STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS
FOR THE DEPARTMENT OF LABOR AND INDUSTRY

In the Matter of the Proposed Rules of the Department of Labor and Industry Governing Workers Compensation Treatment Parameters, Minnesota Rules, Chapter 5221.

REPORT OF THE ADMINISTRATIVE LAW JUDGE

A hearing concerning the above rules was held by Administrative Law Judge Richard C. Luis at 10:00 a.m. on March 2, 2010, at the Minnesota Department of Labor & Industry, 443 Lafayette Road North, St. Paul, Minnesota.

That hearing and this Report are part of a rulemaking process that must occur under the Minnesota Administrative Procedure Act[1] before an agency can adopt rules. The legislature has designed that process to ensure that state agencies — here, the Minnesota Department of Labor & Industry (Department or Agency) — have met all the requirements that Minnesota law specifies for adopting rules. Those requirements include assurances that the proposed rules are necessary and reasonable and that any modifications that the Agency may have made after the proposed rules were initially published do not result in their being substantially different from what the Agency originally proposed. The rulemaking process also includes a hearing to allow the Agency and the Administrative Law Judge reviewing the proposed rules to hear public comment about them.

Kathryn R. Berger, Compensation Attorney Principal, Minnesota Department of Labor and Industry, 443 Lafayette Road North, St. Paul, Minnesota 55155 appeared at the rule hearing on behalf of the Department of Labor & Industry. Also present and testifying on behalf of the Department was Dr. William Lohman. Approximately 25 persons attended the hearing; 15 signed the hearing register. Nine persons asked to be notified when the Administrative Law Judge's report is available. The hearing continued until all interested persons, groups or associations had an opportunity to be heard concerning the proposed amendments to these rules.

After the hearing ended, the Administrative Law Judge kept the administrative record open for another twenty calendar days – that is, until March 22, 2010 – to allow interested persons and the Department to submit written comments. Following the initial comment period, Minnesota law[2] required that the hearing record remain open for another five business days to allow interested parties and the Agency to respond to any written comments. The hearing record closed for all purposes on March 29, 2010.

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[1] Minn. Stat. §§ 14.131 through 14.20.
[2] Minn. Stat. § 14.15, subd. 1.

NOTICE

The Agency must make this Report available for review by anyone who wishes to review it for at least five working days before the Agency takes any further action to adopt final rules or to modify or withdraw the proposed rules. If the Agency makes changes in the rules, it must submit the rules, along with the complete hearing record, to the Chief Administrative Law Judge for a review of those changes before it may adopt the rules in final form.

After adopting the final version of the rules, the Department of Labor and Industry must submit them to the Revisor of Statutes for a review of their form. If the Revisor of Statutes approves the form of the rules, she will submit certified copies to the Administrative Law Judge, who will then review them and file them with the Secretary of State. When they are filed with the Secretary of State, the Administrative Law Judge will notify the Board, and the Agency will notify those persons who requested to be informed of their filing.

Based upon all the testimony, exhibits, and written comments, the Administrative Law Judge makes the following:

FINDINGS OF FACT

I. Nature of the Proposed Rules

A. Introduction

1. This rulemaking proceeding involves a proposal by the Minnesota Department of Labor and Industry to amend rule provisions currently set forth in Minnesota Rules Chapter 5221 about the workers' compensation treatment parameters, including new parameters for the use of non-steroidal anti-inflammatory drugs, muscle relaxant drugs, and opioid (narcotic) analgesic drugs; updates to general and medical imaging parameters and ICD-9 codes; functional capacity evaluation; traction; electrical muscle stimulation, acupuncture and manual therapy modalities; and complex regional pain syndrome and cognate conditions.[3]

2. These amendments reflect new technology, changes in terminology, technology and health care provider techniques and practices, and decisions by the workers' compensation court of appeals.[4]

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[3] Hearing Exhibit (Ex.) 6D, Notice of Hearing on Department's Proposed Amendment to Rules Governing Worker's Compensation Treatment Parameters, Minn. R. Parts 5221.6030 to 5221.6305, 34 SR 1015 (Jan 25, 2010).

[4] Ex. 21, Statement of Kathryn Berger (March 3, 3020) (Berger Statement).

B. Summary of Non-Controversial Rules

3. Part 5221.6040 adds the term "medical contraindication" to the definitions section of the rules. This addition is necessary because the term is used in the new part 5221.6105 which governs parameters for appropriate use of medication in the treatments of workers' compensation musculoskeletal conditions.[5]

4. Part 5221.6050, subparts 1 and 9 add cross-references that were inadvertently omitted in the initial rulemaking. Subpart 1 adds references to part 5221.6305, governing reflex sympathetic dystrophy and cognate conditions. Subpart 9 adds previously inadvertently omitted language concerning a required second opinion for certain surgeries.[6]

5. Part 5221.6100 changes wording for the purpose of consistency. References to "spinal surgery to the lumbar spine" and "spinal" surgery will be changed to "surgery to the lumbar spine" and references to progressive neurologic "deficit or changes" and "symptoms or changes" will be changed to progressive neurologic "deficit."[7]

6. Part 5221.6200, subp. 1A adds new ICD-9 codes to the list of codes that reflect the narrative description of low back pain and radicular pain as necessary to reflect updates to the ICD-9.[8]

7. Part 5221.6200, subp. 1I is amended to clarify that it deals with a comprehensive functional capacity evaluation (FCE) that is only intended to be used when it is necessary and appropriate to develop permanent restrictions. Other kinds of FCEs, such as those performed as part of physical therapy or work hardening, are addressed in other parts of the treatment parameters. Because of the limited role of the comprehensive FCE, only one per injury is permitted, although other kinds of FCEs may be performed more frequently.[9]

8. Part 5221.6200, subp. 3 is amended to include additional types of modalities use to provide the passive treatment listed. Item E include updates of modalities that provide electrical muscle stimulation; item F includes a description of mechanical traction and a list of examples of types of mechanical traction; item G deletes acupressure from the definition of acupuncture because acupressure is now considered a part of manual therapy; and item H expands the examples of manual therapy.[10]

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[5] Ex. 4, Statement of Need and Reasonableness, p. 12 (Oct. 13, 2009).
[6] *Id.* at 12-13.
[7] *Id.* at 13.
[8] *Id.* at 32-33.
[9] *Id.* at 33-34.
[10] *Id.* at 34.

9. Part 5221.6200, subp. 8, which deals with durable medical equipment, adds a cross reference to the low back conditions described in subpart 1A because this subpart specifically applies to those conditions.[11]

10. Part 5221.6200, subp. 10 deletes language related to certain medications now governed by the new medication treatment parameters in part 5221.6105, which the subpart cross-references. The amendments also require the provider to document the rationale for use of all medication prescribed as required by Minn. Stat. § 176.135, subd. 7 and Minn. R. 5221.0700, subp. 2.[12]

11. Part 5221.6205, subps. 1A(1), (2) and (4) add new ICD-9 codes to the list of codes that reflect the narrative description of regional pain and radicular pain; and hereditary and degenerative diseases of the central nervous system and unspecified disease of the spinal cord, as necessary to reflect updates to the ICD-9.[13]

12. Part 5221.6205 I governs FCEs for neck pain and is amended so that it is identical to the amendments dealing with low back pain FCEs at part 5221.6200, subp. 1I.[14]

13. Part 5221.6205, subps. 3, E, F, G and H amend passive treatment modalities for neck pain in the same way that they are amended in part 5221.6200, subp. 3 for low back pain.[15]

14. Part 5221.6205, subp. 8 which deals with durable medical equipment, adds a cross reference to the low back conditions described in subpart 1A because this subpart specifically applies to those conditions.[16]

15. Part 5221.6205, subp. 10 deletes language related to certain medications now governed by the new medication treatment parameters in part 5221.6105, which the subpart cross-references. The amendments also require the provider to document the rationale for use of all medication prescribed as required by Minn. Stat. § 176.135, subd. 7 and Minn. R. 5221.0700, subp. 2.[17]

16. Part 5221.6210, subp. 1A(4) adds a new ICD-9 code which reflects the narrative description of thoracic compressive myleopathy: "Hereditary and degenerative diseases of the central nervous system; unspecified disease of the spinal cord," as necessary to reflect updates to the ICD-9.[18]

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[11] *Id.* at 34.
[12] *Id.*
[13] *Id.* at 35.
[14] *Id.*
[15] *Id.*
[16] *Id.*
[17] *Id.* at 35-36.
[18] *Id.* at 36.

17. Part 5221.6210, subp. 1I governs FCEs for thoracic back pain and is amended so that it is identical to the amendments dealing with low back pain FCEs at part 5221.6200, subp. 1I.[19]

18. Part 5221.6210, subps. 3E, F, G and H amend passive treatment modalities for thoracic back pain in the same way that they are amended in part 5221.6200, subp. 3 for low back pain.[20]

19. Part 5221.6210, subp. 8D which deals with durable medical equipment, adds a cross reference to the low back conditions described in subpart 1A because this subpart specifically applies to those conditions.[21]

20. Part 5221.6210, subp. 10 deletes language related to certain medications now governed by the new medication treatment parameters in part 5221.6105, which the subpart cross-references. The amendments also require the provider to document the rationale for use of all medication prescribed as required by Minn. Stat. § 176.135, subd. 7 and Minn. R. 5221.0700, subp. 2.[22]

21. Part 5221.6300, subps. 1A (2) and (5) add new ICD-9 codes to the list of codes that reflect the narrative description of tendonitis of the forearm, wrist and hand; and shoulder impingement syndromes.[23]

22. Part 5221.6300, subp. 1E adds a cross reference to the specific clinical conditions covered by this part, as described in Item A. This language appears in the corresponding items of other parts of the rules but was inadvertently omitted from this item.[24]

23. Part 5221.6300, subp. 1J governs FCEs for upper extremity disorders and is amended so that it is identical to the amendments dealing with low back pain FCEs at part 5221.6200, subp. 1I.[25]

24. Part 5221.6300, subp. 3E, F, G and H amend passive treatment modalities for upper extremity disorders in the same way that they are amended in part 5221.6200, subp. 3 for low back pain.[26]

25. Part 5221.6300, subp. 8D, which deals with durable medical equipment, adds a cross reference to the low back conditions described in subpart 1A because this subpart specifically applies to those conditions.[27]

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[19] *Id.*
[20] *Id.*
[21] *Id.*
[22] *Id.* at 36-37.
[23] *Id.* at 37.
[24] *Id.*
[25] *Id.*
[26] *Id.*
[27] *Id.*

26. Part 5221.6300, subp. 10 deletes language related to certain medications that are now governed by the new medication treatment parameters in part 5221.6105, which the subpart now cross-references. The amendments also require the provider to document the rationale for use of all medication prescribed as required by Minn. Stat. § 176.135, subd. 7 and Minn. R. 5221.0700, subp. 2.[28]

27. Part 5221.6305, subp. 1 amends the clinical categories that are covered by this part, which deals generally with reflex sympathetic dystrophy. The amendments are necessary because clinicians and others use different names to describe the same or similar constellations of symptoms and clinical findings. Terminology must be broadened so that the name of the condition does not preclude application of the appropriate treatment parameter.[29]

28. Part 5221.6305, subp. 2A is amended to refer to injections to a limb, rather than a "site" because "site" could be interpreted to permit multiple injections to the affected arm or leg, which is not the standard of care.[30]

29. Part 5221.6305, subp. 2D is amended to require the same practices and standard of care required for the use of medications in other parts of the treatment parameters and includes a reference to the medication treatment parameters at part 5221.6105.[31]

C. Medication Treatment Parameters: Development Process

30. Part 5221.6105 is completely new language providing, for the first time, parameters for the appropriate use of medications in the outpatient treatment of workers' compensation injuries. The rule specifically addresses the use of nonsteroidal anti-inflammatory drugs (NSAIDs), opioid analgesics and muscle relaxants.[32]

31. The proposed medication rules are a result of many years of exploration and discussion convened by the Department concerning increases in the cost of medications in workers' compensation cases over the years. From 1997-2003, expenditures per claim for outpatient pharmacy in Minnesota's workers' compensation system increased 142%.[33]

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[28] *Id.* at 37-38.
[29] *Id.* at 38-39.
[30] *Id.* at 39.
[31] *Id.*
[32] *Id.* at 13-14.
[33] *Id.* at 14.

32. The Department first convened a public meeting of the Workers' Compensation Advisory Council (WCAC) and the Medical Services Review Board (MSRB) and other interested persons to explore whether pharmacy cost controls used in general health care could be applied to the workers' compensation system in November 2002.[34]

33. In 2003, the Department convened a Workers' Compensation Medical Costs Task Force, consisting of representatives from labor, business, health care, insurance, hospital and pharmacy industries. The Task Force met seven times from August through December of 2003. It considered three cost control strategies for pharmacy costs, including pharmacy networks, fee schedules and drug formularies.[35]

34. Legislative changes in 2005 allowed workers' compensation payers to establish pharmacy networks and a 2006 amendment to the workers' compensation fee schedule established a lower maximum fee for prescription drug charges submitted and paid electronically.[36]

35. After considering and rejecting the idea of a drug formulary, which controls which medications a pharmacist may dispense, the Department and the Task Force turned to the possibility of changing the way that physicians prescribe medications by encouraging generic and therapeutic substitutions, requiring prior authorization for certain medications and imposing quantity limitations, both on the quantity of doses in an individual prescription; and on the number of refills allowed.[37]

36. The Department focused on the three classes of drugs that accounted for at least two-thirds of pharmacy costs in workers' compensation in 2005 when it developed the medication treatment parameters in the proposed rules.[38] The Department developed the medication parameters rules based on recommendations made by the MSRB, which considered the results of numerous scientific studies, comments from interested parties in the community, and its own experience in treating work-related injuries.[39]

37. The MSRB was established by Minn. Stat. § 176.103 to advise the Department about workers' compensation medical issues and to act as a liaison between the Department and the medical provider community. It is composed of two chiropractic representatives, one hospital administrator representative, one registered nurse, one physical therapist, six physicians of different specialties, one employee representative, one employer/insurer representative and one general public representative.[40]

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[34] *Id.*
[35] *Id. See* Minn. Stat. § 165.135, subd. 1(g) and (h).
[36] *Id.* at pp.14-15. *See* Minn. R. 5221.4070.
[37] *Id.* at p. 15.
[38] *Id.*
[39] *Id.*
[40] Ex. 4, p. 2; Minn. Stat. § 176.103.

38. The scientific studies considered by the MSRB in developing the medication parameters rules were identified by the Department's medical consultant, Dr. William Lohman, who used an evidence-based approach.[41]

39. Evidence-based medicine "is the process of systematic reviewing, appraising, and using clinical research findings to aid in the delivery of optimum medical care of patients."[42]

40. Dr. Lohman and the MSRB reviewed and evaluated the medical literature by "levels of evidence" with Level I evidence being the most compelling, while Level VI evidence is the weakest. Level I evidence is based on systematic reviews, meta-analyses of multiple, randomized, controlled trials. Level II is individual randomized, controlled trials. Level III are other kinds of experimental studies that are not as rigidly controlled for bias as randomized, controlled trials. Level IV are descriptions of cases, Level V is case series and Level VI is expert opinion (not based on scientific studies).[43]

41. Level I studies were the preferred studies, but the MSRB considered Level II and III evidence when there was insufficient Level I evidence available.[44]

42. The MSRB searched several databases with millions of articles, limiting their searches by date, language and subject matter. Each article was reviewed and scored based on consistent, widely-accepted criteria.[45]

43. For muscle relaxants, the MSRB retrieved 86 articles presumed relevant based on their titles, 39 of which met the inclusion criteria. Eleven were available electronically and of sufficient quality to be included. The 11 articles relied on 74 randomized, controlled trials on effectiveness and 70 randomized, controlled trials on safety.[46]

44. For NSAIDs, the MSRB retrieved 299 articles presumed relevant based on their titles, 81 of which met the inclusion criteria. Forty-nine were available electronically and of sufficient quality to be included. The 49 articles relied on 435 randomized, controlled trials on effectiveness and 482 randomized, controlled trials on safety and 121 on patient subgroups.[47]

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[41] *Id.* at p. 15; Lohman testimony (Lohman), Transcript (T.), pp. 30-41.
[42] Lohman, T., p. 30.
[43] Lohman T., pp. 31-32.
[44] Lohman T., p. 33.
[45] Lohman T., pp. 37-39, 46; Ex. 14, 16, 19-S.
[46] Lohman T., p. 41.
[47] Lohman T., p. 42.

45. For opioids, the MSRB retrieved 111 articles presumed relevant based on their titles, 46 of which met the inclusion criteria. Thirty were available electronically and of sufficient quality to be included. The 30 articles relied on 368 randomized, controlled trials on effectiveness and 301 randomized, controlled trials on safety.[48]

46. Dr. Lohman created draft reports to the MSRB based on all of the information in the articles. Once the MSRB had fully reviewed, discussed and approved the reports' conclusions and recommendations, they were provided to the Department which drafted the rules based on the reports.[49]

47. The draft of the rules was circulated to the MSRB and to anyone who had expressed an interest in seeing it. Comments were collected, reviewed, changes made to the draft and it was re-circulated. That process continued several times until the Department was not receiving any new comments.[50]

D. Medication Treatment Parameters: Overview of Part 5221.6105

48. Subpart 1 states that subparts 2 to 4 of this rule apply only in an outpatient setting and "do not require a physician to prescribe any class of drugs in the treatment of any patient."

49. The initial paragraph in subpart 2 defines nonsteroidal anti-inflammatory drugs (NSAIDs).

50. Item A describes the type of pain for which NSAIDs are indicated, and requires that NSAIDs "must be prescribed at the lowest clinically effective dose . . . ."

51. Regarding musuloskeletal pain, Item B states that "a generic nonselective NSAID is indicated unless a COX-2 inhibitor is indicated as specified in item C." Subitem (1) states which medications should be tried first and permits treatment to occur in a different order if there is a medical contraindication to starting with the medications in that subitem. Subitem (2) states that "other generic nonselective NSAID's are not indicated unless one-week trials" of the medications listed in subitem (1) have been ineffective at reducing the patient's pain by at least 50 percent as determined by the prescribing health care provider. Subitem (3) states that nonselective NSAIDs not available as generics are not indicated.

52. Item C provides a list of circumstances where a COX-2 inhibitor may be indicated instead of a nonselective NSAID.

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[48] *Id.*

[49] Lohman T., pp. 42-43; Ex. 16-A, Report to the MSRB on NSAIDs, Received, Reviewed and Adopted by the MSRB (October 13, 2005); Ex. 16-B, Report to the MSRB on Narcotic Analgesics, Received, Reviewed and Adopted by the MSRB (July 20, 2006); Ex. 16-C, Report to the MSRB on Muscle Relaxers, Received, Reviewed and Adopted by the MSRB (April 20, 2006).

[50] Lohman T., pp. 44-45.

53. Item D lists time frames for prescribing NSAIDs.

54. The initial paragraph of subpart 3 defines opioid analgesics.

55. Item A describes the type of pain for which opioid analgesics are indicated, and requires that opioid analgesics "must be prescribed at the lowest clinically effective dose . . . ."

56. Item B states that a generic oral opioid analgesic is indicated when treating pain. Subitem (1) states which medications should be tried first and permits treatment to occur in a different order if there is a medical contraindication to starting with the medications in subitem (1). Subitem (2) states that "other generic opioid analgesics are not indicated . . . unless one-week trials" of the medications listed in subitem (1) have been ineffective at reducing the patient's pain by at least 50 percent as determined by the prescribing health care provider. Subitem (3) permits prescription of generically available combinations of an oral opioid and a nonopioid analgesic as otherwise allowed under subitems (1) and (2). Subitem (4) states that oral opioid analgesics not available as generics and combinations of an oral opioid analgesic and nonopioid analgesic not available as generics are not indicated.

57. Item C lists time frames for prescribing oral opioid analgesics and combinations of an oral opioid analgesic and nonopioid analgesics.

58. Item D states that meperidine is not indicated in the treatment of acute or chronic pain.

59. Item E states that transcutaneous opioid analgesics are only indicated in patients with a documented disorder that prevents adequate oral dosing.

60. Item F states that oral transmucosal and buccal preparations are only indicated for the treatment of breakthrough pain and only in patients with a documented disorder that prevents adequate dosing with swallowed medications.

61. The initial paragraph of subpart 4 defines muscle relaxants.

62. Item A describes the type of pain for which muscle relaxants are indicated, and requires that muscle relaxants "must be prescribed at the lowest clinically effective dose . . . ."

63. Item B states that muscle relaxants are indicated when treating musculoskeletal pain. Subitem (1) states which medications should be tried first and permits treatment to occur in a different order if there is a medical contraindication to starting with the medications in subitem (1). Subitem (2) states that "[m]etaxolone and orphenadrine are not indicated unless one-week trials" of the medications listed in subitem (1) have been ineffective at reducing

the patient's pain by at least 50 percent as determined by the prescribing health care provider. Subitem (3) permits prescription of generically available combinations of a muscle relaxant and an analgesic as otherwise allowed under subitems (1) and (2). Subitem (4) states that muscle relaxants not available as generics and combinations of a muscle relaxant and an analgesic not available as generics are not indicated.

64. Item C lists time frames for prescribing muscle relaxants and combinations of a muscle relaxant and an analgesic.

65. Item D states that benzodiazepines are not indicated as muscle relaxants for the symptomatic relief of acute and chronic musculoskeletal pain.

II. Rulemaking Legal Standards

66. Under Minn. Stat. § 14.14, subd, 2, and Minn. Rule 1400.2100, one of the determinations which must be made in a rulemaking proceeding is whether the agency has established the need for and reasonableness of the proposed rule by an affirmative presentation of facts. In support of a rule, the Department may rely on legislative facts, namely general facts concerning questions of law, policy and discretion, or the Department may simply rely on interpretation of a statute, or stated policy preferences.[51] The Department prepared a Statement of Need and Reasonableness ("SONAR") in support of the proposed rules, along with extensive documentation of the development process used by the MSRB and the Department in creating the new medication treatment parameters. At the hearing, the Agency relied upon the SONAR and upon the MSRB's process for developing the rules as its affirmative presentation of need and reasonableness for the proposed amendments. The SONAR was supplemented by comments made by Dr. Lohman and Kathryn Berger, Compensation Attorney Principal with the Department.

67. The question of whether a rule has been shown to be reasonable focuses on whether it has been shown to have a rational basis, or whether it is arbitrary, based upon the rulemaking record. Minnesota case law has equated an unreasonable rule with an arbitrary rule.[52] Arbitrary or unreasonable agency action is action without consideration and in disregard of the facts and circumstances of the case.[53] A rule is generally found to be reasonable if it is rationally related to the end sought to be achieved by the governing statute.[54] The Minnesota Supreme Court has further defined an agency's burden in adopting rules by requiring it to " explain on what evidence it is relying and how the evidence connects rationally with the agency's choice of action to be

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[51] *Mammenga v. Department of Human Services*, 442 N.W.2d 786 (Minn. 1989); *Manufactured Housing Institute v. Pettersen*, 347 N.W. 2d 238, 244 (Minn. 1984).
[52] *In re Hanson*, 275 N.W. 2d 790 (Minn. 1978); *Hurley v. Chaffee*, 231 Minn. 362. 367, 43 N.W. 2d 281, 284 (1950).
[53] *Greenhill v. Bailey*, 519 F.2d 5, 19 (8th Cir. 1975).
[54] *Mammenga*, 442 N.W. 2d at 789-90; *Broen Memorial Home v. Minnesota Department of Human Services*, 364 N.W. 2d 436, 44 (Minn. Ct. App. 1985).

taken."[55] An agency is entitled to make choices between possible approaches as long as the choice made is rational. Generally, it is not the proper role of the Administrative Law Judge to determine which policy alternative presents the "best" approach since this would invade the policy-making discretion of the agency. The question is rather whether the choice made by the agency is one a rational person could have made.[56]

68. In addition to need and reasonableness, the Administrative Law Judge must also assess whether the Department complied with the rule adoption procedures, whether the rule grants undue discretion, whether the Department has statutory authority to adopt the rule, whether the rule is unconstitutional or illegal, whether the rule constitutes an undue delegation of authority to another entity, or whether the proposed language is not a rule.[57]

69. Because the Department suggested changes to the proposed rules after original publication of the rule language in the State Register, it is also necessary for the Administrative Law Judge to determine if the new language is substantially different from that which was originally proposed. The standards to determine whether changes to proposed rules create a substantially different rule are found in Minn. Stat. § 14.05, subd. 2. The statute specifies that a modification does not make a proposed rule substantially different if:

> "the differences are within the scope of the matter announced . . . in the notice of hearing and are in character with the issues raised in that notice;"
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> the differences "are a logical outgrowth of the contents of the . . . notice of hearing, and the comments submitted in response to the notice;" and
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> the notice of hearing "provided fair warning that the outcome of that rulemaking proceeding could be the rule in question."

70. In reaching a determination regarding whether modifications result in a rule that is substantially different, the Administrative Law Judge is to consider:

> whether "persons who will be affected by the rule should have understood that the rulemaking proceeding . . . could affect their interests;"
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> whether the "subject matter of the rule or issues determined by the rule are different from the subject matter or issues contained in the . . . notice of hearing;" and

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[55] *Manufactured Housing Institute*, 347 N.W. 2d at 244.
[56] *Federal Security Administrator v. Quaker Oats Co.*, 318 U.S. 218, 233 (1943).
[57] Minn. R. 1400.2100.

whether "the effects of the rule differ from the effects of the proposed rule contained in the . . . notice of hearing."

III. Compliance with Procedural Rulemaking Requirements

71. The Department first published a Request for Comments pertaining to the proposed rules on August 28, 2006, at 31 State Register 307.[58] On August 18, 2008, at 33 State Register 342, the Department published an updated Request for Comments, expanding the number of treatment modalities to be included in the scope of the rules, as well as adding amendments to the rules concerning functional capacity evaluations and complex regional pain syndrome (reflex sympathetic dystrophy).[59]

72. On September 18, 2009, the Department filed a request with the Chief Administrative Law Judge requesting approval of its Additional Notice Plan. The Additional Notice Plan was approved on September 25, 2009.

73. On October 15, 2009, the Department mailed a copy of the SONAR to the Legislative Reference Library as required by law.[60]

74. On October 15, 2009, the Department mailed the Notice of Intent to Adopt Rules Without a Public Hearing (Notice of Intent) to all persons and associations on the Department of Labor and Industry's rulemaking mailing list for workers' compensation and all agency rules, established pursuant to Minnesota Statutes, section 14.14, subdivision 1a.[61]

75. On October 15, 2009, the Department posted the proposed rules, the SONAR and the Notice of Intent on the Department's rulemaking docket website.[62]

76. On October 16, 2009, the Department e-mailed links to the Department's website where the Notice of Intent, the proposed rules and the SONAR were posted pursuant to its Additional Notice Plan.[63]

77. After publishing its Notice of Intent on October 19, 2009, the Department received approximately 36 requests for a hearing on the rules.[64]

78. On December 29, 2009, the Department requested the scheduling of a hearing regarding the proposed rules and filed the following documents with the Chief Administrative Law Judge:

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[58] Ex. 1A.
[59] Ex. 1B.
[60] Ex. 5 ; Minn. Stat. § 14.131 and Minn. R. 1400.2220, subp. 1(E).
[61] Ex. 7A.
[62] Ex. 8H.
[63] Ex. 8B, E and F.
[64] Ex. 6B, Notice of Intent to Adopt Rules Without a Hearing; Ex. 9A, Requests for Hearing.

a. a copy of the proposed rules certified by the Revisor of Statutes;

b. a copy of the Notice of Hearing proposed to be issued; and

c. a draft of the Statement of Need and Reasonableness ("SONAR").

79. By letter dated January 8, 2010, the Administrative Law Judge approved the Department's Notice of Hearing.

80. On January 20, 2010, the Department posted the Notice of Hearing on the Department's rulemaking docket website.[65]

81. On January 22, 2010, the Department mailed the Notice of Hearing to all persons and associations on the Department of Labor and Industry's rulemaking mailing list for workers' compensation and all agency rules, established pursuant to Minnesota Statutes, section 14.14, subdivision 1a and e-mailed the Notice of Hearing to all persons and associations on the rulemaking mailing lists for workers' compensation and agency rules who had contacted the agency with a preference of e-mail notification as permitted by 2009 Laws of Minnesota ch. 71, § 2.[66]

82. On January 22, 2010, the Department e-mailed links to the Department's website where the Notice of Hearing was posted pursuant to its Additional Notice Plan.[67]

83. On January 22, 2010, the Department mailed the Notice of Hearing to all persons who commented or requested a hearing following publication of the Notice of Intent to Adopt Rules Without a Public Hearing on October 19, 2009.[68]

84. The Department published a Notice of Hearing on January 25, 2010.[69]

85. On the day of the hearing, the Department placed the following documents into the record:

a. the Requests for Comments as published in the State Register (Exhibits 1A and 1B);

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[65] Ex. 8I.
[66] Ex. 7C and 7E.
[67] Ex. 8C, D and G.
[68] Ex. 13.
[69] Ex. 6D, Notice of Hearing.

b. A statement that a petition for rulemaking was not submitted because the Department did not receive such a peititon (Exhibit 2);
c. copies of the proposed rules as certified by the Revisor of Statutes; the SONAR, along with certificates of mailing to the Legislative Reference Library; the Notice of Intent to Adopt a Rule Without a Public Hearing; the Notice of Hearing, as mailed and published in the State Register; the Certificates of Mailing and e-mailing the Notices and of Accuracy of the Mailing List; and the Certificates of e-mailing Additional Notice and posting the rule, the SONAR and the Notices on the Department's rulemaking docket website (Exhibits 3-8);
d. copies of written comments on the proposed rules received by the agency, including requests for hearing received during the comment period; comments not requesting a hearing received during the comment period; and untimely and incomplete requests for hearing (Exhibits 9A, 9B, 9C and 9D);
e. a statement that a copy of the document from the Chief Administrative Law Judge authorizing the agency's omission of the text of any proposed rule publication in the *State Register* is not submitted because the text of the proposed rules was not omitted from publication (Exhibit 10);
f. the Certificate of Sending the Notice of Intent to Adopt Rules Without a Hearing and the Notice of Hearing and the Statement of Need and Reasonableness to Legislators (Exhibits 11A and 11B);
g. a copy of the transmittal letter showing that the agency consulted with the Department of Finance, and the response received by the agency (Exhibit 12);
h. the Certificate of Mailing the Notice of Hearing to those who submitted comments or requested a hearing following publication of the Notice of Intent to Adopt Rules Without Hearing on October 19, 2009 (Exhibit 13);
i. a computer disc with the following documents in electronic form (Exhibit 14):
    1) Proposed rules
    2) SONAR
    3) Report to the MSRB: Muscle Relaxers
    4) Report to the MSRB: NSAIDs
    5) Report to the MSRB: Narcotic Analgesics
    6) MSRB Minutes: January, April, July, October 2005; April, July, November 2006; April 2007; April, October 2008; February 2009;
j. paper copies of the minutes of the 12 meetings of the MSRB from January 2005 to July 2009 (Exhibits 15A-15L); and of the Reports to the MSRB on Muscle Relaxers, NSAIDs and Narcotic Analgesics (Exhibts 16A-16C);

k. Workers' Compensation System Reports published by the Department's Policy Development and Research and Statistics unit for the years 2006 (published July 2008 and corrected September 2008) and 2007 (published May 2009) (Exhibits 17A and 17B);
l. copies of court cases cited in the SONAR: *Jacka v. Coca Cola Bottling; Darvell v. Wherley Motors; Stone v. Harold Chevrolet; and Mundy v. American Red Cross* (Exhibits 18A-18D);
m. copies of Power Point slides prepared by Dr. Lohman for presentation at the hearing (Exhibit 19);
n. a proposed change to proposed Minn. R. 5221.6105, subp. 3 in response to a public comment (Exhibit 20); and
o. a copy of the text of the statement made by Kathryn Berger on behalf of the Department at the hearing (Exhibit 21).

86. The Administrative Procedure Act requires that proposed rules be published in the State Register, that persons on the agency rulemaking mailing list be notified of proposed rules, along with the chairs and ranking minority party members of the legislative policy and budget committees with jurisdiction over the subject matter of the proposed rules, and that the agency make "reasonable efforts to notify persons or classes of persons who may be significantly affected by the rule being proposed by giving notice of its intention in newsletters, newspapers, or other publications, or through other means of communication." By publishing the proposed rule in the State Register on October 19, 2009, providing required notice to certain members of the Legislature, notifying all the individuals and organizations who had asked the Department to notify them of rulemaking, providing additional notice to a broad variety of other persons and organizations as detailed above, publishing the proposed rules, the Statement of Need and Reasonableness and the both the Notice of Intent to Adopt Rules Without a Hearing and the Notice of Hearing on the Department's rulemaking docket website, and sending information about the hearing to all persons who requested that a hearing be held, the Administrative Law Judge finds that the Department satisfied the notice requirements set forth in the Minnesota Administrative Procedure Act.

87. The Administrative Law Judge finds that the Department met all of the procedural requirements established by statute and rule.

IV. Regulatory Analysis

A. Statutory Authority

88. As statutory authority for the proposed rule changes, the Department cites Minn. Stat. §§ 176.83, subd. 5, requiring the Commissioner of Labor and Industry, in consultation with the MSRB, to:

> adopt rules establishing standards and procedures of health care provider treatment [which must be] used to determine whether a provider of health care services and

> rehabilitation services, including a provider of medical, chiropractic . . . or other services, is performing procedures or providing services at a level or with a frequency that is excessive, unnecessary, or inappropriate . . . .

The Department cites as additional authority, Minn. Stat. § 176.03, subd. 2, which requires the Commissioner, in consultation with the MSRB, to "adopt rules defining standards of treatment, including inappropriate, unnecessary or excessive treatment . . . ." Subdivisions 3 and 4 of Minn. Stat. § 176.83 also authorize the Commissioner of Labor and Industry to adopt these rules.[70]

89. The Minnesota Supreme Court has held that Workers' Compensation treatment parameter rules adopted by the Department of Labor and Industry which 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" but which are "substantial enough to establish standards and procedures based on good medical practice . . . should have the force and effect accorded other properly promulgated administrative rules."[71]

90. The Administrative Law Judge finds that the Department has established its statutory authority to adopt the proposed rules.

B. Impact on Farming Operations

91. Minn. Stat. § 14.111 imposes an additional notice requirement when rules are proposed that affect farming operations. In essence, the statute requires that an agency must provide a copy of any such proposed rule change to the Commissioner of Agriculture at least thirty days prior to publishing the proposed rule in the State Register.

92. The proposed rules do not impose restrictions or have a direct impact on fundamental aspects of farming operations. The Administrative Law Judge finds that the proposed rule change will not affect farming operations in Minnesota, and thus finds that no additional notice is required.

C. Additional Notice Requirements

93. Minn. Stat. § 14.131 requires that an agency include in its SONAR a description of its efforts to provide additional notification to persons or classes of persons who may be affected by the proposed rule or must explain why these efforts were not made. The Agency made appropriate efforts to inform and involve interested and affected parties in this rulemaking, submitting an additional notice plan to the Office of Administrative Hearings, which reviewed and approved it on September 25, 2009. The Department mailed both the Notice of Intent to Adopt a Rule Without a Hearing and the Notice of Hearing to

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[70] Ex. 4, pp. 1-2.
[71] Ex. 4, p. 3, *quoting Jacka v. Coca-Cola Bottling Co.*, 580 N.W. 2d 27 (Minn. 1998).

all persons who had registered to be on the Department's rulemaking mailing list under Minnesota statutes, section 14.14, subdivision 1a and posted the proposed rules, both notices, and the SONAR on its rulemaking docket website. The Department also provided a copy of each notice to:[72]

a. Members of the Workers' Compensation Advisory Council;
b. members of the Workers' Compensation Insurers Task Force, along with persons who have requested to receive notice of the WCITF meetings;
c. members of the Workers' Compensation Medical Services Review Board and persons who have requested to receive notice of that board's meetings;
d. persons and organizations who are on the Department's e-mail list for health care providers;
e. persons and organizations who are on the Department's e-mail list for workers' compensation insurers;
f. attorneys on the Office of Administrative Hearings' e-mail list for workers' compensation attorneys;
g. the Minnesota Medical Association, the Minnesota Chiropractic Association, the Minnesota Nurses Association, the Minnesota Chapter of the American Physical Therapy Association, the Minnesota Occupational Therapy Association, and the Minnesota Pharmacy Association;
h. the three workers' compensation managed care plans certified under Minn. Stat. § 176.1351;
i. the League of Minnesota Cities, the Association of Minnesota Counties, the University of Minnesota workers' compensation department; and the Minnesota Department of Finance, Employee Relations division;
j. those who commented on the draft amendments since the Request for Comments was published on August 18, 2008.

94. The Administrative Law Judge finds that the Board fulfilled its additional notice requirement.

D. Cost and Alternative Assessments in the SONAR

95. Minn. Stat. § 14.131 requires an agency adopting rules to include in its SONAR:

a. a description of the classes of persons who probably will be affected by the proposed rule, including classes that

[72] Ex. 4, pp. 9-10.

will bear the costs of the proposed rule and classes that will benefit from the proposed rule;

b. 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;

c. a determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule;

d. 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;

e. 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 government units, businesses, or individuals;

f. 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; and

g. 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.

96. With respect to the first requirement, the Department indicated in the SONAR that injured workers and health care providers who treat injured workers, along with workers' compensation employers and insurers, certified workers' compensation managed care plans, and others involved in the workers' compensation system such as attorneys and pharmacies, will be affected by the proposed rule. The Department stated that all of the named classes of persons will benefit from the proposed rules because the rules reflect the current standard of medical care and should reduce disputes and costs related to unnecessary or inappropriate treatment. Additional cost is not anticipated because the rules reflect the current standard of care. The Department acknowledged that there may be reduced revenues for those who do not currently comply with the standard of care, but the Department lacks sufficient information to estimate how many providers this might involve. There will be

savings to the extent payers no longer pay for non-standard care, and additional costs to the extent payers were previously not paying for appropriate care.[73]

97. The Department addressed the second requirement in the SONAR, stating that no implementation or enforcement costs to the Department or any other agency are anticipated, because the amendments update existing rules according to accepted medical standards. The SONAR states that the updated rules will not affect state revenues.[74]

98. In addressing the third requirement, the SONAR states that no less costly or less intrusive method has been identified for updating "the 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."[75]

99. With respect to the fourth requirement, the SONAR states that the Department worked closely with the MSRB, which extensively reviewed medical research, to ensure that the updated treatment parameters reflect accepted medical standards for providing quality and cost-effective health care to cure and relieve injured workers of the effects of their injuries. The Department widely circulated drafts of the rules that it and the MSRB reviewed. The SONAR indicated that the Department seriously considered all of the comments received in response, including incorporating all of the recommendations the MSRB made in response to the comments. The Department declined to seriously consider any amendments unsupported by applicable medical research and by the MSRB.[76]

100. The SONAR addresses the fifth requirement, stating that there are no costs of compliance to providers or payers in that the rules do not require either group to spend money to comply. The proposed rules may reduce or increase revenue for providers, depending on whether or not they currently meet the standards of practice reflected in the proposed amendments. The rules may require additional payment by insurers 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 costs analysis is the same for governmental units because they act in the capacity of employer, insurer, or provider. Neither the MSRB nor the Workers' Compensation Insurers Task Force identified costs of compliance when the Department inquired about any concerns their members might have about costs of compliance.[77]

101. With respect to the sixth requirement, the SONAR states that failure to adopt the proposed rules would probably result in injured workers not receiving treatment consistent with accepted medical practice for quality health care, and payers paying for treatment that does not meet the standard of

[73] Ex. 4, pp. 5-6.
[74] Ex. 4, p. 6.
[75] Ex. 4, pp. 6-7.
[76] Ex. 4, p. 7.
[77] Ex. 4, pp. 7-8.

accepted medical practice or denying payment for treatment that does meet the standard.[78]

102. The SONAR states, with respect to the seventh requirement, that there are no federal regulations governing Minnesota workers' compensation treatment.[79]

103. Minnesota statutes section 14.131 also requires that the SONAR must "describe how the agency, in developing the rules, considered and implemented the legislative policy supporting performance-based regulatory systems set forth in section 14.002."

104. The SONAR includes a discussion of the analysis that was performed by the Department to meet the requirements of this statute, pointing out that Minn. Stat. § 176.83, subd. 5 requires that the rules 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 . . . based upon accepted medical standards . . . ." Thus, by their nature, the treatment parameters are performance-based rules. This is consistent with the rules themselves, which do not rigidly prescribe or proscribe specific treatment, but provide flexibility to providers to determine how best to treat injured workers within the parameters of acceptable medical standards for quality health care.[80]

105. Minn. Stat. §§ 14.131 also requires that the agency consult with the Commissioner of Finance to help evaluate the fiscal impact and fiscal benefits of the proposed rule on units of local government. The Department consulted with the Commissioner of Finance and, in a memo dated July 24, 2009, the Executive Budget Officer at the Office of Management and Budget opined that the proposed changes will not impose a significant cost on local governments.[81]

106. The Administrative Law Judge concludes that the Department has met the requirements set forth in Minn. Stat. § 14.131 for assessing the impact of the proposed rules.

E. Cost to Small Businesses and Cities under Minn. Stat. § 14.127

107. Effective July 1, 2005, under Minn. Stat. § 14.127, agencies must "determine if the cost of complying with a proposed rule in the first year after the rule takes effect will exceed $25,000 for: (1) any one business that has less than 50 full-time employees; or (2) any one statutory or home rule charter city that has less than ten full-time employees."[82] Although this determination is not required to be included in the SONAR, the statute states that the agency "must make

[78] Ex. 4, p. 8.
[79] Ex. 4, p. 8.
[80] Ex. 4, p. 8.
[81] Ex. 12; Ex. 4, p. 11.
[82] Minn. Stat. § 14.127, subd. 1.

[this] determination . . . before the close of the hearing record" and the Administrative Law Judge must review the determination and approve or disapprove it.[83] In the SONAR, the Department states that it has considered whether the cost of complying with the proposed rules in the first year after the rule takes effect will exceed $25,000 for any small business or small city and determined that it will not. The Department states that, since workers' compensation health care is a relatively small percentage of general medical care (approximately 1.5%), it is not likely that the proposed rules will result in reduction in revenue of greater than $25,000 for any small health care provider currently providing non-standard treatment. Small cities (with ten or fewer full-time employees) typically do not pay workers' compensation claims directly and therefore there will be no cost of compliance that will exceed $25,000 in the first year.[84]

108. The Administrative Law Judge concludes that the Department has met the requirements set forth in Minn. Stat. § 14.127 for determining whether the cost of complying with the proposed rule in the first year after the rule takes effect will exceed $25,000 for any small business or small city.

F. Determination for Rules Requiring Local Implementation

109. 2009 Minnesota Laws, chapter 152, § 1, codified as Minn. Stat. § 14.128, requires agencies to 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. Although this determination is not required to be included in the SONAR, the statute states that the agency "must make [this] determination . . . before the close of the hearing record" and the Administrative Law Judge must review the determination and approve or disapprove it.[85] The Department addressed this requirement in the SONAR, stating 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 already required to comply with the workers' compensation law, including the treatment parameters adopted pursuant to Minn. Stat. § 176.83, subd. 5.[86]

110. The Administrative Law Judge concludes that the Department has met the requirements set forth in Minn. Stat. § 14.128 for determining whether 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.

V. Analysis of the Proposed Rules

111. This Report is limited to the discussion of the portions of the proposed rules that received critical comment or otherwise need to be examined.

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[83] Minn. Stat. § 14.127, subd. 2.
[84] Ex. 4, p. 11.
[85] Minn. Stat. § 14.128, subd. 1.
[86] Ex.. 4, p. 11.

Accordingly, the Report will not discuss each comment or rule part. Many sections of the proposed rules were not opposed by any member of the public and were adequately supported by the SONAR. For these reasons, it is unnecessary to engage in a detailed discussion of each part and subpart of the proposed rules in this Report.

112. The Administrative Law Judge has read and considered all written comments submitted during this rulemaking proceeding, regardless of whether any particular comment is referred to in this Report.

113. The Administrative Law Judge specifically finds that the Agency has demonstrated the need for and reasonableness of all rule provisions not specifically discussed in this Report by an affirmative presentation of facts. He also finds that all provisions not specifically discussed are authorized by statute and there are no other problems that would prevent the adoption of the rules.

A. Objections to the Proposed Rules

Pre-Hearing Comments

114. A number of individuals and organizations submitted written comments in advance of the hearing, including many similar requests for hearing, mostly by attorneys who represent injured workers. Several of their concerns were about subjects which are not addressed by these rules but are or will be addressed by other rules. For example, there were comments about long-term use of medications, spinal cord stimulators, payment for a prescribed bed, and cost-shifting to or from Medicare, none of which are part of this proceeding.[87]

115. A number of comments from attorneys stated that the changes "appear to favor employers and insurers over injured workers (e.g. by placing heavy restrictions on doctors' abilities to treat their patients who are injured on the job as opposed to other patients) . . . ."[88]

116. The Department pointed out that "workers' compensation insurance covers all 'reasonable and necessary' treatment" and that the rules are not burdensome for health care providers who provide treatment consistent with the current research and standard of care on which the rules are based. The Department also pointed out that these comments did not raise objections to any specific rule part.[89]

117. One commentator expressed concerns that a lack of "open discussion" leaves "significant questions unanswered and input unheard. This is

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[87] Department of Labor and Industry's Response to Public Comments (DOLI Response) , pp. 1-3 (March 22, 2010); Ex. 9, Pre-Hearing Comments.
[88] DOLI Response, p. 3; Ex. 9; *see* Charles Cochrane Reply Letter (Cochrane Reply), pp. 1-3 (March 29, 2010).
[89] DOLI Response, p. 3.

unfair to workers, advocates, and most certainly to the Workers' Compensation Advisory Council . . . ."[90]

118. As the Department described in great detail at the hearing and in its written response, there was extensive notice throughout this rulemaking process to all interested parties, including the Workers' Compensation Advisory Council, which received rule drafts even before official notices were published. In addition, Dr. Lohman's testimony at the hearing detailed the way in which public input was carefully considered by the MSRB and the Department as the rules were drafted.[91]

Healthesystems Pre-Hearing Comments

119. Healthesystems, Inc. submitted pre-hearing comments relating to part 5221.6105. Regarding subpart 3, Healthesystems suggested replacing the term "pethidine" at line 7.21 of the Revisor's draft, with the synonymous term "meperidine" which is used later in the rules.[92]

120. The Department agreed with this recommendation and proposed amending the proposed Minn. R. 5221.6105, subp. 3 by deleting the word "pethidine" and replacing it with the word "meperidine." The words are synonymous, but the former term is more commonly used in Europe while the latter is used in the United States.[93]

121. The Administrative Law Judge agrees that this change is needed and reasonable and would not constitute a substantial change from the rule as originally proposed.

122. Healthesystems also suggested removing methadone as a treatment option included in opioid analgesics at part 5221.6105, subp. 3, line 7.21 of the Revisor's draft.[94] The Department rejected this suggestion based on the medical studies of using methadone as a treatment option presented to the MSRB, and the MSRB's subsequent decision to retain methadone as a treatment option.[95]

123. Healthesystems recommended removing propoxyphene products, included at line 8.10, due to unacceptable toxicity and high risk of respiratory depression. Healthesystems noted that the FDA requires a black box warning on the risk of overdose.[96]

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[90] DOLI Response, p. 3; Ex. 9.
[91] DOLI Response, p. 3; Lohman T., pp. 43-45.
[92] Letter from Ralph Kendall, on behalf of Healthesystems (Healthesystems), p. 1 (November 5, 2009).
[93] DOLI Response, p. 4; Ex. 20.
[94] Healthesystems, p. 1.
[95] DOLI Response, p. 4.
[96] Healthesystems, p. 1.

124. The Department noted that Healthesystems made this comment earlier in the process as well and re-stated the MSRB's response, which was that banning this medication is not justified and that it is not one that can be prescribed unless other options have failed. The MSRB noted "[t]his is unlikely given the relative potencies." The Department noted that the FDA does continue to permit use of propoxyphene products.[97]

125. Healthesystems suggested adding a requirement, at line 9.6 of the Revisor's draft, that all opioid prescriptions be written with specific instructions and that "take as directed" instructions be prohibited. Healthesystems also suggested that products containing acetaminophen contain instructions that the patient take no more than a specified number of doses per day.[98]

126. The Department disagreed with these suggestions, preferring that health care professionals be able to provide contingent flexible dosing instructions. The Department noted that the requirement for a limitation on the number of doses per day for combination products containing acetaminophen is unnecessary because standard medical practice requires a physician to instruct a patient in the safe use of all prescribed medications.[99]

127. Healthesystems recommended inserting the words "including soluble films" after "buccal preparations which would then include the newly approved ONSOLIS (fentanyl buccal soluble film)" at line 9.10 of the Revisor's draft.[100]

128. The Department stated "[t]his change is unnecessary because, as the commenter notes, a soluble film placed on the inside to the cheek is a buccal preparation ('fentanyl buccal soluble film')." (Underline in original.)[101]

129. Healthesystems advised adding Baclofen to Minn. R. 5221.6105, subp. 4, which deals with muscle relaxants, at lines 9.14, 9.23 and 10.4 of the Revisor's draft.[102]

130. The Department countered that others had made this comment and the MSRB discussed it at two separate meetings. The "MSRB specifically excluded consideration of Baclofen in this process" because it has "a different mechanism of action and a different spectrum of application." The Department noted that "the proposed rules are silent on the indications and appropriate uses of Baclofen and so do not limit the [health care provider's] use of this medication." The rules expressly state "This subpart does not limit the use of medications that may be used to treat spasticity."[103]

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[97] DOLI Response, p. 4.
[98] Healthesystems, pp. 1-2.
[99] DOLI Response, pp. 4-5.
[100] Healthesystems, p. 2.
[101] DOLI Response, p. 5.
[102] Healthesystems, p. 2.
[103] DOLI Response, p. 5.

131. Finally, Healthesystems proposed that the language in subpart 4, page 10.21 of the Revisor's Draft be amended to exclude Diazepam "because other agents offer equivalent therapeutic value without the drug interaction and dependence/addiction liability of Diazepam. It should be excluded for treatment of both muscle spasm and musculoskeletal pain."[104]

132. The Department observed that the rule already states benzodiazepines are not indicated as muscle relaxants and that diazepam is a benzodiazepine. The Department chose not to list one specific benzodiazepine because to do so "without listing all others could be potentially confusing, leading users to conclude that only diazepam is not indicated for this use." The Department noted again that "medication for treatment of spasticity is beyond the scope of the proposed rules."[105]

Progressive Medical, Inc. Comments

133. Susan Martin submitted comments on behalf of Progressive Medical, Inc. during the post-hearing comment period. All of her comments concerned the medication parameters, part 5221.6105.[106]

134. Ms. Martin asked whether part 5221.6105, subp. 3, discussing generic codeine, hydrocodone and oxycodone, presumes that these medications may be combined with a nonopioid analgesic such as acetaminophen. The Department replied that the subpart 3B(3) does expressly permit such combinations.[107]

135. Ms. Martin also asked whether sustained-release agents are permissible, given that the SONAR states that there is no evidence that there are clinically-significant differences between sustained-release and immediate-release narcotic formulations.[108]

136. The Department stated that the proposed rules permit sustained-release agents available in generic form.[109]

137. Ms. Martin asserted that OxyContin is sporadically unavailable in a generic formulation at certain strengths and asked whether the brand OxyContin would be authorized if the generic formulation is not available. Similarly, Ms. Martin asked whether the brand Skelaxin (metaxalone) will be covered "given that it is only available in brand."[110]

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[104] Healthesystems, p. 2.
[105] DOLI Response, p. 5.
[106] Letter from Progressive Medical, Inc. (Progressive) (March 19, 2010), p.1.
[107] DOLI's Reply to Post-Hearing Comments (Reply) (March 29, 2010), p. 1.
[108] Progressive letter, p.1.
[109] DOLI Reply, p. 2.
[110] Progressive letter, pp. 2-3.

138. The Department pointed out that OxyContin is a brand name for a sustained-release formulation of oxycodone, which is generally available generically in an immediate-release form. If the prescribing provider documents a need for a departure from the immediate-release generic form pursuant to Minn. R. 5221.6050, subp.8, OxyContin would be indicated. Similarly, if Skelaxin is not available in generic form, it would be indicated with appropriate documentation of a need for a departure.[111]

139. Quoting the language in 5221.6105, subp. 4.C (3) stating that "[t]reatment with muscle relaxants for more than three consecutive months is not indicated," Ms. Martin asks whether this applies to all conditions where a skeletal muscle relaxant is used, including myofascial pain and cervicogenic headaches. Ms. Martin asked whether this general statement applies to tizanidine, which is appropriate for long term use for most conditions.[112]

140. The Department confirmed that myofascial and cervicogenic pain are both types of musculoskeletal pain and that "[s]tudies indicate there is not a significant clinical benefit for long term use of muscle relaxants for the relief of pain."[113] The Department acknowledged that tizanidine is used for long-term treatment of spasticity due to multiple sclerosis and spinal cord injury, but the rules specifically provide that subpart 4 does not limit the use of medications used to treat spasticity.[114]

141. The Department noted that there is a spelling error in line 9.15 of the proposed rules, where "tizanidine" is spelled "tizanide." Therefore, the Department proposes to modify the first paragraph of subpart 4 to read as follows:

> Subp. 4. Muscle relaxants. A muscle relaxant is a drug which decreases the tone of a muscle. For purposes of this subpart, muscle relaxants include carisoprodol, chlorzoxazone, cyclobenzaprine, metaxalone, methocarbamol, orphenadrine, and ~~tizanide~~ tizanidine. This subpart does not limit the use of medications that may be used to treat spasticity.[115]

142. The Administrative Law Judge finds this clerical change to be needed and reasonable and not a substantial change from the rule as proposed.

143. Ms. Martin also asked whether subpart 10, which requires that "[d]ocumentation must be provided for the use of any medication (scheduled and nonscheduled)" requires an insurance claims adjuster or a PBM (pharmacy benefits manager) to obtain documentation for the purposes of payment.[116]

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[111] DOLI Reply, p. 2.
[112] Progressive letter, p.3.
[113] DOLI Reply, p. 3, *citing* SONAR, App. C, p.53.
[114] DOLI Reply, p. 3.
[115] DOLY, Reply, p. 3.
[116] Progressive letter, p. 3.

144. The Department explained that a provider must supply the payer, along with the bill, a copy of a medical record that adequately documents the service and substantiates the nature and necessity of the prescribing provider's service or charge. The rules do not require the provider to provide, or the payer to review, the documentation before the prescription is filled, although, with the availability of electronic bill and payment transactions and prescribing, communication generally occurs quickly, minimizing denials of payment.[117]

Charles Cochrane Comments

145. At the hearing, Mr. Cochrane spoke on behalf of the workers' compensation committee of the Minnesota Association for Justice, which represents attorneys who represent injured workers. All of Mr. Cochrane's comments concerned the language in the new Minn. R. 5221.6195, the medication treatment parameters.[118]

146. Mr. Cochrane's overarching comment was that the rules are not necessary because there was no evidence of "overprescription, overuse, overpayment or the converse." He pointed out that medications "constitute only 7 percent of the total cost of work comp claims in Minnesota" and that Minnesota is a relatively low cost state for medication usage. Mr. Cochrane also emphasized that the cost of drugs in workers' compensation has declined since 2002, under 50-percent of claims involve the use of drugs, and workers' compensation health care is a small piece of the cost of general medical care (only about 1.5 percent of total health care costs).[119]

147. The Department responded by citing the 2007 Minnesota Workers' Compensation System Report, which states that, although drugs accounted for 7 percent of all workers' compensation medical costs for claims originating in 2007, drug costs arose in 46 percent of the 2007 claims and at least 86 percent of those costs were for prescription medication.[120] The Department also cited several other statistics, including that the cost of drugs for an average workers' compensation claim grew 55 percent between 1997 and 2007, after adjusting for inflation, while the average total medical cost per claim grew 19 percent above inflation in the same time period. That increase was the result of a 21 percent increase in the percentage of claims with drug costs and a 28 percent inflation-adjusted increase in the average cost of drugs for those claims.[121] The Department also pointed out that "[t]he fact that a majority of states have a more severe problem than Minnesota does not mean Minnesota does not have a problem."[122]

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[117] DOLI Reply, p. 4.
[118] Testimony of Charles Cochrane, Transcript (Cochrane T.), pp.58-83; Cochrane Reply, p.1.
[119] Cochrane T., pp. 61-65.
[120] DOLI Response, p. 6, *citing* Ex. 17A and 17B.
[121] *Id.*
[122] DOLI Reponse, p. 7.

148. Although the cost of drugs declined per claim from 2002 to 2006, the Department asserted that that was "largely because the insurer providing the data initiated major cost-control measures during the analysis period such as utilizing pharmacy networks." These declines stand in contrast to extremely large increases in drug costs during the first part of the analysis period. Furthermore, the Department noted that "drug costs began increasing again in 2006."[123]

149. In Minnesota workers' compensation cases in 2008, with drug costs involved in an estimated 51,800 claims (46 percent of a total of 112,600 paid claims involving medical payments), approximately 44,550 (86 percent) involved prescription medications.[124]

150. Mr. Cochrane stated at the hearing that the proposed rules will probably increase litigation, at least in the short term, because people do not know how to implement them.[125] He also commented that section 3 of the SONAR failed to provide a "true explanation of other methods that could be used here."[126]

151. The Department argued that Mr. Cochrane's concern about an increase in litigation is generalized and could be raised regarding any change to a law or rule. Although a period of uncertainty surrounding implementation may carry with it a risk of increased litigation, in the Department's view, the rules provide clear direction and clarity that should reduce litigation because the standards for prescribing the medications specified in the rules will be clear. Because the stated purpose of the proposed rule is "to establish rules for health care provider treatment of workers' compensation injuries that reflect accepted medical standards for quality healthcare," the Department was not required to consider alternatives to rules, or standards. The Department did consider suggested alternatives to specific rule language and standards, and in some cases, incorporated those suggestions into the final language.[127]

152. Mr. Cochrane speculated that the medication parameters of the proposed rules will "dramatically increase the paperwork these doctors have to do" but cited no evidence to support his concern.[128]

153. The Department replied that current laws and rules, including the existing treatment parameter rules, already require health care providers to document in the medical record the necessity for medication prescription and treatment decisions.[129] Although the proposed rules were widely distributed to

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[123] *Id.*
[124] *Id.*
[125] Cochrane T., p. 67; Cochrane Reply, p. 5.
[126] Cochrane T., pp. 68-69, Cochrane Reply, p. 5.
[127] DOLI Response, p. 8, *citing* Minn. Stat. § 176.83, sub. 5. *See* Ex. 15A-15L.
[128] DOLI Response, p. 9; Cochrane Reply, pp. 5-6.
[129] *Id.*, *citing* Minn. Stat. §§ 176.135, subd. 7, Minn. R. 5221.6050, subp. 5, 5221.0100, subp. 1b, 5221.6200, subp. 10, Minnesota Board of Medical Practice, "Management of Prescribing" at http://www.state.mn.us/portal/mn/jsp/content.do?programid=536903225&id=-536886235&agency=BMP.

health care providers, provider organizations and insurers for several years before the Notice of Intent and Notice of Hearing were published, the Department had not received any comment from either a health care provider or an insurer expressing concerns that the proposed rules will dramatically increase paperwork or costs.[130]

154. Mr. Cochrane challenged the rule language requiring the use of generic drugs except in limited circumstances, arguing that cost was being elevated over effectiveness as a primary consideration for medication selection and that requiring generics "is telling a physician how they have to practice medicine."[131]

155. The Department responded that generics are as effective and safe as brand names, and are among the lowest cost and the most available medications. In addition, generic drugs are "routinely required by general health insurers as part of their formularies" and that the proposed rule language reflects accepted medical standards in Minnesota. Furthermore, Minn. R. 5221.4070 already requires that "a generically equivalent drug must be dispensed according to Minn. Stat. § 151.21" which requires a pharmacist to substitute a generically equivalent drug to the one prescribed unless the health care provider writes "dispense as written" on the prescription. The Department indicated that the rules already permit a provider to order a brand name using the "dispense as written" language when the provider believes a generic is not appropriate for medical reasons.[132]

156. Mr. Cochrane questioned the use of the phrase "not indicated" throughout the proposed rules, interpreting it to prohibit use of medications that are described as "not indicated."[133]

157. The Department stated "'indicated' is used throughout the treatment parameter rules to refer to treatment that is reasonable and necessary according to the accepted standard of quality medical care, and therefore compensable" under the workers' compensation statutes. According to the Department, "[t]reatment that is 'not indicated' does not reflect accepted standards of quality medical care and is not compensable under" the workers' compensation statutes, "unless the rule provides an alternative, there is a reason for departure" under the rules, or "a rare case exception applies under the *Jakka* case."[134]

158. Mr. Cochrane expressed concerns about the "prior authorization" requirement, "particularly with clients who are taking medications that have

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[130] DOLI Response, p. 9; *but see* Dr. Brian Livermore letter, attached to Cochrane letter (March 22, 2010). Dr. Livermore's letter was not submitted until March 22, the same day that the DOLI Response was submitted, so DOLI had not yet received Dr. Livermore's letter at the time the Response was written.

[131] Cochrane T., pp. 74, 77-78; *see* Cochrane Reply, p. 6.

[132] DOLI Response, p. 10, *citing* Minn. R. 5221.6050, subp. 8.

[133] Cochrane T., p. 79.

[134] DOLI Response, p. 10.

withdrawal effects if they are not allowed to get their refills in a timely manner." Mr. Cochrane explained that this is especially a problem "where there's a third-party payer" and "the patient has to go to their pharmacy to request a refill" and then "[t]he pharmacy has to send an e-mail or make a contact to the payer and then the payer has to usually contact the insurer to get it approved. . . ."[135]

159. The Department corrected Mr. Cochrane's characterization of the requirement, stating the language at Minn. R. 5221.6050, subp. 8 requires "prior notice" rather than "prior authorization." The Department says a pharmacy or health care provider "may choose to obtain prior authorization" but that is not required by the proposed rules, and is not limited to the workers' compensation system.[136]

160. Mr. Cochrane also objected to the quantity limitations in the medication rules. While he noted that "many medications are cheaper if bought in bulk," Mr. Cochrane acknowledged a problem exists because patients may not use all the medication they are issued. Mr. Cochrane again expressed the broad concern that the rules impinge on the discretion of physicians, and specifically questioned limitations on refills within the first four weeks.[137]

161. The Department responded that general insurers, outside the workers' compensation system, have similar, or even more restrictive limitations. The limits established by the rule avoid the larger problems of paying for more medication than is needed, as well as of patients being left with stores of excess medications which then pose certain dangers if they are used after they are out of date; and additional dangers related to inappropriate disposal. The rules are consistent with accepted medical standards for quality health care in that they encourage regular re-evaluation of treatment plans. The Department also pointed out that no provider has objected to the time-limit restrictions and emphasized that the MSRB reviewed and approved these restrictions.[138]

162. Mr. Cochrane also expressed concerns about limiting provider discretion by requiring providers to prescribe medication at the lowest clinically effective dose as determined by the provider. In addition to concerns about provider discretion, Mr. Cochrane again stated that this requirement would increase the paperwork burden.[139]

163. The Department noted that the rule was modified during the rule development process, "in response to a comment made by Mr. Cochrane, to reflect that the prescribing . . . provider determines the lowest clinically effective dose. The . . . provider has significant discretion to determine what is clinically effective. This is already the community standard of practice." Because of concerns about side effects, which increase in likelihood and severity with larger

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[135] Cochrane T., pp. 74-75; *see* Cochrane Reply, p. 6.
[136] DOLI Response, p. 11.
[137] Cochrane T., pp. 75-76, 80; *see* Cochrane Reply, p. 7.
[138] DOLI Response, pp. 11-12.
[139] Cochrane T., pp. 76-77.

doses, providers generally start with lose doses of medications. Again, no provider or insurer objected to this requirement, or said it would increase costs or paperwork.[140]

164. Mr. Cochrane criticized the medication parameters because the ineffectiveness of medications is defined as a failure to reduce a patient's pain by at least 50 percent but the proposed rule does not specify criteria for determining whether the patient's pain is reduced by that amount. Mr. Cochrane predicted that this lack of specific criteria would lead to disagreements about whether a medication is effective. Mr. Cochrane also questioned the requirement that there be one-week trials with various medications before another type of medication can be used.[141]

165. The Department noted that, because pain reports and pain relief are subjective, "[t]here is no requirement in the proposed rule that objective measures of pain relief must be measured or documented." It was Mr. Cochrane's concern expressed during the rule development process that resulted in the rule language specifically stating that reduction of pain by 50 percent is "determined by the prescribing health care provider." The Department observed that providers commonly ask patients to describe a pain level based on a 10-point verbal analogue scale. The rule does not require more and this data is not burdensome to elicit or record. In addition, the Department underscored that the one-week trial requirement is a minimum amount of time and that providers may elect longer medication trial periods. Nor do the trials require otherwise unnecessary office visits, because medication changes can be made by telephone consultation. Either a telephone consultation or an office visit is required for a medication change under current community standards of practice, so this is not imposing new burdens on providers or patients.[142]

166. Mr. Cochrane disputes the statement on page 27 of the SONAR that "there is no difference in effectiveness between various oral opioids . . . ." Mr. Cochrane believes that the medication treatment parameters in this area also interfere with provider discretion.[143]

167. Exhibit 16B demonstrates that there is no evidence that one opioid is more effective than others. The MSRB endorsed this finding, which has not been disputed by any health care provider.[144]

168. Mr. Cochrane alleged that price was the driving force in shaping the prescription medication rules, and that by infringing upon the provider's discretion, the health of patients could be compromised. He also paraphrased a portion of the workers' compensation statute (Minn. Stat. § 176.001), which provides, in part, that "it is a specific intent of the legislature that workers' comp

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[140] DOLI Response, p. 12.
[141] Cochrane, T. pp. 78-79; *see* Minn. R. 5221.6105, subp. 2.B. (2), 3.B. (2) and 4.B. (2).
[142] DOLI Response, p. 13.
[143] Cochrane T., p. 81; SONAR, p. 27.
[144] DOLI Response, p. 13, Ex. 16B, recommendation 2.

(sic) cases shall be decided on their merits" and that "the workers' compensation laws are . . . not to be given a broad, liberal construction in favor of" either the employer or the employee. Because he believes that the medication parameters favor the employer's interest in cost containment over the employees' interest in effective treatment, Mr. Cochrane does not think the rules meet the cited statutory imperative.[145]

169. The Department reiterated that effectiveness and safety were the primary concerns driving the development of the medication parameters; and that cost was only taken into account when medications were shown by the medical research to be equivalent to one another in effectiveness and safety.[146] The Department emphasized that Minn. Stat. § 176.001 states "that chapter 176 [is to] be interpreted so as to assure the quick and efficient delivery of . . . medical benefits to injured workers at a reasonable cost to the employers . . . ." The Department affirmed that the treatment parameter rules "reflect the accepted standards of quality medical care as evidenced by the medical research and recommended by the Medical Services Review Board."[147]

Dr. Brian Livermore Comments

170. In an undated letter submitted to the Administrative Law Judge by Mr. Cochrane on March 22, 2010, Dr. Brian Livermore expressed concerns that the Department has failed to define the problem the rules are intended to solve in a way that permits measurement of the program pursuant to the proposed rules.[148]

171. The Department responded by asserting that Dr. Livermore's focus on performance measurement is not a legal requirement. Minn. Stat. § 14.131 requires that the SONAR "describe how the agency, in developing the rules, considered and implemented the legislative policy supporting performance-based regulatory systems set forth in section 14.002." Section 14.002 requires state agencies, "whenever feasible" to "develop rules and regulatory programs 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." The Department pointed out that nothing in section 176.83, subd. 5 requires or even suggests that the Commissioner must be able to measure the performance of each requirement in the treatment parameter rules individually. Nor does the statutory authority permit the Commissioner to use treatment parameters only if treatment costs are excessive or out of control. On the contrary, the Department argues that the approach to workers' compensation laws is about balancing the employers' obligations with the employees' need for quality health care based on accepted medical standards.

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[145] Cochrane T., pp. 81-83; *see* Minn. Stat. § 176.001; *see* Cochrane Reply, p. 8.
[146] DOLI Response, p. 14; *see* SONAR, pages 21-30.
[147] DOLI Response, pp. 14-15.
[148] Livermore letter, pp. 1-2.

The Department argues that the Administrative Law Judge must view the need for and reasonableness of the proposed rules in this context.[149]

172. Dr. Livermore asserts that the "hassle factor" for providers administering the new rules is a cost that is not recognized by the Department in its submissions in this proceeding.[150]

173. Despite broad notice to the medical community, and in-depth involvement of a number of health care providers during the development of the rules, Dr. Livermore is the only physician to express this concern. As the Department emphasizes, the proposed rules reflect accepted standards of care, so most providers are already practicing in accordance with them. Dr. Lohman added that health care providers document their prescription and treatment decisions for a variety of reasons, not just to satisfy the workers' compensation rules; and that, as a medical educator, he is aware of "the importance placed on accurate and complete documentation of the diagnosis and treatment of patients as a fundamental skill necessary to the successful completion of training . . . ."[151]

174. Dr. Livermore discusses the standard of care as "an evolving consensus of the group to whom it is applied" and argues that it cannot be established as a static concept by these rules.[152]

175. The Department responds that the rules "reflect the accepted standard of care, [they do] not establish it." It reiterates that providers have significant discretion under the rules and that the rules are limited in scope – that is, they are used to determine a workers' compensation payer's liability for payment of treatment, not to establish a standard in a medical malpractice lawsuit, as Dr. Livermore suggests.[153]

176. Dr. Livermore raised questions about specific rule language requiring a trial of both ibuprofen and naproxen before other NSAIDs are prescribed. Dr. Lohman replied that Dr. Livermore's concerns arise from a hypothetical understanding of the medications in question, based on biochemical theory, rather than from clinical experience, which has shown that ibuprofen can be effective when naproxen has failed and vice versa, despite the fact that they are both in the same subclass of NSAIDs.[154]

177. Dr. Livermore also objected to allowing carisoprodol to be used as a muscle relaxant. Dr. Lohman responded, stating that the MSRB received this comment from others during the rulemaking process, reviewed the relevant

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[149] DOLI Reply, pp. 4-5.
[150] Livermore letter, p. 3.
[151] DOLI Reply, p. 5; Letter of Dr. William H. Lohman, M.D. (Lohman letter), pp. 1-2 (March 25, 2010).
[152] Livermore letter, p.3
[153] DOLI Reply, p. 5.
[154] Livermore letter, p. 4; Lohman letter, p. 3.

research and determined that, despite the risks noted by the FDA, use of carisoprodol should be permitted under the treatment parameters.[155]

178. Dr. Livermore criticized the makeup of the MSRB because many of the providers have practices involving "occupational medicine" and questioned whether the providers represent "different specialties" as contemplated by Minn. Stat. § 176.103, subd. 3. Dr. Lohman confirmed that five of the physician members of the MSRB do have practices in occupational medicine, but clarified that "this is a second board certification for all of them. They have primary board certification in a number of medical specialties including family medicine and internal medicine. One is . . . board certified in medical toxicology and another obtained a pharmacy degree before attending medical school."[156]

B. Comments in Support of the Rules: SFM Mutual Insurance Company

179. Margaret Kasting, Vice President of Claims Services at SFM, wrote in support of the proposed rules. Ms. Kasting stated that the proposed rules are "a reasonable manageable approach for all parties to mitigate misuse of drugs and to maximize their use for treatment and relief."[157]

180. Ms. Kasting said that "[g]reater medication use and more expensive medications have been factors in escalating medical costs in workers' compensation." Noting the cost statistics introduced by the Department concerning medication costs from 1997-2007, Ms. Kasting added that "they represent a fraction of the true costs incurred due to long-term disablement, medical complications, and diminution of quality of life brought on by poor medication management." Ms. Kasting characterized the medication treatment parameters as an "opportunity to benchmark and provide state of the art medication usage to injured workers."[158]

Administrative Law Judge Comments

181. The Administrative Law Judge noted during the hearing that part 5221.6305, subp. 1A identifies an ICD9-CM code as 733.7 while the SONAR identifies an ICD9-CM code as 733.3 and asked for clarification of this apparent conflict.

182. The Department replied that the reference to ICD9-CM code 733.7 in the proposed rules is correct and that no change in the proposed rule language is required.[159]

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[155] Livermore letter, p. 4; Lohman letter, p. 3.
[156] Livermore letter, pp. 4-5; Lohman letter, pp. 3-4.
[157] Letter of Margaret Kasting (Kasting letter), p. 1 (March 22, 2010)
[158] *Id.*, p. 2.
[159] DOLI Response, p. 15.

183. The Administrative Law Judge inquired during the hearing about why the word "physician" is used in proposed rule part 5221.6105, subp. 1 (lines 5.21 to 5.23 of the Revisor's Draft) rather than the phrase "health care provider" which is used elsewhere in the rule.

184. The Department agreed that the term should be "health care provider" instead of physician, because other types of health care providers, such as certified registered or clinical nurse specialists, have authority to prescribe medications under certain conditions. Furthermore, the workers' compensation statute defines "health care provider" to include a number of kinds of providers, including physicians, podiatrists, chiropractors, dentists and several others.[160] The Department proposes to correct the oversight, by modifying part 5221.6105, subp. 1 as follows:

> Scope: Subparts 2 to 4 apply to use of medication in an outpatient setting. Subparts 2 to 4 do not require a ~~physician~~ health care provider to prescribe any class of drugs in the treatment of any patient.

185. The Administrative Law Judge finds that this change is needed and reasonable and will provide consistency with applicable statutes and rules. It is not a substantial change from the rule as proposed.

186. At the hearing, the Administrative Law Judge asked whether there are other rules already in existence that have already been approved that could be viewed as interfering with or intruding into a health care provider's discretion.

187. The Department responded that the *Jacka* case involved allegations that workers' compensation treatment parameters impermissibly interfered with prescribed treatments for an employee's pain. The Court noted that "the basic medical treatment provisions of Minn. Stat. § 176.135, subd. 1 have never been interpreted to obligate the employer to pay for all treatment which cures or relieves, but only such medical treatment 'as may reasonably be required . . . .'"[161] In approving the challenged rules, the Minnesota Supreme Court found that 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."[162]

188. The Administrative Law Judge concludes that the proposed medication parameters meet the requirements for flexibility established by the Supreme Court in *Jacka.* The reasons for departure set forth in Minn. R. 5221.6050, subp. 8 apply to the medication parameters. The "rare case

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[160] Minn. Stat. § 176.011, sub. 12a.

[161] DOLI Response, p. 18, *quoting Jacka v. Coca-Cola Bottling Co.*, 580 N.W. 2d 27, 34-35 (Minn. 1998).

[162] ***Id., Jacka* at 36.**

exception" described by the *Jacka* decision applies as well.[163] Minn. Stat. § 176.106 provides procedures for appealing a decision by a payer that a particular treatment is not supported by the parameters. In addition, the rules allow significant provider discretion, including choices among categories of medications, types of equally-effective medications or medications that are not preferred if there is a medical contraindication to the preferred medications. The provider determines the lowest clinically-effective dose and determines whether the preferred medication is effective and whether to try another medication. Finally, the provider determines how long the medication should be used.[164]

189. The *Jacka* case establishes that treatment parameters are permissible, even if they are perceived to limit a provider's choices to some extent, as long as the rules include sufficient flexibility and there are procedural safeguards to protect the patient. These rules meet the *Jacka* standards.

Based on the Findings of Fact, the Administrative Law Judge makes the following:

CONCLUSIONS

1. The Department of Labor and Industry gave proper notice in this matter.

2. The Department has fulfilled the procedural requirements of Minn. Stat. § 14.14 and all other procedural requirements of law or rule.

3. The Department has demonstrated its statutory authority to adopt the proposed rules, and has fulfilled all other substantive requirements of law or rule within the meaning of Minn. Stat §§ 14.05, subd. 1, 14.15, subd. 3, and 14.50 (i) and (ii).

4. The Department has demonstrated the need for and reasonableness of the proposed rules by an affirmative presentation of facts in the record within the meaning of Minn. Stat. §§ 14.14, subd. 2 and 14.50 (iii).

5. Any Findings that might properly be termed Conclusions and any Conclusions that might properly be termed Findings are adopted as such.

6. A Finding or Conclusion of need and reasonableness in regard to any particular rule subsection does not preclude and should not discourage the Department from further modification of the proposed rules based upon an examination of the public comments, provided that the rule finally adopted is based upon facts as appearing in this rule hearing record.

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[163] In *Jacka*, the Court recognized that, because "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." *Jacka*, 580 N.W. 2d 27, 35-36.

[164] DOLI Response, p. 19. *See* Minn. R. 5221.6105, subp.1-4.

Based on the Conclusions, the Administrative Law Judge makes the following:

RECOMMENDATION

IT IS RECOMMENDED that the proposed rules be adopted, with an effective date five days after publication of the Notice of Adoption in the State Register.

Dated: April 27, 2010

RICHARD C. LUIS
Administrative Law Judge

Transcript Prepared by Kirby A. Kennedy & Associates
(One volume)
Gail Hinrichs, Court Reporter