely be offset by savings from better patient selection and outcomes due to better treatment and a reduced number of disputes. Therefore, the Department has determined that the cost of complying with the proposed rules in the first (or any) year after the rules take effect will not exceed $25,000 for any small business or small city.

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[35] Minnesota Statutes § 176.021, subd. 1 provides that the workers' compensation law applies to all employers unless excluded by chapter 176. Under Minnesota Statutes, § 176.011, subd. 10, the definition of "employer" includes counties, towns, cities, school districts, and governmental subdivisions. Minnesota Statutes, § 176.021, subd. 6 requires home rule charter cities to pay the compensation provided under Minnesota Statutes, chapter 176, although the charter may provide for compensation that exceeds the amount an employee is entitled to under chapter 176.

[36] A small business is defined as a business (either for profit or nonprofit) with less than 50 full-time employees and a small city is defined as a city with less than ten full-time employees.

[37] Workers' compensation total medical expenditures were an estimated $549 million in 2012. (Department of Labor and Industry, Research and Statistics Unit.) Total state health expenditures in Minnesota (public and private) were estimated at $39.8 billion for 2012 by the Minnesota Department of Health, Minnesota Health Care Spending and Projections, 2012, available at: www.health.state.mn.us/divs/hpsc/hep/publications/costs/healthspending2013.pdf.

EFFECT ON FARMING OPERATIONS AND CHICANO/LATINO PEOPLE

Minnesota Statutes, section 14.111 imposes additional requirements if the proposed rules affect farming operations. These proposed amendments will not have any significant impact on farming operations, and therefore the requirements of Minn. Stat. § 14.111 do not apply.
The requirements of Minnesota Statutes, section 3.9223 do not apply because the rules do not have their primary effect on Chicano/Latino people.

LIST OF WITNESSES

If these rules go to a public hearing, the Department may have the following witnesses testify in support of the need for and reasonableness of the rules, in addition to Department staff:

1. William Lohman, M.D., the Department's Medical Consultant.
2. Member(s) of the Medical Services Review Board.

BACKGROUND ON GUIDELINES FOR LONG-TERM TREATMENT WITH OPIOIDS

The use of opioid analgesics has become an accepted and routine treatment for patients with intractable pain, including those with non-cancer intractable pain. There has been a dramatic increase in the number of patients receiving opioid prescriptions.[38] This has been associated with a similarly increasing problem with the excessive and inappropriate use of these medications. According to a study published by the American Medical Association on October 27, 2014, opioid overdose is a leading cause of injury-related mortality in the United States.[39] Prescription opioids were involved in 67.8% of all overdoses.[40] The study noted that health care providers who prescribe opioids to patients with comorbidities "should do so with care and counsel all patients about the risk for overdose."[41]

In 2009, the Minnesota Boards of Nursing, Medical Practice, and Pharmacy issued a Joint Statement on Pain Management. The Joint Statement identifies pain management as a significant issue in health care, noting that millions of Americans live with serious pain lasting a year or more, that "common pain conditions among workers result in over $60 billion in lost productivity," and that "untreated or inadequately treated pain impacts patients' quality of life and increases health care costs."[42] The Joint Statement was issued "to provide maximum pain relief with minimal side

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[38] Opioid prescriptions increased from 44 million in 1991 to 179 million in 2009. Figure 1-2, National Institute on Drug Abuse Strategic Plan (2010); National Institutes of Health, U.S. Department of Health and Human Services. http://www.drugabuse.gov/sites/default/files/stratplan.pdf.

[39] The overall death rate for patients who arrived in the emergency room with opioid overdose (prescription or nonprescription) was 1.4 percent. About half of those who arrived in the emergency room with opioid overdose were admitted to the hospital. Yokell MA, Delgado MK, Zaller ND,EwenWang N, McGowan SK,Green TC "Presentation of Prescription and Nonprescription Opioid Overdoses to US Emergency Departments" JAMA Internal Medicine (published on-line October 27, 2014). http://media.jamanetwork.com/news-item/prescription-opioids-involved-in-most-overdoses-seen-in-emergency-departments/.

[40] Id.

[41] Id.

[42] http://mn.gov/health-licensing-boards/images/Joint_Statement_on_Pain_Management-BMP.pdf.

effects," and "in the interest of public protection." The Joint Statement provides guidelines for health care providers as follows:[43]

> To effectively assist patients in the management of pain, health care professionals should, within their scope of practice:
>
> - Consistently and thoroughly assess all patients for pain. If pain is reported, the pain should be evaluated with a complete history and physical with laboratory and diagnostic testing, if indicated. The assessment of pain should be individualized, on-going and clearly documented;
> - Work collaboratively in a multi-disciplinary approach to develop and implement an individualized, written treatment plan utilizing pharmacologic and non-pharmacologic interventions with specific objectives for the patient;
> - Regularly evaluate the effectiveness of the treatment plan, using a consistent, developmentally appropriate, standardized pain scale, and make adjustments as needed;
> - Document all aspects of pain assessment and care in a timely, clear, consistent, complete and accurate manner;
> - Anticipate and effectively manage side effects of pain medications;
> - Provide adequate and culturally appropriate information to patients and family members or caregivers to support patients in making informed decisions and participating in the management of their pain;
> - Be aware of the risks of diversion and abuse of controlled substances and take appropriate steps to minimize these risks;
> - Recognize individuals with chemical dependency may experience pain requiring medications, including opioids, and may require specialized management;
> - Consult with, and refer patients to, other providers when appropriate;
> - Develop organization-appropriate and evidence-based policies and protocols for pain management;
> - Become and remain knowledgeable regarding effective pain management; and
> - Comply with all state and federal laws and regulations regarding prescribing dispensing, and administering legend drugs, including controlled substances.

The Minnesota Board of Medical Practice also references on its Web site a guideline for physicians called the Model Policy for the Use of Controlled Substances for the Treatment of pain.[44] The Board also references Opioid Prescribing: Clinical Tools and Risk Management Strategies, which includes additional detail for providers who want to implement the Model Policy into their practices.[45] Table 12 of this document recommends:

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[43] Id.

[44] *Model Policy for the Use of Controlled Substances for the Treatment of Pain* (2004); Federation of State Medical Boards of the United States, Inc. http://mn.gov/health-licensing-boards/medical-practice/licensees/practice/pain-mgmt-guidelines.jsp.

[45] Anderson AV, Fine PG, and Fishman SM. Opioid prescribing: Clinical tools and risk management strategies; http://mn.gov/health-licensing-boards/images/Opioid_Prescribing_Clinical_Tools_and_Risk_Management_Strategies.pdf.

- Patient evaluation and history of pain, comorbidities, history of substance abuse and indications for treatment with opioids;
- A treatment plan with objectives that include pain relief, improved physical and psychosocial function, adjustment of treatment to reflect patient needs, and the use of nonopioid therapies when needed;
- Informed consent and agreement for treatment, including a discussion of the risks and benefits of controlled substances; the use of one physician and pharmacy when possible; a written agreement if the risk of abuse is high, drug screening, the number and frequency of refills and the reason for discontinuing the drug (such as violation of the agreement);
- Periodic review, including evaluation of progress toward treatment objectives such as decreased pain, increased function and quality of life, objective indicators and treatment modification if progress is not satisfactory;
- Consultations with other providers if there is a history of substance abuse, a comorbid psychiatric disorder or if the patient is at risk for misuse, abuse, or diversion;
- Accurate and complete medical records, including history and exam results; diagnostic, therapeutic and lab results; evaluations and consultations; treatment objectives; discussion of risks and benefits; informed consent to treatment; the date, type, dosage, and quantity of medication prescribed; other treatments prescribed; patient-prescriber agreements and instructions; and periodic reviews; and
- Physician compliance with state and federal controlled substance laws and regulations.

The Board of Medical Practice disciplines physicians who do not meet the accepted standard of care when prescribing opioids. Examples of violations include: prescribing excessive quantities of controlled substances; failing to document objective findings in support of the need for ongoing medications; failing to assess patients for the risk of chemical dependency, toxicity, diversion, or suicide; failing to monitor the efficacy of the medications; failing to implement narcotic agreements or enforce the agreements when patients violate them; failing to conduct biological fluid screens to monitor patients' compliance with the medication regimen or use of illicit drugs; failing to heed concerns raised by other health care providers about patients' excessive or inappropriate use of controlled substances; failing to recognize drug seeking behavior in patients; and failing to document details of prescriptions in clinic records.[46]

In addition to other requirements, physicians who are found to have inappropriate controlled substance prescribing practices are often required to read the Model Policy for Pain Control published by the Federation of State Medical Boards and *Responsible Opioid Prescribing, A Clinician's Guide, Second Edition;* complete training in chronic pain management, chemical

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[46] Public disciplinary stipulations and orders are available from the Board of Medical Practice and on the Board's website at http://mn.gov/health-licensing-boards/medical-practice/public/disciplinary-action/.

dependency awareness, medical records management, and boundaries; maintain records reflecting patient complaints, clinical findings, the treatment plan, response to treatment, and prescriptions authorized, including refills; submit to a Board committee a written protocol for managing and tracking controlled substance prescriptions, including the use of the Prescription Monitoring Program; and develop and submit for approval a written controlled substance agreement for use with all chronic pain patients. [47]

The book that the Board of Medical Practice requires providers with inappropriate prescribing practices to read, *Responsible Opioid Prescribing, a Clinician's Guide,* is authored by Scott M. Fishman, M.D. and trademarked by the Federation of State Medical Boards Foundation.[48] This book is a treatise for physicians explaining and detailing the principles reflected in the Model Policy and the Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain.[49] In the book, Fishman summarizes the "fundamental tenets of responsible opioid prescribing" as follows: [50]

PATIENT EVALUATION AND SELECTION

- Reserve long-term opioid therapy for patients who have tried other potentially effective treatments that pose less risk, including physical therapy, exercise, cognitive-behavioral therapy, and non-opioid analgesics.
- Screen patients before and during treatment for risks of all adverse outcomes, including those with mental illness and substance misuse, cardiopulmonary disease, and endocrine disorders.
- Understand that patients may be reluctant to disclose a history of substance misuse. Always check the medical record, a prescription drug–monitoring database, and third parties within the allowable circle of care.
- Don't start long-term use of opioids by default. Long-term opioid prescribing should generally be reserved for persistent or chronic pain and should only occur after careful patient election, discussion of risks, and the setting of realistic expectations and functional goals.
- Educate patients about the risks and benefits of opioid medications, as well as about their proper storage and disposal, so that they can make informed decisions about choosing or rejecting opioid therapy.

TREATMENT PLANS

- Be sure that the decision to start treatment is clearly agreed to by the patient and prescriber, and that each is informed about (and is willing to work toward)

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[47] Board of Medical Practice Publishable Press Release, September 13, 2014 Board Meeting. http://mn.gov/health-licensing-boards/images/Actions%2520Taken%2520September%252013%252C%25202014%2520%28click%2520here%2520for%2520details%29.pdf.

[48] Fishman SM *Responsible Opioid Prescribing, a Clinician's Guide* (2012), Waterford Life Sciences, Wash.DC.

[49] Id. The author states that the recommendations in the book "are grounded in two well-respected and widely adopted guidance documents. The Federation of State Medical Boards (FSMB) 'Model Policy for the Use of Controlled Substances for the Treatment of Pain.' [and] 'Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain,' a joint effort of the American Pain Society (APS) and the American Academy of Pain Medicine (AAPM)."

[50] Id. p. 15-16.

treatment continuation or discontinuance, based on functional goals and safety.

- Explain to patients that opioids used to treat acute pain are for time-limited use. At the outset, set expectations that opioids should be discontinued when the pain problem is no longer acute.
- Avoid dispensing more medication than necessary. A 30-day supply for acute pain may be more than necessary. In treating acute pain with opioids, give only the amount believed to be needed. Be aware that excess medication may serve to stock an uncontrolled medicine cabinet and increase the risks of accidental toxicity or diversion.
- Be sure that patients understand the exit strategy if treatment needs to be discontinued.

PERIODIC REVIEW AND MONITORING

- Never continue long-term opioid therapy with patients who, after reasonable efforts, show inadequate progress toward functional goals.
- Consult with more specialized healthcare providers if a patient's problems exceed your range of expertise. Do not accept unmanageable risk just because the appropriate consultant may not be available.
- Don't abandon patients with aberrant behaviors or a prescription drug problem. Consider all possible causes for the behavior and remain open to employing other potentially safe treatments.
- Question how your patient is using his or her opioids. Some patients may not use the drugs you prescribe as directed. They may vary the dosing or combine them with other dangerous substances, drugs, or alcohol in ways that are not advisable.
- Have clear treatment parameters beyond which continued use requires re-evaluation. For instance, acute pain that continues to require opioid therapy should be fully re-evaluated.
- Exercise compassion and trust – but verify. Recognize that misuse and addiction often coincide with denial and a striking lack of insight. Clinicians, therefore, must use all available tools to discern these problems as early as possible. This includes closely monitoring functional and behavioral status, utilizing urine toxicity screens and prescription drug monitoring systems, and remaining engaged in care before and after any potential adverse outcomes.

In chapter 4, Fishman provides guidance on the importance of documentation, informed consent and patient agreements. Documentation is important because it is impossible for a provider to remember the details of a patient's care in a busy practice and documentation in the record is the only way to recall the treatment plan and changes over time, "including progress toward functional goals, severity of side effects, or subtle changes in patient demeanor or affect. In the event the need arises to refer a patient to another clinician, careful documentation will enable optimal continuity of care."[51] With respect to informed consent, Fishman emphasizes that the patient must understand treatment options and the potential benefits and risks associated with treatment

[51] Id. p. 55.

options, must not be coerced into any option, and must have the capacity to communicate preferences. Finally, Fishman notes that opioid treatment agreements are the standard of care when a patient is prescribed long-term treatment with opioids.[52]

The Centers for Disease Control, in partnership with the National Institute on Drug Abuse, the Substance Abuse and Mental Health Services Administration, and the Office of the National Coordinator for Health Information Technology, reviewed opioid prescribing guidelines for chronic pain to identify common elements.[53] The common elements identified are:

- Conducting a physical exam, pain history, past medical history, and family/social history;
- Conducting urine drug testing, when appropriate;
- Considering all treatment options, weighing benefits and risks of opioid therapy, and using opioids when alternative treatments are ineffective;
- Starting patients on the lowest effective dose;
- Implementing pain treatment agreements;
- Monitoring pain and treatment progress with documentation; using greater vigilance at high doses;
- Using safe and effective methods for discontinuing opioids (e.g., tapering, making appropriate referrals to medication-assisted treatment, substance use specialists, or other services); and
- An additional recommendation element appearing in several guidelines that will become more feasible as states enhance their data systems includes: Using data from Prescription Drug Monitoring Programs (PDMPs) to identify past and present opioid prescriptions at initial assessment and during the monitoring phase.

Finally, the American Academy of Neurology recently issued a position paper on the use of opioids for chronic noncancer pain.[54] The paper is the most recent endorsement of the need for guidelines in light of the public health crisis described and the risks to patients when opioids are used to treat noncancer pain.[55] This paper summarizes what health care providers can do to "safely and effectively" use opioids for chronic noncancer pain:

- [Implement an] opioid treatment agreement;
- Screen for prior or current substance abuse/misuse (alcohol, illicit drugs, heavy tobacco use);
- Screen for depression;

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[52] Id. p. 59.

[53] Common Elements in Guidelines for Prescribing Opioids for Chronic Pain, Centers for Disease Control, available online at http://www.cdc.gov/HomeandRecreationalSafety/overdose/guidelines.html. This document also includes a table summarizing guidelines from eight organizations and jurisdictions.

[54] Opioids for chronic noncancer pain: A position paper of the American Academy of Neurology. GM Franklin (Neurology 2014; 83; 1277-1284), available online at http://neurology.org/content/83/14/1277.full.html.

[55] Id., stating: "Over 100,000 deaths, directly or indirectly, from prescribed opioids in the United States since policies changed in the late 1990s. In the highest-risk group (age 35-54 years), these deaths have exceeded mortality from both firearms and motor vehicle accidents."

- Prudent use of random urine drug screening (diversion and nonprescription drugs);
- Do not use concomitant sedative-hypnotics or benzodiazepines;
- Track pain and function to recognize tolerance and track effectiveness;
- Track daily MED [Morphine Equivalent Dose] using an online dosing calculator;
- Seek help if MED reaches 80-120 mg and pain and function have not substantially improved; and
- Use the state Prescription Drug Monitoring Program to monitor all sources of controlled substances.

APPLICATION OF THE GUIDELINES TO WORKERS' COMPENSATION TREATMENT WITH OPIOIDS AND THE RULE DEVELOPMENT PROCESS

As noted above, the workers' compensation law requires the commissioner to adopt rules that reflect accepted medical standards governing "the long-term use of opioids or other scheduled medications to alleviate intractable pain and improve function, including the use of written contracts between the injured worker and the health care provider who prescribes the medication."[56] The rules proposed in response to this mandate incorporate the accepted medical standards described above for long-term treatment with opioid analgesic medication.

Opioids are frequently prescribed for treatment of workers' compensation injuries. In a study by the Workers' Compensation Research Institute, 43% of nonsurgical workers' compensation claimants with more than seven days of lost time in Minnesota received narcotic pain medication.[57] Of claims with opioids prescribed, 6% were identified as longer-term users.[58] As a result, the same concerns related to use of opioids to treat pain in general health care apply to treatment of workers' compensation injuries. Recent decisions issued by the Workers' Compensation Court of Appeals reflect the serious consequences, including inadequate pain control and even death, resulting from treatment of injured workers with opioids.[59]

The MSRB began studying the issue of long-term opiate use in 2006. The MSRB has considered a wide range of materials, including medical board policies and disciplinary actions; medical society and health care organization guidelines; guidelines from other workers' compensation and governmental jurisdictions; and other reviews of medical literature. Salient features of existing guidelines were extracted to a spreadsheet for comparison.[60]

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[56] Minn. Stat. § 176.83, subd. 5 (a) (7) (2014).

[57] In the report, Table 2.1 shows that 55% of nonsurgical claims with more than seven days of lost time received pain medication; Figure 3.1 shows that 78% of these claims received an opiate pain medication. The underlying data included prescriptions filled by injured workers with injuries from October 1, 2009 through September 30, 2010, and prescriptions filled through March 31, 2012. Wang D Longer-Term Use of Opioids, 2nd Edition, Workers' Compensation Research Institute (May 2014).

[58] Id. Table 3.2. Longer-term users of opioids were identified as injured workers who had them within the first three months after the injury and three or more visits to fill opioid prescriptions between the seventh and twelfth month after the injury.

[59] See footnotes 19 and 20.

[60] Available on the Department's Web site at: http://www.dli.mn.gov/PDF/docket/5221_6020_8900TrtmPar_2.pdf.

The MSRB made its recommendation after considering these materials, comments from interested parties in the community, and their own experience with treatment of work-related injuries.[61] Over the past several years, the MSRB deliberated numerous versions of the proposed rules, which were made available for comment to health care providers, insurers, members of the bar, and other interested parties. The MSRB considered all comments and proposed amendments based on those comments consistent with their own estimation of the current standard of care and best medical practices in the state of Minnesota. This process of drafting, consultation with the public and revision was continued until the Department, based on the MSRB recommendations and cited materials, concluded that the current proposed rules represent the accepted standard of care for patients receiving long-term opiate analgesia.

The proposed rules governing long-term use of opioids in the treatment of injured workers are primarily geared toward health care providers because, as reflected in the guidelines described above, it is the provider's responsibility to assess the injured worker to ensure that treatment with opioids is safe and appropriate; obtain informed consent; effectively control pain and improve function; monitor the treatment to safeguard ongoing effectiveness and minimize risk to the patient and possible misuse, overdose or diversion; and document the safety, effectiveness and use in the medical record. The accepted standard for long-term treatment with opioids requires considerable expertise and commitment on the part of the health care provider to meet this responsibility, whether the treatment is for a work injury or not. While the proposed rules are detailed, so are the accepted standards of care, and it is not anticipated that a provider who is already compliant will need to change his or her practice to be compliant in the workers' compensation context. A health care provider who diligently treats an injured worker according to these accepted standards will improve the quality of the injured workers' life by improving function, reducing pain and minimizing risk.

RULE-BY-RULE ANALYSIS

5221.6040 DEFINITIONS.

Subp. 8a. Intractable pain. "Intractable pain" is as defined in Minn. Stat. § 152.125.

This amendment adds a new definition, for "intractable pain," which is the basis for the prescription of long-term use of opioids in the proposed Minn. R. 5221.6110, subp. 1 and Minn. Stat. § 176.83, subd. 5 (a) (7). The definition cross-references the definition of intractable pain in Minn. Stat. § 152.125 (Minn. Stat. ch. 152 governs controlled substances).[62] This statute further

[61] The MSRB minutes reflect its consideration of comments and corresponding recommendations. The minutes are linked on the docket page for these proposed rules at http://www.dli.mn.gov/PDF/docket/5221_6020_8900TrtmPar_2.pdf .

[62] Minn. Stat. § 152.125 states: "For purposes of this section, 'intractable pain' means a pain state in which the cause of the pain cannot be removed or otherwise treated with the consent of the patient and in which, in the generally accepted course of medical practice, no relief or cure of the cause of the pain is possible, or none has been found after reasonable efforts. Reasonable efforts for relieving or curing the cause of the pain may be determined on the basis of, but are not limited to, the following:
(1) when treating a nonterminally ill patient for intractable pain, evaluation by the attending physician and one or more physicians specializing in pain medicine or the treatment of the area, system, or organ of the body perceived as the source of the pain; or
(2) when treating a terminally ill patient, evaluation by the attending physician who does so in accordance with the level of care, skill, and treatment that would be recognized by a reasonably prudent physician under similar conditions and circumstances.

provides that a physician is not subject to disciplinary action by the Board of Medical Practice for appropriately prescribing or administering a controlled substance in the course of treatment of an individual for intractable pain, provided that the physician keeps accurate records of the purpose, use, prescription, and disposal of controlled substances, writes accurate prescriptions, and prescribes medications in conformance with Minn. Stat. chapter 147 (which governs the Board of Medical Practice). The statute also requires the physician to discuss the risks associated with the controlled substances and document the discussion in the individual's medical record. The principles set out in Minn. Stat. § 152.125 are reflected in the proposed rules and the requirements of the Board of Medical Practice, as described on pages 17-25.

Subp. ~~8a~~ 8b. Medical contraindication. This subpart defines "medical contraindication" as a condition that makes the use of a particular treatment or medication inadvisable because of an increased risk of harm to the patient. This amendment does not add a new definition, but simply renumbers subpart 8a to 8b because of the new definition for "intractable pain."

Subp. 10a. Modality. This is a new definition for the term "modality," which is defined as "The application or use of a therapeutic agent or regiment. 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."

This definition of "modality" is necessary because it is used in the proposed Minn. R. 5221.6110, subp. 6, items E and F, to describe the types of treatment to be used in conjunction with long-term use of opioids or for episodic pain under a plan for long-term use of opioids.

The definition is derived from a compilation of the entries in Dorland's Medical Dictionary for Health Consumers (Saunders, 2007); The American Heritage Medical Dictionary Copyright (Houghton Mifflin Company, 2007); Gale Encyclopedia of Medicine (The Gale Group, 2008); Mosby's Medical Dictionary, 8th edition (Elsevier, 2009); Segen's Medical Dictionary (Farlex, 2012); Miller-Keane Encyclopedia and Dictionary of Medicine, Nursing, and Allied Health, Seventh Edition (Saunders, 2003); Jonas: Mosby's Dictionary of Complementary and Alternative Medicine (Elsevier, 2005); Farlex Partner Medical Dictionary (Farlex, 2012); and, Medical Dictionary for the Health Professions and Nursing (Farlex, 2012). All of these sources are available on the internet.

Subp. 10b. Morphine-equivalent milligrams. This subpart provides that, for purposes of part 5221.6110, subpart 8, morphine-equivalent milligrams are 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.

This subpart provides morphine equivalencies to other types of narcotics, all of which would be covered by the proposed rules. This is necessary to establish a uniform dosage standard for determining when a closer monitoring is needed in the referenced rule.[63]

Subp. 11a. Pain medicine specialist. This subpart adds a definition of "pain medicine specialist" as "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."

A definition of "pain medicine specialist" is needed because referral to one is required or permitted in several parts of Minn. R. 5221.6110. The MSRB recommended that pain medicine specialists have expertise in the assessment and treatment of complex pain problems. The rule provides two options for documenting expertise. The provider must have a history of treating multiple (more than one) patients with complex pain problems for at least five years or must have completed fellowship training in pain management. Five years' experience is reasonable to ensure significant experience with a variety of patients with intractable pain. Fellowship training is post-graduate medical training in an accredited program.

5221.6105 MEDICATIONS

Subp. 3. Opioid analgesics. This existing rule governs the types of opioids that can be prescribed to treat work injuries. The proposed amendment is to subitem 3, which provides:

> 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.
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> . . . .
>
> 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).

[63] The equivalencies are derived from a compilation of equivalency tables in the medical literature. Cynthia G. Tudor "Supplemental Guidance Related to Improving Drug Utilization review Controls in Part D," Center for Medicare and Medicaid Services, Department of Health & Human Services, September 6, 2012; "Equianalgesic Chart-Opioid Analgesics" Family Medicine, University of Iowa, "Oral Opioid Dosing Equivalents and Conversions" University of Michigan Health Services, May 2009; "Opioid Dosing. Clinical Guidelines for Safe and Cost-Effective Prescribing" San Francisco Health Plan, 2011; "Equianalgesic Dosing of Opioids for Pain Management" Pharmacists' Letter, August 2012; "Dosing and Conversion Hart for Opioid Analgesics" American College of Physicians and Surgeons; "Opioid Analgesic Comparison Chart" Medical University of South Carolina, nd; Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain. Part B: National Opioid Use Guideline Group, April 2010.

. . . .

(3) Continued prescription of oral opioid analgesics ~~prescribed~~ for more than 12 weeks ~~after the injury~~ may be for more than one month of medication ~~per prescription if there has been a clinical evaluation to confirm the need for an efficacy of the prescription and a clinical evaluation at least every six months thereafter during continued use of opiate analgesics~~ and must comply with all of the requirements of part 5221.6110.

This subpart was initially adopted in 2010. The proposed amendments to subitem (3) are needed to cross-reference and ensure consistency with the proposed rules governing long-term treatment with opioid analgesic medications in Minn. R. 5221.6110.

5221.6110 LONG-TERM TREATMENT WITH OPIOID ANALGESIC MEDICATION

Subp. 1. Application.
Subpart 1 provides that the rules governing long-term treatment with opioid analgesic medication applies to the use of 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 subpart, "long-term prescription of 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.

These rules apply to opiate preparations that are used in long-term treatment of outpatients with intractable pain. In addition to oral opioids, the rules also apply to opioids delivered transmucosally (entering through a mucous membrane), buccally (dissolving in the mouth by placement next to the cheek), and transdermally (using a skin patch). The rules do not apply to parenteral (intravenous) and intrathecal (into the spinal column) preparations, which would be used in in-patient and hospice settings because these must be administered by licensed health care providers. The proposed rules are intended to govern only patients who are administering opioid analgesic medications to themselves.

The rule governs patients who are or will be taking opioids daily for at least 90 days. The MSRB determined that the rules should govern daily opioid use that lasts longer than three months because at that point it is likely to continue indefinitely.

These medications may be started with the intention of long-term use to address pain in a patient who has intractable pain despite other treatments. Alternatively, some patients are started on opiates initially as a temporary intervention for an acute injury or after a procedure but are still requiring opiate analgesia three months later. In either case, once a patient has been prescribed

daily opioid use for more than three months, the risks of serious complications, addiction and misuse increase and require more intensive and structured management.

Subpart 2. Indications and documentation. This subpart provides that 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.

Documentation of all treatment is the standard of care as shown in the documents referenced on pages 17- 26 and in the source documents listed in Appendix A. The Board of Medical Practice also requires thorough documentation of treatment with opiate medication. Because the risks of this treatment are significant, documentation assists the provider track the elements specified in the rule. A provider would not be able to recall all the specific details of the assessments, potential contraindications, the elements of the treatment program, and the results of treatment without being able to refer back to the written documentation. A contract detailing the agreement between the provider and patient must also be in the medical record so the provider can readily determine the patient and provider's agreed-upon obligations throughout the treatment. Requiring documentation also allows all interested parties to ascertain whether the treatment meets the requirements of the rule.

Subpart 3. Pain and function assessment tools. This subpart provides that when a health care provider initiates a plan to treat intractable pain by prescribing opioid analgesic medication on a long-term basis, or when a health care provider continues prescribing opioid analgesic medication for a patient who has been taking opioid analgesic medication daily for three months, the provider must assess the patient's level of pain and function using the tools specified in this subpart. The assessments must also be performed when a patient has been receiving long-term treatment with opioid analgesic medication before the effective date of the rules, as provided in subpart 10.

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

Since treatment with long-term opiates is only appropriate if it relieves a patient's pain and improves their function and quality of life, there must be some means for the prescribing health care provider to determine if the medication and dosage prescribed is effective. However, there are no laboratory tests or imaging studies that quantify the intensity of a patient's pain or the extent to which that pain interferes with the patient's function and quality of life. Instead, a number of paper-and-pencil questionnaires (referred to in the medical literature as "tools") have been developed, tested and validated by medical researchers that quantify the patient's perception of pain and its impact on their function. There is no clear evidence that any one of these tools is superior to the others; therefore, the treating physician is allowed to choose the ones that they are most familiar with or that best suit the particular patient being evaluated. The same tools are

required to be used in follow-up so that reliably comparable longitudinal data is available to assess the efficacy of on-going treatment with opiates. The examples are commonly used for these purposes and are drawn from existing guidelines, the medical literature and recommendations from members of the MSRB.

Subpart 4. Patient selection criteria. This subpart provides that patients may be considered for long-term treatment with opioid analgesic medication if the prescribing health care provider determines 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 urine drug test confirms that the patient is not using any illegal substances.

There is a significant risk of serious complications with the long-term use of opiate medications, as well as important concerns with the promotion of addiction and the possibility of diversion of medication for illegal uses. Therefore it is reasonable and necessary that the medication is only prescribed to patients who can benefit from it, will not be harmed by it, and cannot be treated by some alternative therapy.

Item A. Long-term use of opiates is a palliative treatment; i.e. it focuses on providing of the pain of a chronic condition and improving the patient's quality of life but does not improve or resolve the underlying medical problem, and so it is only indicated for patients whose pain interferes with their function and quality of life and who have reduced pain and improved function while taking them.

Item B. Unfortunately, pain due to Somatic Symptom Disorder as defined by the DSM-5 (pain of psychiatric origin) is not relieved by opiates and use of these medications in these patients would expose them to all of the risks of long-term opiate use without any potential benefit.

Item C. Palliative treatment is only appropriate if all reasonable curative treatment has been attempted. Because the pain has not resolved, a measure of patient protection is provided by requiring that a specialist in pain medicine or a provider specializing in the treatment of the underlying source of the pain should determine that all other reasonable treatment options have been exhausted.

Item D. Patients taking long-term opiates must be compliant with use of prescription medications because the benefit and safety of these medications is only realized when they are used as prescribed. Moreover, compliance with the prescribed dosage and regimen reduces the risk of side effects and the chance of developing an addiction. Therefore, patients who have a history of noncompliance with prescribed medical treatment or medication are not candidates for successful long-term treatment with opioids.

Item E. Patients with a current Substance Use Disorder as defined in the DSM-5 (those with an active addiction disorder) cannot safely take opiates; they are at high risk of abusing the medication, exacerbating their existing addiction problems and overdose or serious side effects.

Item F. Patients who use illegal substances are at extreme risk of misusing opiates, developing an addiction problem (if they do not already have one), or of diverting their medication for illegal purposes. Therefore, before initiating long-term treatment with opioids a urine drug test must confirm that the patient is not using illegal substances.

Subpart 5. Potential contraindications.

Item A provides that before beginning long-term prescription of opioid analgesic medication, the prescribing health care provider must assess whether the specified circumstances are present and, if present, whether they constitute contraindications to the ongoing prescription of opioid analgesic medication. The specified circumstances are not an absolute bar to long-term treatment with opioids, but the health care provider must consider them before making the decision to initiate the treatment. The potential contraindications are:

(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.

Identification of potential contraindications is necessary to protect the safety of the patient. There are a variety of serious side effects that can occur with long-term opiate use. It is important for the prescribing health care provider to determine if the patient has any medical or psychiatric conditions that could increase their individual risk of side effects and whether the increase in risk is great enough to be a contraindication to the use of opiates by that patient. The listed conditions could create significant risks for a patient taking opiates long-term. Opiates can decrease

respirations; they can interfere with the normal course of pregnancy and the fetus can become physically dependent; a patient with a history of substance use disorder is at increased risk of relapse; opiates can be used to commit suicide; a patient with poor impulse control or other psychiatric disorders may have difficulty complying with all of the exacting requirements of the treatment program; and patients who engage in activities that could be unsafe for a person taking opioids, such as flying commercial airlines or commercial bus drivers, could also endanger the safety of others.

Item B provides that the prescribing health care provider may obtain an appropriate specialty consultation to assist in evaluating the contraindications or to determine if long-term treatment with opioid analgesic medication is appropriate. The listed circumstances are only potential, not absolute, contraindications that require the provider to weigh the risks against the benefits of long-term treatment with opiates on a case-by-case basis. Providers are expressly allowed to obtain a consultation because these are difficult decisions, sometimes requiring expertise beyond the prescribing provider's area of practice, and the consequences are potentially significant.

Subpart 6. Opioid risk assessment; program of treatment.

Item A. Long-term prescription of opioid analgesic medication must be part of an integrated program of treatment that includes all of the elements in items B to M, which must be documented in the medical record. This subpart describes the elements of a safe, effective and coordinated plan for long-term opioid treatment. Documentation of treatment is the standard of care and noted in the standards described on pages 17-25 and is necessary so the health care provider can track the patient's progress and document the basis for initiating treatment, the patient's level of pain and function in response to the treatment and any contraindications or adverse side effects that may develop.

Item B. This item requires the prescribing health care provider to complete an opioid risk assessment using a tool validated in the peer-reviewed scientific literature. Examples of peer-reviewed assessment tools are given: 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.

Subitem (1) provides that 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.

Subitem (2) provides that, 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 screening 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 monthly for the first six months of treatment and every three months thereafter.

An on-going concern in patients who are using long-term opiates is the possibility of misuse of medication for recreational purposes and/or the development of addiction. A number of screening tools have been developed, tested and validated in the medical literature to help identify patients who may be at higher risk of misusing opiates or developing an addiction to their medication. As there is no clear evidence that any one of these tools is superior, the treating provider is allowed to choose the tool that they are most familiar with or that suits the needs of a particular patient. The examples are tools that are commonly used for these purposes and are drawn from existing guidelines, the medical literature and recommendations from members of the MSRB.

If the selected tool indicates that a patient is at higher risk of dependency or abuse, then special care should be exercised in determining whether opiates are an appropriate treatment and a second opinion is therefore required. If after consultation, a high risk patient is started on long-term opiates, then increased vigilance in follow-up is required so as to maximize the chances of detecting any developing problem as soon as possible and thereby mitigating the extent of any adverse consequences to the patient. Urine drug testing, review of the patient's prescription history at every visit and more frequent follow-up visits provide a framework for this increased vigilance.

Item C. This item requires the patient and the prescribing health care provider to sign a formal written treatment contract that meets the requirements of subpart 7.

Written treatment contracts are used to increase patient compliance (and therefore the safety and effectiveness of treatment with opioids) and minimize the chance of misuse and diversion of opiate medications. They serve to clearly establish in a durable format available to all interested parties the plan of treatment, the schedule of medications, the required follow-up, the provider responsibilities, and the patient responsibilities. Use of a written contract allows for truly informed consent by the patient for the entire process of the treatment and serves as a disclosure of future actions and decisions by the provider. Written treatment contracts are expressly provided for in Minn. Stat. § 176.83, subd. 5 (b) (7) and are consistently recommended in the standards referenced on pages 17-25, including by the Board of Medical Practice and the MSRB.

Item D. This item provides that 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.

Relief of pain and improvement of function is maximized in patients with intractable pain when opiates are used on a fixed schedule because regular, fixed dosing provides a consistent blood level of the medication. The patient needs to be compliant with the prescribed regimen and the treating provider has an obligation to ensure that the patient has adequate medication to comply and will not run out of medication before their next prescription, which could result in inadequate pain control and the patient visiting an urgent care facility or emergency department for pain.

Item E. This item permits the use of other treatment modalities in conjunction with long-term treatment with opioid analgesic medication, to the extent indicated by parts 5221.6010 to 5221.6600.

Long-term treatment with opioids is not meant to preclude the use of other palliative interventions that can help assist in pain relief and maintenance of function. The use of other modalities is subject to the other workers' compensation treatment parameters. For example, physical medicine treatment for low back pain is permitted as provided in Minn. R. parts 5221.6200, subpart 2. Treatment with physical medicine modalities may be extended beyond what is indicted in Minn. R. 5221.6200, subp. 2 if there is a basis for departure under part 5221.6050, subp. 8 (see footnote 28).

Item F. This item requires the prescribing health care provider to provide 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.

While patients with intractable pain may always have some baseline pain, which is the target of their fixed schedule of medication, they do sometimes have significant and unpredictable exacerbation of their pain. The treating provider is required to develop a plan with the patient to address these episodic increases in pain, including prescription of any medications allowed for exacerbations. This plan eliminates the need for patients to modify their use of long-term opiate and run out of medication before their next scheduled prescription. This is a key element of the contract with the patient.

Item G. Under this item, all prescriptions for long-term opiate treatment 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.

This again is the standard of care in Minnesota. Abuse, diversion, and accidental overdose are significant problems that can occur among patients receiving long-term opiate therapy. Requiring that a single provider write all opiate prescriptions helps minimize the risk of these problems. It reduces the likelihood that two providers fail to coordinate their prescribing and the patient suffers an accidental overdose or other complication. It also helps prevent patients from receiving more medication than they need, which is then used for recreational or illegal purposes. The rule recognizes that there are certain limited situations in which opiates are legitimately prescribed by more than one provider and allows for these exceptions but requires that patient to inform the prescribing health care provider so that adjustments in treatment can be made if needed. The rule also recognizes that the prescribing health care provider may not always be available and so requires that the provider designate a proxy to handle prescribing if needed.

Item H. This item requires the prescribing health care provider to discuss with the patient the risks associated with the long-term prescription of opioid analgesic medication, the specific medications to be used, and possible side effects.

Long-term use of opiate medications exposes the patient to a number of serious side effects, complications and risks – including addiction and death due to overdose. It is incumbent upon the provider to have fully reviewed and discussed these issues, so that the patient can give a truly informed consent to the treatment plan. This is also required by Minn. Stat. § 152.125 and the Board of Medical Practice and is reflected in the standards referenced on pages 17-25.

Item 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.

This requires that the prescribing health care provider coordinate other treatments being prescribed for the management of the patient's intractable pain so as to maximize the benefit received from the entire program of treatment, to minimize complications that can occur when multiple medications are prescribed by different providers and also to help reduce the amount of opiate medication needed.

Item 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.

This item reflects the standard of care for any prescription written, not just opioids. This ensures that prescriptions are refilled consistent with the schedule established in the treatment plan. It also helps the provider assess the effectiveness of the treatment program and detect possible misuse. It also ensures communication between other providers in the clinic who may see the patient.

Item K. This requires the prescribing health care provider to establish a schedule of follow-up visits for monitoring the treatment.

Treatment with these medications should only be continued so long as they are effective in reducing pain and increasing function. Additionally, long-term treatment with opioids exposes the patient to a persistent risk of misuse, diversion, and accidental overdose, as well as a number of significant side effects and even complications. Regular follow-up is required to determine if the medication continues to be effective and to detect any adverse consequences of treatment. Subpart 8, item A, establishes the minimum schedule of visits; the prescribing health care provider may require additional visits that in the provider judgment are necessary to ensure safe and effective treatment.

Item L. The prescribing health care provider must provide written reports of work ability or restrictions as required by part 5221.0410, subpart 6.[64]

While overall pain and function must improve for long-term treatment with opioids to be considered successful under subpart 8, item B, there is a risk that opiates can impair performance of some specific activities (for example, driving motor vehicles and operating machinery). This item requires that the prescribing health care provider assess the impact of the medication prescribed on the patient's ability to work safely and restrict work activities if necessary. The patient's work ability or restrictions related to the opioid medication must be included in the report of work ability that health care providers must complete for all injured workers at regular intervals by Minn. R. 5221.0410, subp. 6.

Item M. This item provides that if treatment with long-term opiates is discontinued, the prescribing health care provider must prescribe an appropriate schedule of tapering doses 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.

Long-term use of opiates creates a physical dependence on the medication. In patients with a physical dependence, abruptly stopping opiates will cause symptoms of withdrawal, including anxiety, irritability, craving, muscle aches, vomiting, abdominal cramping, diarrhea, confusion, tremors, and anorexia. Symptoms of withdrawal are avoided by a schedule of tapering doses of opiates based on the physician's judgment, taking into account the type of medication, dose, and duration of use of the medication prescribed. The rule recognizes that stopping opiates may cause an increase in the patient's pain and requires the prescribing health care provider to offer alternative pain management therapies.

Subpart 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 a 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 done according to a tapering schedule as described in subpart 6, item A. The contract must include the elements listed in items A to J.

Item A. This item requires the contract to include the goals of treatment with long-term prescription of 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.

[64] https://www.revisor.mn.gov/rules/?id=5221.0410

Given the risk of misuse, diversion, and accidental overdose attendant on the use of long-term opiates, a number of procedures and protocols are used to minimize these risks.[65] The success of these procedures requires compliance and commitment by both the patient and the prescribing health care provider. A written treatment contract allows for explicit identification of the obligations of both the patient and the prescribing provider, a description of the program of treatment, and a tool for obtaining informed consent for the treatment. Written contracts are consistently recommended in the standards described on pages 17-25, by the MSRB and in the statutory authority for the rule (Minn. Stat. §176.83, subd. 5 (b) (7). The information in the items listed in subpart 6 is information that the patient needs to know to provide informed consent for the treatment.

Item B requires the contract to include the patient's agreement to comply with treatment prescribed in addition to the opioid analgesic medication.

A variety of therapies and modalities can be used in conjunction with opioids to help manage the patient's intractable pain and reduce the amount of opiate medication required. Unless the patient complies with these recommendations, the prescribed dose of opiates may be ineffective and this could result in unnecessary and potentially harmful dose escalation.

Item C requires the contract to include the patient's agreement 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.

Misuse or diversion of opiate medication is often accompanied by requests for additional prescriptions. In these situations, patients present a number of reasons for needing an unscheduled refill. One of the most common excuses is that medications have been lost or stolen. In order to minimize this risk, the rule requires that the written contract disclose that only one exception can be made and only if the prescribing health care provider agrees that the patient's explanation warrants an unscheduled refill. Some experts argue that no refills should be allowed under any circumstance for lost or stolen prescriptions. However, such a rigid prohibition limits a provider's discretion and cannot foresee every possible situation. Therefore, this rule gives the provider discretion whether or not to allow a single refill but the patient is put on notice by the contract that they must exercise diligence in protecting their medication, and that repeated assertions that the medication was lost or stolen will not be accepted.

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

Another possible indicator of misuse or diversion of opiate medication is requests that medications be refilled earlier than planned. Patients with intractable pain are prescribed opiates on a fixed

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[65] In a study of emergency room visits for opioid overdoses, nearly 68% involved prescription opioids. JAMA for the Media; October 27, 2014;
http://media.jamanetwork.com/news-item/prescription-opioids-involved-in-most-overdoses-seen-in-emergency-departments/

schedule. The patient is required to be compliant with the prescribed regimen and the treating provider is required to prescribe adequate medication so that the patient will not run out before their next prescription. As previously noted, the treating health provider is also required to provide the patient the means to deal with episodic increases in pain and be available for consultation. Therefore, except in cases of misuse or diversion there should be no unanticipated need for early refills.

Item E. This item requires the patient to agree 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.

Patients are required to notify other providers of the treatment contract before receiving prescription medication from other providers in order to minimize the possibility of overdose or side effects from the interaction of different medications, and reduce the potential for misuse or diversion of medication. This eliminates the possibility that two providers fail to coordinate their prescribing and the patient suffers an accidental overdose or other complication. It also helps prevent patients from receiving more medication than they need.

Item F requires the prescribing health care provider to agree that arrangements will be made ahead of time to renew prescriptions when the prescribing health care provider is on vacation or otherwise unavailable.

If patients can only receive medications on a fixed schedule of refills, the prescribing health care provider must agree to make arrangements to ensure that prescriptions are refilled when scheduled. Otherwise the patient would be left with insufficient treatment to treat their pain or forced to violate the treatment contract to obtain their regularly scheduled prescription.

Item G requires the prescribing health care provider to agree to be available or provide coverage for episodic pain not responsive to planned interventions.

The rules recognize that patients with intractable pain do sometimes have significant and unpredictable exacerbation of their pain and the prescribing provider is therefore required to develop a plan to deal with these situations, including prescription of any medications recommended for exacerbations. However, the plan may not be adequate for all situations that occur. In these instances the provider must be available or provide on-call coverage with another provider to consult with the patient. Otherwise the patient would be left with insufficient treatment or might be try to obtain relief by taking more medication than prescribed or seeking emergency treatment with another provider.

Item H requires the contract to include a statement that, except when discontinuance is required by 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.

In order to provide fair warning, this statement informs the patient that violations of the treatment contract may result in the provider terminating the prescription of opioids. The statement also notifies the patient that the health care provider will terminate treatment in a way to minimize withdrawal symptoms, and that the prescribing health care will offer alternative pain management therapies or a referral to another provider who can treat the patient's pain. This statement is included as part of ensuring the patient gives informed consent to the possible outcomes of the treatment.

Item I. This item requires the patient to agree 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;
(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.

These requirements serve as a record of informed consent by the patient of his or her specific obligations under the written contract to ensure that opiates are used appropriately, safely and responsibly. They also ensure that the patient complies with other treatment and evaluations by other health care providers. Together these agreements help to ensure that the patient receives the most effective and safe treatment for the injury.

Item J requires the contract to include the dated signatures of the patient and prescribing health care provider. Additionally, the commissioner is required to 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 is deemed to meet the requirements of subpart 7 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.

Dated signatures are used to confirm that the patient was fully informed of the risks and benefits of the treatment, of the procedures and protocols that will be used in implementing the treatment, and their obligations under the treatment contract, as well as the consequences of violating the contract. Because the contract may change, the date shows what version of the contract is in effect. The contract must be included in the medical record so that it is available to the provider and the parties to the workers' compensation claim. The prescribing provider is allowed to require a new contract at their discretion so as to address any changes in the provider's practice, the patient's condition, or the treatment plan. The Department has developed a model contract for use by providers that meets

all of the requirements of this part.[66] This eliminates the need for providers to develop their own forms and avoids the risk of inadvertent violation of the rule for technical deficiencies in the forms that might be used or inconsistent interpretation of rules by payers.

Subpart 8. Monitoring long-term treatment with opioid analgesic medications. This subpart requires that long-term treatment with opioid analgesic medications must be monitored by the prescribing health care provider who is party to the treatment contract. Monitoring must be documented in the medical record and must include the requirements in items A to G.

Item A requires regularly scheduled follow-up visits with the patient; 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;

Regular follow-up is needed to adequately monitor the patient's response to treatment and screen for the development of side effects, symptoms of addiction, and signs of misuse or diversion. Follow-up is needed more often when the treatment is being initiated and the dose is being adjusted for maximum efficacy. Frequency of follow-up can be reduced once a satisfactory regimen of medication has been established but should always be more frequent for patients taking high daily doses of opiates and in those at higher risk of addiction, misuse, and diversion. The higher the daily dose, the higher the patient's risk of side effect and of addiction, regardless of the patient's inherent risk as established by the screening tools required in subpart 6, item B.

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

Long-term treatment with opioids is indicated to relieve pain and improve function, as discussed in the standards discussed on pages 17-25. If it does not relieve pain and improve function within six months, continued prescription of opiates is not reasonable. This item does not prohibit the provider from adjusting the dosage as needed to establish pain relief and improve function. Therefore, six months is given to adjust the dosage and determine whether there has been improvement in pain and function. The rules require the use of tools to assess pain and function at the initiation of treatment. Repeat testing with the same tools allows the treating provider to quantify whether the treatment is effective in meeting its goals. Treatment that is initially effective but later fails to maintain pain control and improved function is likewise no longer reasonable.

[66] The model contract can be viewed online at http://www.dli.mn.gov/PDF/docket/5221_6020_8900TrtmPar_2.pdf.

Item C requires the provider to assess at each follow-up visit the possible side effects of treatment, misuse of medications, aberrant behaviors indicative of addiction, or contraindications to continuing treatment.

Patients receiving long-term opiate therapy are at risk for abuse of medication, diversion of medication, and accidental overdose. In addition, these medications are associated with a number of significant side effects. The rules require that the prescribing provider assess the likelihood of these problems at each visit. It is the standard of care recommended by the documents described on pages 17-25 and the MSRB.

Item D requires the provider to assess at each follow-up visit the patient's adherence to the entire program of treatment.

The prescribing provider is required to assess compliance with the other therapies and modalities used in conjunction with opiates to help manage the patient's intractable pain. Compliance with the program of treatment is important in maximizing the effectiveness of the opiates prescribed and minimizing the dose of opiates needed and the risk of side effects and contraindications. Patients who are not compliant may be at increased risk of misuse or diversion of medications and inadequate pain control and maintenance of function.

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

The rules require that the patient receive opiates only from the prescribing provider, except as provided in the contract with the patient. Minnesota has also implemented a Prescription Monitoring Program, which requires dispensers (such as pharmacies) of controlled substances, including opioids, to submit to the Board of Pharmacy information about the patient, the type of prescription, the quantity, the date filled, the number of days supplied, and the name of the prescriber. Health care providers who prescribe or are considering prescribing a controlled substance have electronic access to the data.[67] This item requires the prescribing provider to review the database to confirm that the patient is compliant and requires the provider to discontinue opiates if the patient has not been compliant. Patients who take more than 120 morphine-equivalent milligrams per day are at higher risk of misuse or diversion and so a higher level of scrutiny and review of the prescription history through the Prescription Monitoring Program database is required. This is the purpose of the Prescription Monitoring Program, and is the standard of care for long-term treatment with opioids as described in the standards on pages 17-25 and recommended by the MSRB.

[67] Minn. Stat. § 152.126; https://www.revisor.mn.gov/statutes/?id=152.126.

Item F requires urine drug testing at the discretion of the prescribing health care provider, except for patients taking more than 120 morphine-equivalent milligrams per day and patients at high risk for dependence or abuse under subpart 6, item B, who must have urine drug testing at least twice per year.

Subitem (1) provides that 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 illegal substances 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 an appropriate schedule of tapering dosages as described in subpart 6, item M;

The frequency of urine drug testing is at the provider's discretion, unless the patient is taking more than 120 morphine-equivalent milligrams per day or is at high risk for dependence or abuse, in which case the testing must be more frequent because a higher level of scrutiny is necessary. The testing protocol (how the urine drug testing is performed, such as the type of tests, the sequence of tests and the timing of tests) is also at the discretion of the provider. The rules require that the patient agree to take only the medications prescribed to them and abstain from any use of illegal drugs. Urine drug testing is allowed in order to confirm that the patient is compliant with the treatment contract. The rule requires that opiates be discontinued if urine drug testing shows that the patient has not been compliant with the treatment contract. Patients who take more than 120 morphine-equivalent milligrams per day are at higher risk of misuse or overdose and so a higher level of scrutiny is required. Patients who are at high risk for dependence or abuse also require increased scrutiny.

Subitem (2) provides that 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.

There is considerable variation in the cost of urine drug testing, without a corresponding difference in quality. The rule allows the payer to choose the laboratory, thereby controlling costs, so long as it is appropriately accredited. Patients currently do not typically chose the laboratory that will perform testing, and providers have no reason to be concerned about quality so long as the lab is accredited.

Item G requires that the provider refer the patient to a pain medicine specialist for consultation if:

(a) there is a sudden or progressive increase in the dosage of opioid analgesic required;
(b) the goals of the treatment program are not met; or
(c) the patient requires more than 120 morphine-equivalent milligrams per day to meet or maintain the program's treatment goals.

These are warning signs that treatment with long-term opiates may not be working. Specialty consultation is required to review the appropriateness, efficacy and safety of the treatment.

Subpart 9. Notice and plan for compliance. This subpart provides that 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 these rules 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.

It is medically inappropriate to suddenly discontinue long-term treatment with opioids. Some patients may receive treatment from providers who treat very few injured workers or who are otherwise uninformed about these rules. In such cases there may be inadvertent violations of these rules that could constitute grounds for denying payment, thereby interrupting the patient's care. This provision gives providers and patients a reasonable time to come into compliance once they have been informed of the rules. Once the provider and patient have been informed of the rules and given time to comply, further noncompliance need not be considered inadvertent.

Subpart 10. Patients currently receiving treatment. For patients who are 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 rule from the insurer to the provider and patient:

A. assess the patient's current level of pain and function using tools validated in the 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.

Some patients will already be receiving long-term opiates when these rules become effective. Some of the provisions of the rule would be irrelevant or impossible to apply in these cases, especially those concerning the initial selection of patients and their initial evaluation. However, the rules regarding the program of treatment, written contracts, follow-up and ongoing evaluation of the efficacy of treatment apply to these cases. Providers and patients are given three months after receiving notice of the rules to comply with items A to D. Three months is a reasonable amount of time for providers and patients to schedule an additional appointment (if needed) to perform the necessary assessments, complete a written contract, and establish a treatment plan and ongoing monitoring consistent with the rules. As some of these providers may treat very few injured workers, the time allowed to comply with the rules begins once the provider and patient have been notified by the insurer. This prevents an unreasonable interruption in care for a technical violation of the rule while ensuring that ongoing treatment is effective and safe according the rules.

Subpart 11. Incorporation by reference. The fifth edition of the Diagnostic and Statistical Manual (DSM-5) is incorporated by reference because it is referred to in the proposed rules. It can be ordered online or from bookstores and online retailers or from the Minitex interlibrary loan system throughout libraries in Minnesota. This ensures that providers, payers and patients have

the ability to review DSM-5 as needed to understand the rules where that document is referenced.

CONCLUSION: Based on the foregoing, the proposed rules are both needed and reasonable.

Dated: March 4, 2015

Ken B. Peterson, Commissioner
Department of Labor and Industry

This Statement of Need and Reasonableness was made available for public review on March 4, 2015

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All of the above documents are available on the Department's rule docket page at http://www.dli.mn.gov/PDF/docket/5221_6020_8900TrtmPar_2.pdf, except for documents numbered 2, 22, 23 and 24, which, for copyright reasons, may be reviewed at the Department.