Minnesota Department of Labor and Industry

STATEMENT OF NEED AND REASONABLENESS

Proposed Amendment to Rules Governing Workers' Compensation Treatment Parameters, *Minnesota Rules*, Parts 5221.6200 to 5221.6305, R-04120.

ALTERNATIVE FORMAT

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

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

STATUTORY AUTHORITY AND INTRODUCTION

Statutory Authority

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

Subd. 5. **Treatment standards for medical services.**

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

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

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

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

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

(4) criteria for diagnostic imaging procedures;

(5) criteria for inpatient hospitalization;

(6) criteria for treatment of chronic pain; and

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

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

(d) A rehabilitation provider who is determined by the rehabilitation review panel board, after hearing, to be consistently performing procedures or providing services at an excessive level or cost may be prohibited from receiving any further reimbursement for procedures or services provided under this chapter. A prohibition imposed on a provider under this subdivision may be grounds for revocation or suspension of the provider's license or certificate of registration to provide health care or rehabilitation service in Minnesota by the appropriate licensing or certifying body. The commissioner and Medical Services Review Board shall review excessive, inappropriate, or unnecessary health care provider treatment under section 176.103.

Additional authority for the rules is in Minnesota Statutes, section 176.103, subdivision 2, which provides that the commissioner, in consultation with the MSRB, "shall adopt rules defining standards of treatment, including inappropriate, unnecessary or excessive treatment and the sanctions to be imposed for inappropriate, unnecessary or excessive treatment."[1] The MSRB was established by Minnesota Statutes, section 176.103 in 1983. The MSRB is composed of the commissioner or commissioner's designee as an ex officio member, two chiropractic representatives, one hospital representative, one physical therapist, one registered nurse, one occupational therapist, six physicians of different specialties, one employee representative and one

[1] The rules governing the sanctioning process are in part 5221.8900.

employer or insurer representative.[2] Under Minnesota Statutes, section 176.103, the MSRB advises the Department about workers' compensation medical issues and is a liaison between the Department and the medical-provider community. As discussed in the Rule-by-Rule analysis section, the Department has extensively consulted with the MSRB in the development of the proposed rules.[3]

Finally, Minnesota Statutes, section 176.83, subdivisions 3 and 4 also provide authority. Subdivision 3 authorizes the commissioner to adopt rules, specifically, "[r]ules establishing standards for reviewing and evaluating the clinical consequences of services provided . . . to an employee by health care providers." Subdivision 4 authorizes the commissioner to adopt "[r]ules establishing standards and procedures for determining whether or not charges for health services or rehabilitation services rendered under this chapter are excessive."

Therefore, the Department has the necessary statutory authority to adopt the proposed amendments to the treatment parameter rules. [4]

Jacka v. Coca-Cola

The Department adopted permanent treatment parameter rules effective on January 4, 1995. In *Jacka v. Coca-Cola Bottling Co.*, 580 N.W.2d 27 (Minn. 1998), the Minnesota Supreme Court upheld the permanent treatment parameter rules. The Court found that the permanent treatment parameter rules did not exceed the Department's rulemaking authority and did not violate the due process clause of the United States and Minnesota constitutions. Specifically, the Court determined that the rules did not place absolute limits on the duration of treatment, the rule allowing departures (Minn. R. 5221.6050, subp. 8) did not state that it provides the exclusive means of departing from the rules and furthermore, the legislature clarified "how the rules should interact with the compensation judge's role" in the 1995 amendments. The court stated:

> In summary, we hold that the permanent treatment parameter rules adopted by D.O.L.I. are flexible and yielding and, therefore, ensure that reasonably priced, appropriate medical care will not be denied simply because of a time-line or rigid categories. At the same time, the rules are substantial enough to establish standards and procedures based on good medical practice that can be used to regulate provider abuses and reduce litigation over compensable treatment. We recognize, as the broader medical community has done, that rules establishing standards and procedures for managed care do not have to be at odds with the purpose of restoring the employee to good health. We conclude that these rules have struck the right balance between flexibility and substance and should have the respect, force and effect accorded other properly promulgated administrative rules."[5]

Format of the rules

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[2] A list of current MSRB members is at www.dli.mn.gov/PDF/msrb/msrbmembers.pdf. Note that MSRB members serve four-year terms, which may be renewed. Previous years' membership lists are available by contacting the agency contact person.

[3] The MSRB addressed this rule at the following MSRB meetings: 4/19/2007, 7/19/2007, 1/17/2008, 4/17/2008, 10/23/2008, 7/16/2009, 10/22/2009, 10/13/2011, 1/19/2012, 4/19/2012, 10/11/2012, 1/17/2013, 4/18/2013. These MSRB meeting minutes are at www.dli.mn.gov/ScsIddsSonarDocs.asp.

[4] Minnesota Statutes, section 14.125 does not apply because all sources of statutory authority were adopted and effective prior to January 1, 1996, and these are amendments to existing treatment parameter rules. See also Minnesota Laws 1995, chapter 233, article 2, section 58, regarding effective date.

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

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

These proposed rule amendments reorganize and clarify the existing rules related to morphine pumps and dorsal column stimulators (n.k.a. spinal cord stimulators ("SCS") and intrathecal drug delivery systems ("IDDS"), respectively) with some updates to be consistent with current accepted medical standards of practice. To better understand the proposed rule amendments, it is helpful to know how the amendments fit with the other rule parts. Because not all treatment parameter rule parts are being amended at this time, additional detail about other treatment parameter rule parts is in the 1994 Statement of Need and Reasonableness.[6]

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

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

- Part 5221.6030 incorporates by reference the International Classification of Diseases diagnostic coding manual referred to throughout the treatment parameters.[7] No amendments are proposed to this part.

- Part 5221.6040 provides definitions of terms used throughout the parameters. No amendments are proposed to this part.

- Part 5221.6050 provides general treatment parameters, including bases for departure from the parameters.[8] No amendments are proposed to this part.

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

- Part 5221.6105 governs the use of medications in the treatment of workers' compensation injuries. No amendments are proposed to this part.

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[6] The 1994 Statement of Need and Reasonableness is available from the Department contact person by phone at 651-284-5006 or by e-mail at dli.rules@state.mn.us or the Revisor's website at www.leg.mn/archive/sonar/SONAR-02317.pdf

[7] Minn. R. 5221.6030 provides in part: "The ICD-9-CM diagnostic codes referenced in parts 5221.6010 to 5221.6600 are contained in the fourth edition of the International Classification of Diseases, Clinical Modification, 1994, and corresponding annual updates. For information see www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/. The Department intends to update ICD-9 to ICD-10 in a subsequent rule proceeding.

[8] See footnote 14 on page 9 for the full rule part language.

- Part 5221.6200 (low back pain); 5221.6205 (neck pain); and 5221.6210 (thoracic back pain) provide parameters for the diagnosis and treatment of back and neck injuries.[9] The proposed amendments begin with subpart 6 of these rule parts. Generally, the first five subparts in each of these rule parts address diagnostic procedures, general treatment parameters, passive treatment modalities, active treatment modalities and therapeutic injections. In particular, subpart 2(B) identifies three treatment phases: the first phase is initial nonsurgical care, which may include any combination of passive, active, injection and medication treatment modalities; the second phase is surgical evaluation for patients with persistent symptoms following initial nonsurgical management ; the third phase is chronic management, when the injured worker is not a candidate for surgery or when there has not been complete resolution of symptoms following surgery. A patient cannot proceed to phase two until all appropriate nonsurgical options have been exhausted.[10]

  The proposed amendments reorganize and clarify the surgery parameters in the second phase to reflect the current standard of care for the evaluation and use of spinal cord stimulators and intrathecal drug delivery systems.

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

- Part 5221.6305 describes parameters for complex regional pain syndrome and related conditions (a.k.a. reflex sympathetic dystrophy and causalgia), which is a complication of injuries to upper and lower extremities. The proposed amendments to this rule part begin with subpart 3; the first two subparts in rule part 5221.6305 are scope and initial nonsurgical management.

  The proposed amendments update some of the surgery parameters to reflect the current standard of care for the use of spinal cord stimulators and intrathecal drug delivery systems.

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

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

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

REGULATORY ANALYSIS

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

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[9] Because of the close similarities among these three rule parts, they are addressed together here; the description of "subpart 2(B)" applies to all three rule parts.

[10] Minn. R. 5221.6200, subp. 2(B), 5221.6205, subp. 2(B) and 5221.6210, subp. 2(B).

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

The proposed rule amendments will likely affect injured workers and health care providers who treat injured workers with workers' compensation claims including physicians and psychologists. Additionally, the amendments will likely affect workers' compensation employers and insurers and certified workers' compensation managed care plans.

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

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

No additional costs to this Department or any other agency are anticipated for the implementation and enforcement of the proposed rules because they update existing rules according to current accepted medical standards. The Department consulted with MSRB members regarding costs to implement the proposed rules at the April 18, 2013, MSRB meeting.[11] The Department did not receive any responses. Based on the lack of responses, the Department concluded there are no implementation or enforcement costs to the agency or any other agency. The proposed rules update existing rules according to current accepted medical standards, which payers must already use to determine whether treatment of a work-related injury is appropriate and therefore compensable. The proposed rules should reduce litigation. Therefore, there should be no additional costs to other agencies, such as Minnesota Department of Administration and the Office of Administrative Hearings. There is no anticipated effect on state revenues.

A state agency may be affected by implementation and enforcement of the proposed rules to the extent a state agency is an affected party as described above. For example, a state agency may be a workers' compensation employer or insurer.

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

The purpose of the treatment parameters is stated in Minnesota Statutes, section 176.83, subd. 5 (a) and (c): "(a) In consultation with the Medical Services Review Board or the rehabilitation review panel, the commissioner shall adopt rules establishing standards and procedures for health care provider treatment. . . . The rules shall be used to determine whether a

[11] See MSRB meeting minutes at www.dli.mn.gov/ScsIddsSonarDocs.asp.

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

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

Following extensive consultation with the MSRB, the proposed rules update the treatment parameters to reflect current accepted medical standards for providing quality, cost effective health care to cure and relieve injured workers of the effects of their injuries as required by statute.[12] As a consequence, no less-costly or less-intrusive method for achieving this purpose has been identified.

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

As noted above, under Minnesota Statutes, section 176.83, subdivision 5, the purpose of the proposed rule amendments is to update the treatment parameters to reflect current accepted medical standards for providing quality and cost effective health care to cure and relieve injured workers of the effects of their injuries. The Department has widely distributed the draft rules as they were revised to interested persons, including providers and payers, and received comments in response. At its meetings, the MSRB extensively reviewed medical research to assist the Department in determining current accepted medical standards upon which the amendments are based, as more fully discussed later in this SONAR. The MSRB reviewed the proposed rules and the comments submitted by interested persons. The Department seriously considered all of the comments and incorporated all of the recommendations of the MSRB made in response to the comments. The Department is not proposing any amendments that were not supported by applicable medical research and the MSRB. A compilation of comments discussed by the MSRB and the MSRB responses shows the thorough vetting by the MSRB. These are available online at www.dli.mn.gov/ScsIddsSonarDocs.asp or by contacting the agency contact person specified on page 1.

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

The proposed rules reflect current accepted medical standards for quality and cost-effective health care as supported by research and recommended by the MSRB. There are no costs of compliance to providers or payers in that the rules do not require either group to spend money to comply. However, depending on the variables discussed under regulatory analysis (1) and changes discussed below, the proposed rules may reduce or increase revenue for providers, depending on whether they currently meet the standards of practice reflected in the proposed amendments. They may require additional payment by insurers that are not currently paying for

[12] Minnesota Statutes, section 176.83.

accepted medical treatment, and save costs for insurers who are currently paying for treatment that does not meet the standards. The rules should reduce costs for providers, injured workers, and workers' compensation payers to the extent that they reduce litigation and inappropriate denials of treatment. The cost analysis would be no different for governmental units because governmental units either act in the capacity of an employer, insurer or provider.

The current rules require a personality or psychosocial evaluation but do not indicate who may perform the evaluations. The proposed rules require a referred consultation by a psychologist or psychiatrist. Because the treating health care provider can no longer perform the psychological evaluation, there might be additional costs to payers to the extent that health care providers do not currently refer the psychological evaluation out. However, any additional costs as a result of a referred psychological evaluation are anticipated to be off-set by better patient selection, thus providing savings by avoiding unnecessary surgery or invasive procedures.

The proposed rules provide a specific trial screening period duration where the current rules do not; this does not add costs to comply with the proposed rule because a trial screening period is already required. Specifying the length of the trial screening period does not add costs to doing a trial screening period.

The Department solicited input on the cost of complying with the proposed amendments from members of the Medical Services Review Board on April 18, 2013, and from members of the Workers' Compensation Insurers Task Force on March 8, 2013. [13] The Department did not receive any responses to either inquiry; the Department concluded there are no costs of compliance identified.

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

The probable costs or consequences of not adopting the proposed rules are that injured workers may receive treatment that is not consistent with current accepted medical standards of practice for quality health care, payers might pay for treatment that does not meet those standards, or payers may deny payment for treatment that does meet the standards. Additionally, there would be no reduction in the number of workers' compensation disputes related to the treatment governed by the proposed rules.

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

There are no federal regulations governing Minnesota workers' compensation treatment.

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

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[13] The Workers' Compensation Insurers' Task Force ("WCITF") is a body of representatives of workers' compensation payers, including insurance companies, and employers who self-insure for their workers' compensation coverage (including government entities). The WCITF meets up to four times a year to facilitate the exchange of information about current workers' compensation issues between payers and with the Department. The WCITF is not created by statute. The Department contacted the WCITF via email to inquire about costs.

There are no cumulative effects of the rule with other federal or state regulations as there are no federal or state regulations related to the specific purpose of the rule.

PERFORMANCE-BASED RULES

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

According to Minnesota Statutes, section 176.83, subdivision 5: "The rules shall be used to determine whether a provider of health care services . . . . is performing procedures or providing services at a level or with a frequency that is excessive, unnecessary, or inappropriate under section 176.135, subdivision 1, based upon accepted medical standards for quality health care and accepted rehabilitation standards." As is evident by this statute, the treatment parameters are performance-based rules. The treatment parameters provide health care providers with flexibility to determine what treatment to provide based on the unique needs of each injured worker within the guidelines set forth in the treatment parameters. They do not rigidly proscribe or prescribe specific treatment, but rather reflect what the medical research and the Medical Services Review Board have identified as acceptable standards of quality health care.

The bases for departing from the parameters also apply to the proposed amendments.[14] As stated by the Minnesota Supreme Court in *Jacka*, ". . . the treatment parameters are flexible and yielding and, therefore, ensure that reasonably priced, appropriate medical care will not be denied simply because of a time-line or rigid categories. At the same time, the rules are substantial enough to establish standards and procedures based on good medical practice that can be used to regulate provider abuses and reduce litigation over compensable treatment." *Jacka v. Coca Cola Bottling Co.*, 580 N.W.2d 27, 36 (Minn. 1998).

ADDITIONAL NOTICE

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

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

reviewed by the Office of Administrative Hearings and approved, contingent upon notice being provided to specific workers' compensation payors (see item 14 below) in an amended order dated May 6, 2014, issued by Judge Ann C. O'Reilly.

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

1. The members of the Workers' Compensation Advisory Council, which consists of labor, employer, and legislative representatives, established pursuant to Minnesota Statutes, section 175.007, and persons who have requested to receive notice of WCAC meetings;

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

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

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

5. Persons and organizations who are on the Department's e-mail list for medical providers;

6. Persons and organizations who are on the Department's e-mail list for workers' compensation adjusters;

7. Attorneys on the Office of Administrative Hearing's e-mail list for workers' compensation attorneys;

8 The Minnesota Medical Association, the Minnesota Chiropractic Association, the Minnesota Nurses Association, the Minnesota Board of Nursing, the Minnesota Chapter of the American Physical Therapy Association, the Minnesota Occupational Therapy Association, the Minnesota Psychological Association, the Minnesota Psychiatric Society and the Minnesota Hospital Association;

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

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

11. Those who have commented on the draft amendments since the Request for Comment was

published on February 11, 2013;

12. Pain clinics in Minnesota identified as specializing in treatment of chronic pain likely to be interested in this rule;

13. The Department will place the Notice of Intent to Adopt the proposed rules, the proposed rule amendments, and the Statement of Need and Reasonableness on the department's rule docket Web site: www.dli.mn.gov/PDF/docket/5221_6020_8900TrtmPar_3.pdf; and

14. The Minnesota Workers' Compensation Assigned Risk Plan, Berkley Assigned Risk Services, RTW, Inc., and SFM.

The Department's Notice Plan also includes giving notice required by statute. The proposed rules and Notice of Intent to Adopt will be mailed or emailed to everyone who has registered to be on the Department's rulemaking mailing lists under Minnesota Statutes, section 14.14, subdivision 1a. Notice will also be given to the Legislature as required by Minnesota Statutes, section 14.116.

CONSULT WITH MMB ON LOCAL GOVERNMENT IMPACT

Minnesota Statutes, section 14.131 requires the agency to consult with the Commissioner of Minnesota Management and Budget to help evaluate the fiscal impact and benefits of proposed rules on local governments. As required, the Department has consulted with the Commissioner of Minnesota Management and Budget. The Department sent a letter to the Executive Budget Officer dated March 19, 2014, requesting help evaluating the fiscal impact and fiscal benefits of the proposed rule on units of local government. On April 16, 2014, the Executive Budget Officer opined that, "Based upon the information provided to me by the Department of Labor and Industry, there does not appear to be significant costs to local units of government as a result of this proposed rule."

DETERMINATION ABOUT RULES REQUIRING LOCAL IMPLEMENTATION.

Under Minnesota Statutes, section 14.128, agencies must determine if a town, county, or home rule charter or statutory city will be required to adopt or amend an ordinance or other regulation to comply with a proposed agency rule. The Department has determined that no local government will be required to adopt or amend an ordinance or other regulation to comply with the proposed amendments because local governments are required to comply with the workers compensation law as set forth in Minnesota Statutes, chapter 176, including the treatment parameters adopted under Minnesota Statutes, section 176.83, subdivision 5.[15] Therefore, no ordinance or regulation is required to implement these rules.

COST OF COMPLYING FOR SMALL BUSINESS OR CITY

Agency Determination of Cost

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

As required by Minnesota Statutes, section 14.127, the Department has considered whether the cost of complying with the proposed rules in the first year after the rules take effect will exceed $25,000 for any small business or small city.[16] The Department has determined that the cost of complying with the proposed rules in the first year after the rules take effect will not exceed $25,000 for any small business or small city.

Small businesses potentially affected by the proposed rules would most likely be small health care provider offices. As discussed above in the regulatory analysis section, the proposed rules do not require small-business health care providers to provide any particular treatment or spend money to comply; the proposed rules simply describe what is accepted medical practice in evaluating what is appropriate treatment for injured workers for purposes of payment by workers' compensation insurers and self-insured employers. Since workers' compensation health care is a relatively small percentage (less than 2%) of the cost of general medical care and the procedures addressed by these amendments are rare, it is unlikely that the proposed rules will result in reduction in revenue of greater than $25,000 in the first year for any small-business health care provider who is currently providing nonstandard treatment. [17]

Small cities may also be affected as employers of injured workers. However, small cities typically do not pay workers' compensation claims directly. Furthermore, this is a rare procedure, and any additional costs as a result of the amendments would likely be offset by savings from better patient selection, reduced number of disputes and reduced improper use of the procedures.

Therefore, the Department has determined that the cost of complying with the proposed rules in the first (or any) year after the rules take effect will not exceed $25,000 for any small business or small city.

EFFECT ON FARMING OPERATIONS AND CHICANO/LATINO PEOPLE

Minnesota Statutes, section 14.111 imposes additional requirements if the proposed rules affect farming operations. These proposed amendments will not have any significant impact on farming operations, and therefore the requirements of Minnesota Statutes, section14.111 do not apply.

The requirements of Minnesota Statutes, section 3.9223 do not apply because the rules do not have their primary effect on Chicano/Latino people.

LIST OF WITNESSES

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

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

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

[17] Workers' compensation total medical expenditures were an estimated $549 million in 2012. (Department of Labor and Industry, Research and Statistics Unit.) Total state health expenditures in Minnesota (public and private) were estimated at $41.3 billion for 2012 by the Minnesota Department of Health (Minnesota Health Care Spending and Projections, 2011, available at: www.health.state.mn.us/divs/hpsc/hep/publications/costs/healthspending2013.pdf.

NOTE ON SOURCES CITED IN FOOTNOTES

A number of articles and documents are cited in footnotes throughout this SONAR. Some of the footnotes reference Appendices at the end of this SONAR:

- Appendix A contains Summary Tables of Medical Evidence on SCS (spinal cord stimulators).
- Appendix B contains Summary Tables of Medical Evidence on IDDS (intrathecal drug delivery systems).
- Appendix C is a Glossary of Terms that translates acronyms used in the medical research and throughout this document.

When sources are cited in footnotes, information regarding availability of the cited sources is included in the footnote. Many of the footnote items are available review on the Department's rulemaking web page at www.dli.mn.gov/ScsIddsSonarDocs.asp or by contacting the agency contact person. The medical studies cited in Appendices A and B are copyrighted materials; they are available to view at the Department of Labor and Industry upon request.

BACKGROUND AND RULE DEVELOPMENT PROCESS FOR PROPOSED AMENDMENTS[18]

These rules provide updates to the treatment parameters for the appropriate use of spinal cord stimulators (SCS) and intrathecal drug delivery systems (IDDS) in the surgical treatment of workers' compensation injuries. Providing updates to the treatment parameters for these treatment devices is necessary so that the rules continue to reflect advances in medical science and changes in the standards of practice in the medical community.

The Department has developed these updates to the rules based on recommendations made by the MSRB pursuant to Minnesota Statutes, section 176.103 and 176.83, subdivision 5. The MSRB made their recommendations after considering the results of scientific studies, comments from interested parties in the community, and their own experience with treatment of work related injuries. [19] The scientific studies reviewed by the MSRB were identified by the Department's medical consultant, Dr. William Lohman, using an evidence-based medicine approach endorsed by the MSRB. [20]

For each of the devices, spinal cord stimulators and intrathecal drug delivery systems, the Department identified scientific studies for the MSRB to review that addressed a specific clinical question of relevance:

> What is the proper use of spinal cord stimulators in the treatment of chronic spinal pain and complex regional pain syndrome?[21]

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[18] Much of the information in this background and rule development process section is from the "REPORT TO THE MSRB. SPINAL CORD STIMULATORS. September 2, 2008" adopted October 23, 2008, and "REPORT TO THE MSRB. INTRATHECAL DRUG DELIVERY SYSTEMS. July 16, 2009" adopted October 22, 2009. See www.dli.mn.gov/ScsIddsSonarDocs.asp.

[19] See comments at: www.dli.mn.gov/ScsIddsSonarDocs.asp.

[20] Minnesota Statutes, section 176.103, subd. 1 states: "The commissioner shall hire a medical consultant to assist in the administration of this section. The medical consultant shall be a doctor of medicine licensed under the laws of Minnesota. The medical consultant shall perform all duties assigned by the commissioner relating to the supervision of the total continuum of care of injured employees and shall also advise the department on matters on which the commissioner requires the consultant's advice or if the consultant deems it appropriate."

[21] References to complex regional pain syndrome also include causalgia, reflex sympathetic dystrophy and cognate disorders.

This overall question was addressed by identifying and synthesizing the best available medical data on the following specific issues:

- Are spinal cord stimulators ***effective*** in the treatment of chronic spinal pain and complex regional pain syndrome?
- Are spinal cord stimulators ***safe***?
- What is the appropriate trial period for determining if a patient will have a favorable response to treatment with a spinal cord stimulator?
- What are the appropriate criteria for judging whether a patient had a favorable response during a trial period?

In identifying the scientific literature that addressed these issues, the Department used the evidence-based medicine approach endorsed by the MSRB. Evidence-based medicine "is the process of systematically reviewing, appraising and using clinical research findings to aid the delivery of optimum clinical care to patients."[22] Evidence-based medicine supplements clinical intuition, observations from personal clinical experience, and hypothetical arguments based on pathophysiological principles as the bases for clinical decision-making. Evidence from systematic surveys and critical appraisals of peer-reviewed, methodologically sound clinical research was gathered, reviewed and synthesized by the Department's medical consultant using standardized, objective protocols based on rules of evidence. The MSRB then analyzed that information to make conclusions and ultimately recommendations to the Department.

Key components of the evidence-based medicine approach used by the Department at the direction of the MSRB are:

a) the systematic search for, and retrieval of, all the relevant medical literature regarding the use of these devices for musculoskeletal disorders, which addresses one or more of the specific clinical questions listed above;
b) sorting the retrieved literature by level of evidence;
c) critical appraisal of that literature to systematically examine its validity, results and relevance; and,
d) synthesis of the findings, with a grade of recommendation.

Medical literature search and review process

The search and retrieval of the medical literature was done using computerized search engines and on-line bibliographical database searches of the medical literature. In order to maximize the efficient use of time and resources, a number of strategies were adopted to target the searches to the best and most recent evidence by using a step-wise search process.

First, the Department searched the medical literature by "level of evidence." The levels of evidence (Table 1) are a hierarchy representing the strength of the conclusion that can be drawn from a study of that type. Level I evidence is the most compelling, while Level VI evidence is the weakest. The Department restricted the initial search of the medical literature to Level I evidence – systematic reviews and meta-analyses. Not only is this the strongest evidence available but it also has the additional property of representing the other levels of evidence. A systematic review is itself a review of the medical literature conducted using methods (including systematic search and

[22] Rosenberg W, Donald A. "Evidence-based medicine: an approach to clinical problem solving" BMJ 1995; 310(6987): 1122–1126; Strauss SE, Richardson WS, Glasziou P, Haynes RB Evidence-based Medicine: How to Practice and Teach EBM Edinburgh; Churchill Livingstone, 2005. Available at the University of Minnesota Biomedical Library.

retrieval of all the relevant primary source evidence and critical appraisal of the evidence found using standardized techniques) designed to minimize the likelihood of bias in the results. A meta-analysis is a systematic review in which quantitative methods are used to summarize the results of the review.[23]

Table 1: Levels of Evidence[24]

I	systematic reviews/meta-analyses of multiple randomized, controlled trials
II	randomized, controlled trials
IIIA	controlled studies without randomization
IIIB	other types of quasi-experimental study
IV	non-experimental descriptive studies
V	case series
VI	expert committee reports or opinions/clinical experience of respected authorities, or both

Using Level I evidence meant that the MSRB could review efforts by researchers who had already searched the medical literature for Level III and higher evidence, retrieved and reviewed these studies to determine their relevance and methodological quality, abstracted and evaluated their findings, synthesized the results, and submitted their findings to a peer-review process for publication in a scientific journal. This allowed the MSRB to leverage its resources to review a much larger body of evidence.

Second, the Department focused the search on the most recent studies, so as to best represent the most current information. The search began with articles from 1990 going forward. The Department conducted the literature searches in two electronic bibliographic databases:

1. Medline through the PubMed portal at www.ncbi.nlm.nih.gov/entrez/query.fcgi ; and,
2. The Cochrane Library (The Cochrane Database of Systematic Reviews, Database of Abstracts of reviews of Effects, and The Cochrane Central Register of Controlled Trials) through the Lumina portal of the University of Minnesota Libraries at tc.liblink.umn.edu/sfx_local/a-z/default.

PubMed is a service of the National Library of Medicine (NLM) available via the National Center of Biotechnology's Entrez retrieval system. PubMed is a public access search engine for MEDLINE, NLM's premier bibliographic database for medical literature. MEDLINE contains bibliographic citations and author abstracts from more than 4,800 biomedical journals published in the United States and 70 other countries. The database contains over 12 million citations dating back to mid-1960.

The Cochrane Library consists of a regularly updated collection of evidence-based-medicine databases created by the Cochrane Collaboration, an international non-profit independent organization of health care providers and health care researchers. The Cochrane Library is a collection of evidence-based-medicine databases, which is up-dated quarterly from the best available information about healthcare interventions found in both

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[23] Guyatt G, Rennie D Users' Guides to the Medical Literature. Essentials of Evidence-Based Clinical Practice AMA Press, 2002; FOCUS "Critical Appraisal Tool." Available to view at the Minnesota Department of Labor and Industry upon request.

[24] Adapted from Phillips B, Ball C, Sackett D, Badenoch D, Straus S, Haynes B, Dawes M "Levels of Evidence and Grades of Recommendation" Oxford Centre for Evidence-based Medicine, 1998. Available at the University of Minnesota Biomedical Library.

published and unpublished medical studies from around the world. The Cochrane Database of Systematic Reviews (CDSR) is the collection of systematic reviews done by Cochrane Collaboration work groups. The Database of Abstracts of Reviews of Effects (DARE) contains summaries of systematic reviews done by others, which have met strict quality criteria established by the Cochrane Collaboration. Included reviews have to be about the effects of interventions. The Cochrane Central Register of Controlled Trials (CENTRAL) includes details of clinical trials found in bibliographic databases (notably MEDLINE and EMBASE), and other published and unpublished sources.

The Cochrane Library search for systematic reviews used the Cochrane Database of Systematic Reviews with key words identifying each device.

A sufficient number of studies were obtained for each device using these strategies so that further extensions of the search were not needed. For each device, the results of each search were saved as Word documents identifying the parameters of the search and displaying the title of the articles retrieved, their authors, and their journal citations.

Pre-analysis selection of medical literature

The Department used the above inclusion criteria developed by the MSRB to determine which of the studies found in the automated searches would be retrieved for further analysis. First, the title of the article was reviewed to confirm that the article was about the therapeutic use of the devices in humans. References for all the articles chosen for further review based on their titles were combined in an Excel database. The abstracts and bibliographical data were then retrieved for articles meeting the first screening, hyperlinked to the Excel database, and reviewed to determine if:

- the article addressed one of the clinical questions of relevance;
- the article represented a study of the appropriate level of evidence;
- it was a study published during the search time frame;
- the article was published in English; and,
- the article was available on-line through the University of Minnesota Bio-Medical Library.

Articles selected for inclusion after a review of the article abstract were retrieved in electronic format from the University of Minnesota Bio-Medical Library through the Lumina portal. An electronic database was created listing the authors, the title of the article, and the journal reference. Each article's full text was then hyperlinked to its citation in the Department database.

Additional computerized searches for treatment guidelines, using the key words "pain" and "spinal cord stimulation" or "intrathecal drug delivery system" were conducted at the websites of organizations known to be active in guideline development, appraisal, or cataloging:

Country	***Name of organization***	***Website***
Netherlands	Dutch Institute for Healthcare Improvement	www.cbo.nl
New Zealand	New Zealand Guidelines Group	www.nzgg.org.nz
	Accident Compensation Corporation	www.acc.co.nz/index.htm
Scotland	Scottish Intercollegiate Network	www.sign.ac.uk
Sweden	Swedish Council on Technology Assessment in Health Care	www.sbu.se
UK	National Library of Guidelines	www.evidence.nhs.uk/
USA	National Institutes of Health Consensus Development Program	consensus.nih.gov
	National Guideline Clearinghouse	www.guideline.gov
	Agency for Healthcare research & Quality	www.ahrq.gov/

Finally, the computerized searches were supplemented by hand searches of the bibliographies of key articles (particularly systematic reviews and guidelines) and with articles submitted by interested parties.

All of the retrieved articles were evaluated for quality using criteria that were appropriate to the study type.

For systematic reviews (Level I evidence), the criteria were adapted from recommendations for critical appraisal of systematic reviews, found in the peer-reviewed literature and textbooks of evidence-based medicine.[25] The chosen criteria represent the key quality issues in systematic reviews:

Was there a comprehensive search for studies using appropriate sources?
Were studies chosen based on explicit and appropriate criteria?
Was there a systematic evaluation of the evidence using appropriate methods?
Was the data analyzed appropriately?

For randomized controlled trials (Level II evidence), the quality criteria were adapted from recommendations for critical appraisal of randomized controlled trials, found in the peer-reviewed literature and textbooks of evidence-based medicine.[26] The chosen criteria represent the key quality issues in randomized controlled trials:

Were adequate steps taken to minimize any bias in the results of the trial?
Were the results appropriately analyzed for the relevant outcomes?
Were the patients and treatments well-enough described to allow full comparisons with other trials?

For guidelines, the quality criteria were derived from the instrument developed by The AGREE Collaboration started in 1998 as a research project under the Biomedicine and Health Research (BIOMED 2) Programme, funded by the European Union[27]: The chosen criteria represent the key quality issues in guideline development:

Was there involvement of all relevant stakeholders?
Were systematic methods used to identify, appraise and synthesize the supporting evidence?
Are the recommendations clear and supported by the evidence?

Article scoring

Articles were scored "yes", "no", "cannot determine" on each item. A summary score was determined by adding together the "yes" responses, divided by the total number of criteria (22 in

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[25] Oxman AD, Cook DJ, Guyatt GH "Users' guides to the medical literature. VI How to use an overview" Journal of the American Medical Association 1994; 272(17): 1367-1371; FOCUS "Critical Appraisal Tool." Available at the University of Minnesota Biomedical Library.
Crombie IK The Pocket Guide to Critical Appraisal: A Handbook for Healthcare Professionals London; BMJ Publishing Group, 1996. Available at the University of Minnesota Biomedical Library.

[26] Oxman AD, Cook DJ, Guyatt GH "Users' guides to the medical literature. VI How to use an overview" Journal of the American Medical Association 1994; 272(17): 1367-1371; Available at the University of Minnesota Biomedical Library.
Guyatt GH, Sackett DL, Cook DJ "Users' guides to the medical literature. II. How to use an article about therapy or prevention. A. Are the results of the study valid?" Journal of the American Medical Association 1993; 270(21): 2598-601;
Crombie IK The Pocket Guide to Critical Appraisal: A Handbook for Healthcare Professionals London; BMJ Publishing Group, 1996. Available at the University of Minnesota Biomedical Library.

[27] www.agreetrust.org/about-the-agree-enterprise/agree-research-teams/agree-collaboration/

the case of systematic reviews, 12 in the case of randomized controlled trials, and 23 in the case of guidelines) and then expressed as a percentage. This scoring system is a short hand way of indicating overall study quality and is similar to systems used in many systematic reviews for evaluating primary source literature.

In addition, the author's conclusions regarding the device were abstracted, along with the primary literature relied upon by the author(s) of the systematic review in reaching their conclusions. The results of the quality review, the author's conclusions – along with the number of studies supporting each conclusion – and the bibliography of the primary source literature were entered into a "Summary Sheet" for each article. These Summary Sheets were then also hyperlinked to the Department database.

The abstracted conclusions from each article, with the number of supporting studies (when applicable), were also transferred to spreadsheets. There, the conclusions were arranged thematically into columns for comparison across studies. The primary source articles obtained from each systematic review and guideline were combined in a separate database and cross-referenced by article. The studies compared SCS and IDDS with other palliative treatments.

MSRB reports

Draft conclusions of the medical evidence and proposed MSRB recommendations were derived from the findings and set out in two reports to the MSRB; one on IDDS and one on SCS.[28]

The reports, as well as all of the work products of the process, were submitted to the MSRB for review, editing and correction as needed. After review, the MSRB adopted the final reports as representing their conclusions from the evidence and their general recommendations to the Department based on that evidence. The summary tables that contain the conclusions from the medical evidence and the supporting literature on SCS and IDDS from the two reports as adopted by the MSRB are attached as Appendices A and B. Appendix A shows the summary tables of medical evidence on SCS. Appendix B shows the summary tables of medical evidence on IDDS.

After the MSRB approved the conclusions and recommendations of the reports, draft rules were prepared by the Department translating the general recommendations into specific changes to the current treatment parameters. These draft rules were then circulated to the MSRB members. The MSRB reviewed these drafts to determine if the specifics of the proposed rules appropriately represented their recommendations. The draft rules were also circulated to interested parties in the community. All of the comments and suggestions received from members of the community throughout the discussion process were collated and presented to the MSRB for consideration.[29] Based on these deliberations using both the scientific evidence available as represented by the reports and the collective experience of its members when necessary to supplement the available evidence, the MSRB made further recommendations that were incorporated into subsequent rule drafts. These were then circulated and the process of comment and reconsideration by the MSRB was repeated until the MSRB concluded that they had reached a final set of recommendations.

Medical literature conclusion

In summary, the medical conclusions of the reports derived from the research and as adopted by the MSRB are:

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[28] See "REPORT TO THE MSRB. SPINAL CORD STIMULATORS. September 2, 2008" adopted October 23, 2008, and "REPORT TO THE MSRB. INTRATHECAL DRUG DELIVERY SYSTEMS. July 16, 2009" adopted October 22, 2009. See www.dli.mn.gov/ScsIddsSonarDocs.asp

[29] See www.dli.mn.gov/ScsIddsSonarDocs.asp

SCS, as compared to other palliative treatment options:[30]

1. There is limited evidence (predominantly from case series and two RCTs) that permanently implanted spinal cord stimulators are effective in achieving at least a 50% reduction in pain in 50%- 60% of patients with chronic spinal conditions who have a positive response during a screening trial period.[31, 32]
2. There is limited evidence (predominantly from case series and one RCT) that permanently implanted spinal cord stimulators are effective in achieving at least a 50% reduction in pain in 50%- 67% of patients with complex regional pain syndrome who have a positive response during a screening trial period.[33]
3. There is inconsistent evidence as to whether spinal cord stimulators improve other clinical outcomes in patients with either chronic spinal conditions or complex regional pain syndrome.[34, 35]
4. There is inconsistent evidence as to whether spinal cord stimulators are more effective than alternatives for relieving pain in patients with either chronic spinal conditions or complex regional pain syndrome.[36]
5. Complications occur in 1/3 to 1/2 of cases, but are often mild and mostly involving problems with the equipment or local infection. But up to 1/3 of patients will require re-operation in the first two years due to complications.[37]
6. Trial screening periods in the reported case series and clinical trials have lasted from 1 day up to 30 days, with most lasting from 3 to 7 days. There is no information to judge whether the length of the trial period influences the reported efficacy of spinal cord stimulation.[38]
7. The most common measure of success in the trial period was relief of pain and the most common criteria was pain relief of at least 50%.[39]

IDDS, as compared to other palliative treatment options:

1. There is limited evidence that permanently implanted intrathecal drug delivery systems are effective in the *short-term* in achieving at least a 50% reduction in pain in some patients with chronic pain conditions who have a positive response during a screening trial period.[40]
2. There is no reliable evidence that permanently implanted intrathecal drug delivery systems are effective in the *long-term* in achieving at least a 50% reduction in pain in patients with chronic pain conditions who have a positive response during a screening trial period.[41, 42]
3. Economic models indicate that permanently implanted intrathecal drug delivery systems are cost-effective in treating patients who have had at least a 50% reduction in pain during a screening trial period.[43]
4. There is no reliable evidence that permanently implanted intrathecal drug delivery systems

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[30] Palliative treatments are treatments that relieve symptoms rather than cure an ailment.
[31] See Appendix A, page 28.
[32] Limited evidence means there may have been some evidence but not a lot of it; or if there was a lot of evidence, it did not have high quality. Limited evidence is stronger than inconsistent evidence.
[33] See Appendix A, page 28.
[34] Inconsistent evidence means that research studies, either as a collection or within a study, came to contradictory conclusions.
[35] See Appendix A, page 29.
[36] See Appendix A, page 29-30.
[37] See Appendix A, page 30.
[38] See Appendix A, page 31.
[39] See Appendix A, page 31.
[40] See Appendix B, page 33
[41] No reliable evidence means there were methodological concerns or the research did not adequately address the question the MSRB posed.
[42] See Appendix B, page 34.
[43] See Appendix B, page 34.

are more effective than alternative treatment options.[44]

5. Complications occur in 1/3 or more of cases. Most are side effects of the medication delivered by the system, are dose-dependent, and sometimes improve with continued administration. Catheter, procedure and device related complications are relatively uncommon.[45]
6. Trial screening periods in the reported case series and clinical trials have lasted from a single injection up to 10 days, with most being 24 hours or less. There is no information to judge whether the length of the trial period influences the reported efficacy of implanted intrathecal drug delivery systems.[46]
7. The most common measure of success in the trial period was relief of pain and the most common criteria was pain relief of at least 50%.[47]
8. There is limited evidence to support the use of morphine, hydromorphone and ziconotide as first line agents in intrathecal drug delivery systems.[48]

MSRB recommendations

Based on these medical conclusions and their deliberations, the MSRB adopted these recommendations, which formed the bases for these proposed rule amendments:

SCS:[49]

I. Spinal cord stimulators can effectively relieve pain in some patients with chronic spinal pain or complex regional pain syndrome.

II. An adequate trial period of at least three days is needed to determine who might benefit from spinal cord stimulation.

III. Adequate pain relief of at least 50% during the trial period is needed to determine if a patient might benefit from spinal cord stimulation.

IDDS:[50]

I. Intrathecal drug delivery systems can effectively relieve pain in selected patients with chronic pain when other options have failed – at least in the short term.

II. An adequate trial period of 24 hours is needed to determine who might benefit from an intrathecal drug delivery system.

III. Adequate pain relief of at least 50% during the trial period is needed to determine if a patient might benefit from an intrathecal drug delivery system.

These recommendations adopted by the MSRB provide the basis for the proposed rule

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[44] See Appendix B, page 34.
[45] See Appendix B, page 35.
[46] See Appendix B, page 36.
[47] See Appendix B, page 37.
[48] See Appendix B, page 37.
[49] See "REPORT TO THE MSRB. SPINAL CORD STIMULATORS. September 2, 2008" adopted October 23, 2008, page 15 at www.dli.mn.gov/ScsIddsSonarDocs.asp.
[50] See "REPORT TO THE MSRB. INTRATHECAL DRUG DELIVERY SYSTEMS. July 16, 2009" adopted October 22, 2009, page 16 at www.dli.mn.gov/ScsIddsSonarDocs.asp.

amendments described below.

RULE-BY-RULE ANALYSIS

5221.6200 Low Back Pain
5221.6205 Neck Pain
5221.6210 Thoracic Back Pain.

Note: These three rule parts have essentially the same language and requirements in their respective subparts but apply to the three different parts of spine pain (low back, neck and thoracic back). Because of the language similarities among the three parts, they are all addressed at once here. The MSRB reviewed medical evidence that addressed all three pain areas and concluded the treatment should be the same for all three body parts.[51]

Subp. 6. Surgery, including decompression procedures and arthrodesis. This subpart identifies the treatment parameters and notification requirement that must be met before surgery may be performed to treat back and neck pain. Generally, subpart 6 establishes the prerequisite treatment and conditions necessary before surgery, repeat surgery, spinal cord stimulators and intrathecal drug delivery systems can be used for back and neck pain. There are no proposed amendments to this paragraph.

Item A. Subitem(1) The terminology in this subitem, "dorsal column stimulator" and "morphine pump," are replaced with current accepted medical terminology "spinal cord stimulator" and "intrathecal drug delivery system," respectively. A dorsal column stimulator is the same thing as a spinal cord stimulator. A morphine pump is a specific type of intrathecal drug delivery system; because the intent is not to limit the device type, i.e., to a morphine pump, intrathecal drug delivery system is a more accurate term to use here.

Item B. No amendments are proposed to this item.

Explanation of proposed amendments to SCS rule portions

Note: The current rules are organized in a way where SCS and IDDS treatment options are sometimes addressed together and sometimes separately. Both treatments are addressed in subpart 6 item C.[52] Both treatments require a second opinion to confirm that treatment is indicated and within the treatment parameters and a personality or psychosocial evaluation that indicates the patient is likely to benefit from the treatment.

Additionally, SCS is indicated only for patients with *neuropathic pain* who are not candidates for any other surgical therapy and have had a favorable response to a trial screening period; IDDS is indicated only for patients with *somatic pain* who are not candidates for any other surgical therapy and have had a favorable response to a trial screening period.

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[51] See "REPORT TO THE MSRB. SPINAL CORD STIMULATORS. September 2, 2008" adopted October 23, 2008, and "REPORT TO THE MSRB. INTRATHECAL DRUG DELIVERY SYSTEMS. July 16, 2009" adopted October 22, 2009. See also MSRB meeting minutes. At: www.dli.mn.gov/ScsIddsSonarDocs.asp

[52] The current rule uses the terms "dorsal column stimulator" and "morphine pump" instead of "SCS" and "IDDS," respectively, as explained above. To more easily see the similarities and for a more accurate comparison, "SCS" and "IDDS" are used here when referring to the current treatment parameters and throughout this document.

The current requirements are largely maintained in the proposed rules but are further refined to make the parameters clearer and updated to reflect current accepted medical standards. The proposed rules address SCS and IDDS separately in subpart 6 items C and D, respectively.

Item C. This item maintains some current language but many of the original requirements are modified and reorganized below. As amended, this item sets out the indications for SCS, procedures for determining whether consideration of an SCS in a particular patient is appropriate, and criteria for determining whether implantation of an SCS is warranted based on subitems (1), (2) and (3) below.

Patient selection for trial screening period for SCS

Subitem (1): This item sets out the criteria for selecting patients for a trial screening period of an SCS. A trial screening period is indicated if the patient has intractable pain, is not a candidate for another surgical therapy and has no untreatable major psychological or psychiatric comorbidity that would prevent the patient from benefiting from this treatment.

The current rules require candidates to have a favorable trial screening.[53] The proposed rules continue the requirement for a trial screening period because the scientific evidence shows that even among patients who have had a positive response in a trial, only 50-60% benefit from an implanted device. The criteria listed in this subitem indicate when a trial screening period is appropriate and reflect the MSRB members' experience in treating patients with chronic intractable pain, their review of the medical evidence[54] and their familiarity and interpretation of current accepted medical standards of practice.[55] Units (a) to (c) of this subitem are the amended conditions recommended by the MSRB to ensure careful patient selection.

Unit (a). This term "neuropathic pain" in the current rules is changed to "intractable pain."[56] Current science and practice no longer considers the difference between neuropathic pain and other types of pain as significant when considering SCS; whether the pain is intractable or not is significant. This change from a specific type of pain (neuropathic) to a condition of pain (intractable) does not necessarily exclude patients with neuropathic pain because intractable pain is an inclusive term that can include neuropathic pain. The MSRB recommended limiting the use of SCS to patients with intractable pain so that the seriousness of the patient's condition is commensurate with the use of an invasive treatment and the degree of risk of complication.[57]

Unit (b). This is not a new requirement but rather is renumbered to this location in the proposed rules. Because SCS is a palliative treatment, the patient should not be a candidate for a different type of potentially curative surgery. This requirement is in the current rules.

Unit (c). The terms "personality or psychosocial evaluation" in the current rules are replaced with "psychological or psychiatric assessment" and reorganized to this location in the proposed rules.[58] The proposed rules also clarify who may perform the assessment. That is, the current rules allow

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[53] See subpart 6, item C, subitem 1 of the current rules.

[54] The MSRB's review of medical evidence is described above. The MSRB members discussed trial screening periods at multiple meetings.

[55] Pursuant to Minnesota Statutes, section 176.83, subd. 5, the Department must consult with the MSRB.

[56] See subpart 6, item C, subitem (1) of the current rules.

[57] See the MSRB's report on SCS, 1/17/2008 meeting minutes at www.dli.mn.gov/ScsIddsSonarDocs.asp

[58] See subpart 6, item C of the current rules.

the treating physician or a consulting provider to conduct the psychological assessment of the patient. The proposed rules require a consulting psychologist or psychiatrist to assess the patient. The MSRB relied on the collective expertise of its members to recommend the requirements and benchmarks of the assessment.[59]

In summary, the medical evidence reviewed by the MSRB shows that SCS can effectively palliate pain but only in some selected patients. The available evidence shows that permanently implanted SCS are effective in achieving at least a 50% reduction in pain in 50%-60% of patients with chronic spinal conditions who had a positive response during a screening trial period.[60] However, there was inconsistent evidence as to whether SCS are *more effective* than alternative palliative alternatives for relieving pain in patients.[61] The available evidence shows that complications occur frequently in 1/3 to 1/2 of cases. Up to 1/3 of patients require re-operation in the first two years due to complications.[62]

Because the evidence reviewed by the MSRB shows that only some patients benefited from SCS, that SCS had a high rate of complications and re-operation, and that SCS was not clearly better than alternatives, the MSRB concluded that appropriate and careful patient selection is critical when considering SCS.

Second opinion for SCS

Subitem (2): This subitem modifies the existing second opinion requirement.[63] The proposed rules specify what the second opinion should confirm rather than requiring general confirmation that treatment is indicated. The proposed rules require a second opinion by another provider to confirm that all the conditions listed in subitem (1) are satisfied. This requirement is based on the MSRB's recommendation that use of SCS be limited to select patients. Because the available evidence shows that only some patients benefited from SCS, that SCS had a high rate of complications and re-operation, and that SCS was not clearly better than alternatives, the MSRB concluded that appropriate and careful patient selection is critical when considering SCS. A second opinion maximizes the likelihood that the patients chosen for a trial screening will be those most likely to benefit from SCS. Maintaining and modifying the requirement for a second opinion reflects MSRB members' experience in treating patients with chronic intractable pain and their interpretation and familiarity with current accepted medical standards of practice.[64]

Trial screening period duration and results for SCS

Subitem (3): This item sets out minimum trial screening period duration and results of SCS before undertaking long-term treatment. The trial screening period must last at least three days and result in at least a 50% reduction in pain in order for the patient to be a candidate for long-term SCS. These requirements are based on the recommendations made by the MSRB to the Department.

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[59] See MSRB meeting minutes, including minutes for 1/17/2008, 4/17/2008, 10/23/2008 meetings at www.dli.mn.gov/ScsIddsSonarDocs.asp.

[60] See "Summary Tables of Medical Evidence on SCS" in Appendix A; and in "REPORT TO THE MSRB. SPINAL CORD STIMULATORS. September 2, 2008" adopted October 23, 2008 (Conclusion #1, page 10) at www.dli.mn.gov/ScsIddsSonarDocs.asp.

[61] See "Summary Tables of Medical Evidence on SCS" in Appendix A; and in "REPORT TO THE MSRB. SPINAL CORD STIMULATORS. September 2, 2008" adopted October 23, 2008 (Conclusion #4, page 12) at www.dli.mn.gov/ScsIddsSonarDocs.asp.

[62] See "Summary Tables of Medical Evidence on SCS" in Appendix A; and in "REPORT TO THE MSRB. SPINAL CORD STIMULATORS. September 2, 2008" adopted October 23, 2008 (Conclusion #5, page 12) at www.dli.mn.gov/ScsIddsSonarDocs.asp.

[63] See subpart 6, item C of the current rules.

[64] See MSRB meeting minutes at www.dli.mn.gov/ScsIddsSonarDocs.asp.

First, the MSRB recommended that a trial screening period of at least three days is needed to determine who might benefit from SCS.[65] Second, the MSRB recommended that adequate pain relief of at least 50% during the trial period is needed to determine if a patient might benefit from SCS.[66]

These recommendations were based on the conclusions drawn by MSRB members from its review of the medical evidence. The reported case series and clinical trials used trial periods ranging from one to thirty days, with most lasting three to seven days. Because no information indicated whether length of trial period influenced the reported efficacy of SCS and three days was the most common trial screening period used in the studies, MSRB members recommended three days. The most common measure of success in the trial periods of the research reviewed by the MSRB was pain relief of at least 50% because that is the medical industry standard and that is what most studies used.[67]

Explanation of proposed amendments to IDDS rule portions

Note: As mentioned above, the current rules are organized in a way where SCS and IDDS treatment options are sometimes addressed together and sometimes separately. Both are addressed in subpart 6 item C.[68] Both require a second opinion to confirm that treatment is indicated and within the treatment parameters and a personality or psychosocial evaluation that indicates the patient is likely to benefit from the treatment.

Additionally, SCS is indicated only for patients with *neuropathic pain* who are not candidates for any other surgical therapy and have had a favorable response to a trial screening period; IDDS is indicated only for patients with *somatic pain* who are not candidates for any other surgical therapy and have had a favorable response to a trial screening period.

These requirements are maintained in the proposed rules but are further refined to make the parameters clearer and updated to reflect current accepted medical standards. The proposed rules address SCS and IDDS separately in subpart 6 items C (described above) and D (below), respectively.

Item D. This new item sets out the indications for IDDS, procedures for determining whether consideration of an IDDS in a particular patient is appropriate, and criteria for determining whether implantation of an IDDS is warranted based on subitems (1), (2) and (3) below.

Patient selection for trial screening period for IDDS

Subitem (1): This item sets out the criteria for selecting patients for a trial screening period of an IDDS. A trial screening period is indicated if the patient has intractable pain, is not a candidate for another surgical therapy and has no untreatable major psychological or psychiatric comorbidity that would prevent the patient from benefiting from this treatment.

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[65] "Summary Tables of Medical Evidence on SCS" in Appendix A; and in "REPORT TO THE MSRB. SPINAL CORD STIMULATORS. September 2, 2008" adopted October 23, 2008, Recommendation #II (Page 15) at www.dli.mn.gov/ScsIddsSonarDocs.asp.

[66] "Summary Tables of Medical Evidence on SCS" in Appendix A; and in "REPORT TO THE MSRB. SPINAL CORD STIMULATORS. September 2, 2008" adopted October 23, 2008, Recommendation #III (Page 15) at www.dli.mn.gov/ScsIddsSonarDocs.asp.

[67] See "Summary Tables of Medical Evidence on SCS" in Appendix A; and in "REPORT TO THE MSRB. SPINAL CORD STIMULATORS. September 2, 2008" adopted October 23, 2008 (Conclusion #7, page 14).

[68] The current rule uses the terms "dorsal column stimulator" and "morphine pump" instead of "SCS" and "IDDS," respectively, as explained above. To more easily see the similarities and for a more accurate comparison, "SCS" and "IDDS" are used here when referring to the current treatment parameters and throughout this document.

The current rules require candidates to have a favorable trial screening.[69] The proposed rules continue the requirement for a trial screening because scientific evidence shows that permanently implanted IDDS are effective in achieving at least a 50% reduction in pain in 50%-60% of patients with chronic spinal conditions who have a positive response during a trial screening period.[70] The criteria listed in this subitem indicate when a trial screening period is appropriate and reflect the MSRB members' experience in treating patients with chronic intractable pain, their review of the medical evidence[71] and their familiarity with and interpretation of current accepted medical standards of practice.[72] Units (a) to (c) of this subitem are the amended conditions recommended by the MSRB to ensure careful patient selection.

Unit (a). The term "somatic pain" in the current rule is changed to "intractable pain." [73] Current science and practice no longer considers the difference between somatic pain as significant when considering IDDS; whether the pain is intractable or not is significant. This change from a specific type of pain (somatic) to a condition of pain (intractable) does not necessarily exclude patients with somatic pain because intractable pain is an inclusive term that can include somatic pain. The MSRB recommended limiting the use of IDDS to patients with intractable pain so that the seriousness of the patient's condition is commensurate with the use of an invasive treatment and the degree of risk of complication.[74]

Unit (b). This is not a new requirement but rather is reorganized to this location in the proposed rules. Because IDDS is a palliative treatment, the patient should not be a candidate for a different type of potentially curative surgery. This requirement is in the current rules.

Unit (c). The terms "personality or psychosocial evaluation" in the current rules are replaced with "psychological or psychiatric assessment" and reorganized to this location in the proposed rules. [75] The proposed rules also clarify who may perform the assessment. That is, the current rules allow the treating physician or a consulting provider to conduct the psychological assessment of the patient. The proposed rules require a consulting psychologist or psychiatrist to assess the patient. The MSRB relied on the collective expertise of its members to recommend the requirement and benchmarks of the assessment.[76]

In summary, the medical evidence reviewed by the MSRB shows that IDDS can effectively palliate pain but only in some select patients. The available evidence shows that permanently implanted IDDS are effective in achieving at least a 50% reduction in pain in some patients with chronic spinal conditions who have a positive response during a trial screening period. However, there was inconsistent evidence as to whether IDDS was *more effective* than alternatives for relieving pain in patients with chronic spinal conditions.

Because the evidence reviewed by the MSRB shows that only some patients benefited from IDDS, that IDDS has a high rate of complications, and that IDDS was not clearly better than

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[69] See subpart 6, item C, subitem 2 of the current rules.
[70] See "Summary Tables of Medical Evidence on IDDS" in Appendix B; and in "REPORT TO THE MSRB. INTRATHECAL DRUG DELIVERY SYSTEMS. July 16, 2009" adopted October 22, 2009 (Conclusion #1, page 9).
[71] The MSRB's review of medical evidence is described above. The MSRB members discussed trial screening periods at multiple meetings.
[72] Pursuant to Minnesota Statutes, section 176.83, subd. 5, the Department must consult with the MSRB.
[73] See subpart 6, item C, subitem (2) of the current rules.
[74] See "REPORT TO THE MSRB. INTRATHECAL DRUG DELIVERY SYSTEMS. July 16, 2009" adopted October 22, 2009.
[75] See subpart 6, Item C of the current rules.
[76] See MSRB meeting minutes at www.dli.mn.gov/ScsIddsSonarDocs.asp.

alternatives, the MSRB concluded that appropriate and careful patient selection is critical when considering an invasive palliative therapy such as IDDS.

Second opinion for IDDS

Subitem(2): This item modifies the existing second opinion requirement.[77] The proposed rules specify what the second opinion should confirm rather than requiring general confirmation that treatment is indicated. The proposed rules require a second opinion by another provider to confirm that all the conditions listed in subitem (1) are satisfied. This requirement is based on the MSRB's recommendation that use of IDDS be limited to select patients. Because the available evidence shows that only some patients benefited from IDDS, and that IDDS had a high rate of complications and IDDS was not clearly better than alternative treatment options, the MSRB concluded that appropriate and careful patient selection is critical when considering an invasive palliative therapy such as IDDS. A second opinion maximizes the likelihood that the patients chosen for a trial screening will be those most likely to benefit from IDDS. Maintaining and modifying the requirement for a second opinion reflects the MSRB members' experience in treating patients with chronic intractable pain and their interpretation and familiarity with current accepted medical standards of practice. [78]

Trial screening period duration and results for IDDS

Subitem (3): This item sets out minimum trial screening period duration and results of IDDS before undertaking long-term treatment. The trial screening period must last at least 24 hours and result in at least a 50% reduction in pain in order for the patient to be a candidate for long-term IDDS. These requirements are based on recommendations made by the MSRB to the Department.

First, the MSRB recommended that a trial screening period of 24 hours is needed to determine who might benefit from IDDS.[79] Second, the MSRB recommended that adequate pain relief of at least 50% during the trial period is needed to determine if a patient might benefit from IDDS. [80]

These recommendations were based on the conclusions drawn by the MSRB from its review of the medical evidence. The reported case series and clinical trials used trial periods ranging from a single injection up to 10 days, with most being 24 hours or less. There is no information to judge whether the length of the trial period influences the reported efficacy of implanted intrathecal drug delivery systems.[81] Since 24 hours was the most commonly used trial period duration, the MSRB recommended 24 hours. In the medical evidence, the most common measure and criteria of success in the trial period and the medical industry standard was pain relief of at least 50%.[82]

5221.6305 Complex Regional Pain Syndrome (CRPS); Reflex Sympathetic Dystrophy; and

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[77] See subpart 6, item C of the current rules.

[78] See MSRB meeting minutes at www.dli.mn.gov/ScsIddsSonarDocs.asp.

[79] "Summary Tables of Medical Evidence on IDDS" in Appendix B; and in "REPORT TO THE MSRB. INTRATHECAL DRUG DELIVERY SYSTEMS. July 16, 2009" adopted October 22, 2009 at www.dli.mn.gov/ScsIddsSonarDocs.asp.

[80] "REPORT TO THE MSRB. INTRATHECAL DRUG DELIVERY SYSTEMS. July 16, 2009" adopted October 22, 2009, Recommendation #III (page 16) at www.dli.mn.gov/ScsIddsSonarDocs.asp.

[81] See "Summary Tables of Medical Evidence on IDDS" in Appendix B; and in "REPORT TO THE MSRB. INTRATHECAL DRUG DELIVERY SYSTEMS. July 16, 2009" adopted October 22, 2009 (Conclusion #6, page 13) at www.dli.mn.gov/ScsIddsSonarDocs.asp.

[82] See "Summary Tables of Medical Evidence on IDDS" in Appendix B; and in "REPORT TO THE MSRB. INTRATHECAL DRUG DELIVERY SYSTEMS. July 16, 2009" adopted October 22, 2009 (Conclusion #7, page 14) at www.dli.mn.gov/ScsIddsSonarDocs.asp.

Causalgia of the Upper and Lower Extremities.[83]

Subp. 3. **Surgery.** In the current rule, this subpart has only two items A and B. There are no proposed amendments to item A at this time. Item B addresses SCS and IDDS.

Item A. No amendments are proposed to this item.

Item B. The current rule language is deleted and replaced with the same SCS language as in item C above. The MSRB made all of the same findings and recommendations on the use of SCS in the treatment of these conditions as in the case of chronic spinal pain. Specifically, the MSRB concluded that there was limited evidence that permanently implanted SCS are effective in achieving at least a 50% reduction in pain in 50% - 67% of patients with complex regional pain syndrome who have a positive response during a trial screening period.[84] Some inconsistent evidence shows SCS improved other clinical outcomes in patients with either chronic spinal conditions or complex regional pain syndrome.[85] However, the evidence was insufficient to draw conclusions.[86]

Item C. The current rule language is deleted and replaced with the same IDDS language as in item D above. The MSRB made all of the same findings and recommendations on the use of IDDS in the treatment of these conditions as in the case of chronic spinal pain. Specifically, the MSRB concluded that there was some evidence that permanently implanted IDDS are effective in achieving at least a 50% reduction in pain in some patients with complex regional pain syndrome who have a positive response during a trial screening period.[87] However, the evidence was insufficient to draw conclusions.[88]

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[83] The medical evidence the MSRB reviewed for back and neck pain also applied to CRPS, Reflex Sympathetic Dystropy and Causalgia.

[84] See "Summary Tables of Medical Evidence on SCS" in Appendix A; and in "REPORT OT THE MSRB. SPINAL CORD STIMULATORS. September 2, 2008" adopted October 23, 2008 (Conclusion #2, page 10) at www.dli.mn.gov/ScsIddsSonarDocs.asp.

[85] See "Summary Tables of Medical Evidence on SCS" in Appendix A; and in "REPORT TO THE MSRB. SPINAL CORD STIMULATORS. September 2, 2008" adopted October 23, 2008 (Conclusion #3, page 11) at www.dli.mn.gov/ScsIddsSonarDocs.asp.

[86] "REPORT TO THE MSRB. SPINAL CORD STIMULATORS. September 2, 2008" adopted October 23, 2008 at www.dli.mn.gov/ScsIddsSonarDocs.asp.

[87] See "Summary Tables of Medical Evidence on IDDS" in Appendix B; and in "REPORT OT THE MSRB. INTRATHECAL DRUG DELIVERY SYTEMS. July 16, 2009" adopted October 22, 2009 (Conclusions #1 and #2, pages 9-10) at www.dli.mn.gov/ScsIddsSonarDocs.asp. Complex regional pain syndrome was included in the medical evidence search and analysis although not specifically stated in the MSRB IDDS medical literature conclusions.

[88] See "Summary Tables of Medical Evidence on IDDS" in Appendix B; and in "REPORT OT THE MSRB. INTRATHECAL DRUG DELIVERY SYTEMS. July 16, 2009" adopted October 22, 2009 at www.dli.mn.gov/ScsIddsSonarDocs.asp.

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

May 9, 2014

Ken B. Peterson, Commissioner
Department of Labor and Industry

This Statement of Need and Reasonableness was made available for public review on May 9, 2014.

Appendix A: Summary Tables of Medical Evidence on SCS

1. There is limited evidence (predominantly from case series and two RCTs) that permanently implanted spinal cord stimulators are effective in achieving at least a 50% reduction in pain in 50%- 60% of patients with chronic spinal conditions who have a positive response during a screening trial period.

reference	***author's conclusions***
Neurosurgery. 1995 Dec;37(6):1088-95	In sum, approximately 50 to 60% of patients with FBSS report ≥50% pain relief with SCS.
Spine. 2005 Jan 1;30(1):152-60	The level of evidence for the efficacy of SCS in patients with CLBP/FBSS remains "moderate." The greatest level of pain relief following SCS appeared to be associated with case series that were of poor quality, short follow-up duration, undertaken in a multicenter setting, and that recruited patients with CLBP or FBSS specifically.
Neurosurgery. 2005;56(1):98-106	This prospective, randomized trial confirms the inference from previous studies that SCS is superior to reoperation in patients with persistent radicular pain after lumbosacral spine surgery. In patients with persistent radicular pain after lumbosacral spine surgery, therefore, our findings indicate that clinicians should offer SCS as an alternative to repeated operation before exhausting all surgical alternatives.
Pain xxx (2007) xxx–xxx	The favorable effect of SCS on neuropathic pain is consistent with the results of previously reported trials.
Eur Spine J 2006; 15:S192-S300	We cannot recommend the use of spinal cord stimulation for the treatment of chronic nonspecific LBP.
Assessment and management of chronic pain.	Patients with lumbar and cervical radiculopathy who are not surgical candidates, and patients with postlaminectomy syndrome are the best candidates for SCS.
Considered Judgment Form: Neuromodulation-Spinal Cord Stimulation	We do not recommend spinal cord stimulation for the treatment of adults with pain due to failed back surgery syndrome.
Treatment in Workers' Compensation 2006	Recommended only for selected patients in cases when less invasive procedures have failed or are contraindicated, and following a successful temporary trial
J Neurosurg 2004; 100:S254-S67	There is some evidence to indicate that SCS has positive, symptomatic, long-term effects on … failed–back surgery syndrome pain.
Cochrane Database Syst Rev. 2004;(3):CD003783	At the present time there is limited evidence that spinal cord stimulators are effective for some types of chronic pain (FBSS …).
J Pain Symptom Manage 2004; 27:370-378	SCS is economically favorable in comparison to other therapies for patients with FBSS…. The initial acquisition costs of SCS appear to be offset by a reduction in healthcare resources, such as drug therapy, physician visits, and hospitalization episodes.
Spinal cord stimulation for the management of pain: recommendations for best clinical practice	For indications strongly supported by evidence, i.e. …, neuropathic pain following spinal surgery…, SCS should be considered early in the patient's management when simple first line therapies have failed. SCS should not necessarily be considered a treatment of last resort.
Evidence-based clinical practice guideline for interdisciplinary rehabilitation of chronic non-malignant pain syndrome patients	Do not recommend using spinal cord stimulators with chronic pain patients.
Summary and Conclusions of the SBU Report on: Methods of Treating Chronic Pain. A Systematic Review	Spinal cord stimulation has been shown to reduce … low back (Evidence Grade 2) pain.

2. There is limited evidence (predominantly from case series and one RCT) that permanently implanted spinal cord stimulators are effective in achieving at least a 50% reduction in pain in 50%- 67% of patients with complex regional pain syndrome (reflex sympathetic dystrophy) who have a positive response during a screening trial period.

reference	***author's conclusions***
Clin J Pain. 2003 Nov-Dec;19(6):371-83	We conclude that available evidence suggests that SCS is effective for the management of pain for patients with CRPS who did not respond to more conservative medical management (grade B/C).
Eur J Pain 2006 10(2) 91-101	SCS appears to be an effective therapy in the management of patients with CRPS type I (Level A evidence) and type CRPS II (Level D evidence). Moreover, there is evidence to demonstrate that SCS is a cost-effective treatment for CRPS type I.
N Engl J Med. 2000 Aug 31;343(9):618-24	In carefully selected patients with chronic reflex sympathetic dystrophy,

	electrical stimulation of the spinal cord can reduce pain and improve health-related quality of life.
Ann Neurol. 2004 Jan;55(1):13-8	We conclude that after careful selection and successful test stimulation SCS is safe and has long-term effectiveness in reducing pain.
N Engl J Med. 2006 Jun 1;354(22):2394-6	The pain-alleviating effect of SCS in CRPS diminishes with time, and is no longer statistically significant after 3 years.
Spinal Cord Stimulation. Use in Patients with Complex Regional Pain Syndrome	Incorporating the lack of high level medical research on this subject, along with its significant potential adverse effect rate and poor compensation outcome measures when SCS are used, the WCB should continue with its present position of not authorizing its use in the injured worker population.
Eur J Neurol 2007; 14:952-970	Level B evidence for effectiveness of SCS in CRPS I
Assessment and management of chronic pain.	Patients with complex regional pain syndrome (CRPS) type 1 or (RSD) are the best candidates for SCS.
Considered Judgment Form: Neuromodulation-Spinal Cord Stimulation	We recommend spinal cord stimulation should be used in highly selected patients with complex regional pain syndrome type I.
Complex Regional Pain Syndrome type 1 Guidelines	Pain control with spinal cord stimulation is a responsible choice for carefully selected CRPS-I patients who have not responded to other treatments.
Treatment in Workers' Compensation 2006	Recommended only for selected patients in cases when less invasive procedures have failed or are contraindicated, and following a successful temporary trial
Evidence Based Review. Spinal Cord Stimulation	There is no quality evidence that SCS is superior treatment long term especially when a cost/benefit perspective is required
J Neurosurg 2004; 100:S254-S67	There is some evidence to indicate that SCS has positive, symptomatic, long-term effects on CRPS I and II …
Cochrane Database Syst Rev. 2004;(3):CD003783	At the present time there is limited evidence that spinal cord stimulators are effective for some types of chronic pain (… CRPS Type 1).
J Pain Symptom Manage 2004; 27:370-378	SCS is economically favorable in comparison to other therapies for patients with … CRPS. The initial acquisition costs of SCS appear to be offset by a reduction in healthcare resources, such as drug therapy, physician visits, and hospitalization episodes.
Spinal cord stimulation for the management of pain: recommendations for best clinical practice	For indications strongly supported by evidence, i.e. CRPS, … SCS should be considered early in the patient's management when simple first line therapies have failed. SCS should not necessarily be considered a treatment of last resort.
Evidence-based clinical practice guideline for interdisciplinary rehabilitation of chronic non-malignant pain syndrome patients	Do not recommend using spinal cord stimulators with chronic pain patients.
Summary and Conclusions of the SBU Report on: Methods of Treating Chronic Pain. A Systematic Review	Spinal cord stimulation has been shown to reduce peripheral neuropathic (Evidence Grade 3) … pain. Notwithstanding high initial expenses, spinal cord stimulation combined with physical therapy is cost-effective in treating neuropathic pain (Evidence Grade 3).

3. There is inconsistent evidence as to whether spinal cord stimulators improve other clinical outcomes in patients with either chronic spinal conditions or complex regional pain syndrome (reflex sympathetic dystrophy).

reference	***author's conclusions***
Neurosurgery. 1995 Dec;37(6):1088-95	However, there is insufficient evidence to draw conclusions … about the effects of SCS on patient work status, functional disability, and health care and medication use.
Clin J Pain. 2003 Nov-Dec;19(6):371-83	Definitive conclusions cannot be made with regard to any of the secondary outcome measures, in part due to poor methodological design and in part due to inadequate reporting by the authors.
Spinal Cord Stimulation. Use in Patients with Complex Regional Pain Syndrome	Incorporating the lack of high level medical research on this subject, along with its significant potential adverse effect rate and poor compensation outcome measures when SCS are used, the WCB should continue with its present position of not authorizing its use in the injured worker population.
Pain. 2004 Mar;108(1-2):137-47	We conclude that the literature on SCS for FBSS … remains inadequate to make definitive statements about efficacy in reducing physical disability, work disability, and medication consumption.

4. There is inconsistent evidence as to whether spinal cord stimulators are more effective than alternatives for relieving pain in patients with either chronic spinal conditions or

complex regional pain syndrome (reflex sympathetic dystrophy).

reference	*author's conclusions*
Neurosurgery. 1995 Dec;37(6):1088-95	No conclusions may be drawn concerning the efficacy of SCS for FBSS relative to other treatments, placebo treatments, or no treatment.
N Engl J Med. 2006 Jun 1;354(22):2394-6	The pain-alleviating effect of SCS in CRPS diminishes with time, and is no longer statistically significant after 3 years.
Complex Regional Pain Syndrome type 1 Guidelines	Pain control with spinal cord stimulation is a responsible choice for carefully selected CRPS-I patients who have not responded to other treatments.
Treatment in Workers' Compensation 2006	Recommended only for selected patients in cases when less invasive procedures have failed or are contraindicated, and following a successful temporary trial
Evidence Based Review. Spinal Cord Stimulation	There is no quality evidence that SCS is superior treatment long term especially when a cost/benefit perspective is required
Pain. 2004 Mar;108(1-2):137-47	Using recently published criteria for levels of evidence, there is moderate evidence (one high-quality RCT) that SCS plus PT is more effective than PT-only for patients with CRPS type I in relieving pain at 6- and 12-month follow-ups. Both the RCT and lower-quality studies suggest a modest pain-relieving effect on average. Less regarding comparisons with placebo controls, other treatments, or the natural history can be gleaned from the literature.

5. Complications occur in 1/3 to 1/2 of cases, but are often mild and mostly involving problems with the equipment or local infection. But up to 1/3 of patients will require re-operation in the first two years due to complications.

reference	*complications*
Neurosurgery. 1995 Dec;37(6):1088-95	o 13 studies: 42% (range 20-75%) of patients had some kind of complication. o 20 studies: 5% (range 0-12%) of patients had an infection. o 17 studies: 9% (range 0-42%) of patients had a biological complication other than infection. o 13 studies: 30% (range, 0-75%) of patients had one or more stimulator-related complications.
Spine. 2005 Jan 1;30(1):152-60	o RCT: Four (17%) and six (26%) patients with FBSS experienced complications at 6 and 12 months post SCS implantation, respectively. o Case Series: Overall, 43% of patients with CBLP/FBSS experienced one or more complications with SCS. The majority of these complications were due to electrode or lead problems (195/722; 27%). Infections (6%), generator problems (6%), extension cable problems (10%), or other issues, such as cerebrospinal fluid leaks (7%), accounted for the remainder.
Neurosurgery. 2005;56(1):98-106	One SCS patient developed an infection at the receiver site, which was treated by removal of the system followed by specific antibiotic therapy. The system was replaced without further complication. Three SCS patients (9% of permanent implants) underwent hardware revisions because of technical problems (electrode migration or malposition).
Pain xxx (2007) xxx–xxx	Of 84 patients, 27 (32%) experienced a total of 40 device-related complications. For 20 patients (24%), surgery was required to resolve the event. Principal complications were electrode migration (10%), infection or wound breakdown (8%), and loss of paresthesia (7%).
Pain Physician. 2007 Jan;10(1):7-111	Complications with spinal cord stimulation range from infection, hematoma, nerve damage, lack of appropriate paresthesia coverage, paralysis, nerve injury, and death.
Clin J Pain. 2003 Nov-Dec;19(6):371-83	o The proportion of patients with at least one complication ranged from 9% to 50%. o The infection rate ranged from 1.4% to 11.1%. o The rate of complication due to technical problems such as equipment failure, lead migration, or lost coverage ranged from 8.3% to 42.8%. o The rate of reoperation ranged from 11.1% to 50%.
Eur J Pain 2006 10(2) 91-101	o RCT: Six of the 36 patients receiving SCS plus physical therapy experienced complications (n = 11) at 6 months but only one complication (infection) was reported at 12 months. A total of 9 of the 24 patients (38%) experienced 22 complications needing operation

	during the 2-years after implantation. o Case Series: Overall, in eight studies, 33.0% (22/66) of patients reported at least one complication with SCS. The majority of complications were related to electrode issues (20% of patients), infections (4% of patients), generator issues (2% of patients) or extension cable issues (1%) of patients. A further 6% of patients had other complications such as hematomas.
N Engl J Med. 2000 Aug 31;343(9):618-24	Six of the 24 patients had complications that required additional procedures, including removal of the device in 1 patient. Four of the six had long term complications.
Ann Neurol. 2004 Jan;55(1):13-8	o 9 of 24 patients (38%) suffered 22 complications needing operation during the 2 years after implantation. o The most frequent complications were electrode displacement and pain from the pulse generator pocket. o Two patients underwent permanent removal of the system on the grounds of recurrent rejection and relapsing ulcerative colitis subscribed to the system, respectively .o Side effects were reported by all 22 patients who still had an implanted system at 2 years.
Pain Physician. 2007 Jan;10(1):7-111	Complications with spinal cord stimulation range from infection, hematoma, nerve damage, lack of appropriate paresthesia coverage, paralysis, nerve injury, and death.
J Neurosurg 2004; 100:S254-S67	Most complications were not life threatening and could usually be resolved by removing the device. The most common complication was lead migration. The most serious complication was paralysis
Pain. 2004 Mar;108(1-2):137-47	18 articles: average of 34% (range 0–81%) of the patients who received a permanent stimulator had one or more undesirable outcomes during the study follow-up period. These included superficial and deep infections, local pain in the region of stimulator components, biological complications other than infection or local pain (e.g. dural puncture), equipment failure, a stimulator revision (additional operation to correct an equipment problem; we did not include battery changes in this category), and stimulator removal (most commonly because of infection, equipment failure, or lack of pain relief). Removals included both permanent removals and removals followed by eventual re-implantations (e.g. removal due to infection and stimulator implantation after resolution of the infection).

6. Trial screening periods in the reported case series and clinical trials have lasted from 1 day up to 30 days, with most lasting from 3 to 7 days. There is no information to judge whether the length of the trial period influences the reported efficacy of spinal cord stimulation.

reference	***trail period***
Neurosurgery. 1995 Dec;37(6):1088-95	In 34 studies, there were temporary electrode trials, lasting 1 to 3 days in 4studies, 4 to 7 days in 8 studies, 8 to 14 days in 4 studies, and more than 2 weeks in 2 studies. The length of the trial considerably varied across patients in 1 study and was not specified in 15 studies.
Neurosurgery. 2005;56(1):98-106	SCS treatment began with percutaneous placement of a temporary electrode for a therapeutic trial lasting at least 3 days.
Clin J Pain. 2003 Nov-Dec;19(6):371-83	Eleven studies reported the duration of the stimulation trial period that ranged from 3 to 30 days. Six of these studies reported trial stimulation that lasted 7 days or less. The remaining 5 studies reported trial stimulation of greater than 7 days.
Cochrane Database Syst Rev. 2004;(3):CD003783	1of 2 studies: Percutaneous placement of a temporary electrode for routine 2- 1/2 day trial.

7. The most common measure of success in the trial period was relief of pain and the most common criteria was pain relief of at least 50%.

reference	***trial success***
Neurosurgery. 1995 Dec;37(6):1088-95	In the 34 studies in which patients were screened with temporary electrodes to determine suitability for permanent implants, the criteria for permanent implants were specifically stated to be pain relief in 19

	studies, region of paresthesia in 8 studies, decreased medication use in 2 studies, and increased activity in 2 studies. Only eight articles stated a threshold percentage of pain relief for permanent implantation, and across these studies, the minimum percent pain relief for implantation ranged from 30 to 75% (30% in one study, 50% in five, 70% in one, and 75% in one).
Neurosurgery. 2005;56(1):98-106	The SCS patients could receive a permanent implant if they reported at least 50% estimated relief of pain by standard pain rating methods and demonstrated stable or improved analgesic medication intake, with improved physical activity commensurate with neurological status and age.
Pain xxx (2007) xxx–xxx	Criteria for implanting SCS: at least 80% overlap of pain distribution with stimulation-induced paresthesia and at least 50% leg pain relief.
Clin J Pain. 2003 Nov-Dec;19(6):371-83	There was considerable variability in the criteria used to determine successful trial stimulation. Quantitative and validated measures of pain relief were not used by all studies to determine trial success. A 50% decrease in VAS score for pain or a rating of 6 on the global perceived effect (GPE) scale was necessary to define success in 2 studies. Three studies used 50% pain relief from baseline VAS scores, while 1 study used walking distance along with 70% pain relief as the primary outcome measure. Other studies used nonspecific outcomes such as "patient satisfied", "acceptable degree of analgesia", "patient benefited", or "pain relief to avoid heavy analgesic use.".
N Engl J Med. 2000 Aug 31;343(9):618-24	The decision to implant the permanent SCS system was made when pain intensity during the testing period was at least 50% lower as compared with the original (baseline) visual analog score, or if "much improvement" was reported on a seven-point global perceived effect scale.
Cochrane Database Syst Rev. 2004;(3):CD003783	1 of 2 studies: If a patient reports at least 50% estimated relief of pain, while demonstrated stable or improved medication intake, and improved physical activity commensurate with neurologic status and age, a permanent implant was offered.

Appendix B: Summary Tables of Medical Evidence on IDDS

1. There is limited evidence that permanently implanted intrathecal drug delivery systems are effective in the short-term in achieving at least a 50% reduction in pain in some patients with chronic pain conditions who have a positive response during a screening trial period.

Clin J Pain 2007 Feb 23(2) 180-95	SysRev	The studies reviewed found improvement in pain and functioning on average among patients with chronic noncancer pain who received permanent IDDS.
J Pain Symptom Manage 2000 Aug 20(2) S12-36	SysRev	Intrathecal morphine appears to be safe at clinical concentrations, and has favorable efficacy data. Limited information on the other opioid classes also appears favorable, although published literature supporting this is very limited. Based on the currently available literature, both clinical efficacy and toxicology for bupivicaine and clonidine appear favorable. The efficacy of combinations of different drug classes such as opioids/local anesthetics, opioids/ clonidine, and opioids/local anesthetics/ clonidine appears favorable, but is based largely on case studies and retrospective analysis.
Health Technology Assessment 2000; Vol. 4: No. 32	SysRev	Such data as are available indicate a generally positive effect of the therapy, with side effects and complications occurring in about a quarter of the recipients, but it is difficult to draw definite conclusions because the quality of the data is so poor.
Anesth Analg 2000 Dec 91(6) 1493-8	RCT	The combination of morphine and clonidine produced significantly more pain relief than placebo 4 h after administration; either morphine or clonidine alone did not produce as much pain relief.
J Clin Oncol 2002 Oct 1 20(19) 4040-9	RCT	IDDSs improved clinical success in pain control, reduced pain, and significantly relieved common drug toxicities in patients with refractory cancer pain.
J Pain Symptom Manage 2006 May 31(5) 393-406	RCT	Slow titration of ziconotide, a nonopioid analgesic, to a low maximum dose resulted in significant improvement in pain and was better tolerated than in two previous controlled trials that used a faster titration to a higher mean dose.
JAMA 2004; 291:63-70	RCT	Intrathecal ziconotide provided clinically and statistically significant analgesia in patients with pain from cancer or AIDS.
Pain Physician. 2007 Jan;10(1):7-111	Guide	The evidence for implantable intrathecal infusion systems is strong for short-term improvement in pain of malignancy or neuropathic pain.
Guidelines For Longterm Intrathecal Infusions (PM6)	Guide	A range of non-opioid spinal analgesic agents are utilized for long-term therapy, some of which are supported by low levels of evidence and for which safety has not been fully established. There is level II evidence for efficacy in treating neuropathic pain with intrathecal clonidine; neuropathic pain following spinal cord injury with morphine and clonidine combined; neuropathic pain with ziconotide. Intrathecal administration of opioids and local anaesthetics and / or clonidine could be considered as an alternative agent in patients with poorly controlled neuropathic pain … following spinal cord injury. Many of these combinations are … "off label" …
Assessment and management of chronic pain.	Guide	Intrathecal Medication Delivery Systems can provide an excellent therapeutic effect for nonmalignant and cancer pain. However, it should be reserved only for patients who have failed other conservative approaches for the treatment of pain, and should be used cautiously. The best candidates are patients who respond well to oral opioids but who cannot tolerate the side effects (e.g., sedation, nausea, constipation).
Complex Regional Pain Syndrome type 1 Guidelines	Guide	Intrathecal baclofen has no place in the treatment of patients with CRPS-I. Intrathecal baclofen can only be considered for patients with CRPS-I if dystonia is a major problem and conventional therapy has proven ineffective. This treatment must be administered in the context of a trial.

Treatment in Workers' Compensation 2006	Guide	Recommended only as an end-stage treatment alternative for selected patients. This treatment should only be used relatively late in the treatment continuum, when there is little hope for effective management of chronic intractable pain from other therapies. The specific criteria in these cases include the failure of at least 6 months of other conservative treatment modalities, intractable pain secondary to a disease state with objective documentation of pathology, further surgical intervention is not indicated, psychological evaluation unequivocally states that the pain is not psychological in origin, and a temporary trial has been successful prior to permanent implantation as defined by a 50-70% reduction in pain.
Evidence-based clinical practice guideline for interdisciplinary rehabilitation of chronic non-malignant pain syndrome patients	Guide	Given the continued absence of quality research, however, the current guidelines do not recommend using implantable infusion pumps or spinal cord stimulators with chronic non-malignant pain syndrome patients.
Intrathecal drug delivery for the management of pain and spasticity in adults: recommendations for best clinical practice	Guide	Intrathecal drug delivery can be an effective method of pain control. Patient selection is important, particularly when used for CNMP. It must be carried out by a multi-professional team with a comprehensive understanding of the physical, psychological and rehabilitation aspects of the patient's condition.
Pain Med 2004 5 6-13.	Registry	Current clinical practices related to trialing of drug-delivery systems resulted in the majority of patients successfully trialed. At 12-month follow-ups, implanted patients experienced reductions in numeric back and leg pain ratings, improved Oswestry scores, and high satisfaction with the therapy.

2. There is no reliable evidence that permanently implanted intrathecal drug delivery systems are effective in the long-term in achieving at least a 50% reduction in pain in patients with chronic pain conditions who have a positive response during a screening trial period.

Clin J Pain 2007 Feb 23(2) 180-95	SysRev	Methodologic limitations preclude conclusions concerning the effectiveness of this technology long-term and as compared with other treatments.
J Pain Symptom Manage 2000 Aug 20(2) S12-36	SysRev	No information is available on the long-term compatibility of these combinations.
Pain Physician. 2007 Jan;10(1):7-111	Guide	The evidence is moderate for long-term management of chronic pain.

3. Economic models indicate that permanently implanted intrathecal drug delivery systems are cost-effective in treating patients who have had at least a 50% reduction in pain during a screening trial period.

CLIN THER 1997 19(1) 96-112	CE	When both costs and adverse event rates were set at base case values, the expected cost (discounted at 5%) of IMT over 60 months was $82,893 ($1382 per month). With costs and adverse event rates at the best case values, the expected 60-month total cost was $53,468 ($891 per month), and when all the values were set at the worst case, the projected total cost rose to $125,102 ($2085 per month). By comparison, the cumulative 60-month total cost for medical management was $85,186.
Neuromodulation 1999; 2:77-84	CE	Decision Analysis: "For the base case and the best case, the cumulative cost with an implanted, programmable pump is less than the cost of medical management after 22 months and 11 months, respectively." Cost Analysis: "...intrathecal drug delivery becomes more cost effective than oral therapy after 4-6 months have elapsed."

4. There is no reliable evidence that permanently implanted intrathecal drug delivery systems are more effective than alternative treatment options.

J Clin Oncol 2002 Oct 1 20(19) 4040-9	RCT	Sixty of 71 IDDS patients (84.5%) achieved clinical success compared with 51 of 72 CMM patients (70.8%, P = .05). IDDS patients more often achieved >20% reduction in both pain VAS and toxicity (57.7% [41 of 71] v 37.5% [27 of 72], P = .02). The mean CMM VAS score fell from 7.81 to 4.76 (39% reduction); for the IDDS group, the scores fell from 7.57 to 3.67 (52% reduction, P = .055). The mean CMM toxicity scores fell from 6.36 to 5.27 (17% reduction); for the IDDS group, the toxicity scores fell from 7.22 to 3.59 (50% reduction, P = .004). The IDDS

		group had significant reductions in fatigue and depressed level of consciousness (P < .05).
Guidelines For Longterm Intrathecal Infusions (PM6)	Guide	A range of non-opioid spinal analgesic agents are utilized for long-term therapy, some of which are supported by low levels of evidence and for which safety has not been fully established. There is level II evidence for efficacy in treating neuropathic pain with intrathecal clonidine; neuropathic pain following spinal cord injury with morphine and clonidine combined; neuropathic pain with ziconotide. Intrathecal administration of opioids and local anaesthetics and / or clonidine could be considered as an alternative agent in patients with poorly controlled neuropathic pain … following spinal cord injury. Many of these combinations are … "off label" …
Assessment and management of chronic pain.	Guide	Intrathecal Medication Delivery Systems can provide an excellent therapeutic effect for nonmalignant and cancer pain. However, it should be reserved only for patients who have failed other conservative approaches for the treatment of pain, and should be used cautiously. The best candidates are patients who respond well to oral opioids but who cannot tolerate the side effects (e.g., sedation, nausea, constipation).
Treatment in Workers' Compensation 2006	Guide	Recommended only as an end-stage treatment alternative for selected patients. This treatment should only be used relatively late in the treatment continuum, when there is little hope for effective management of chronic intractable pain from other therapies. The specific criteria in these cases include the failure of at least 6 months of other conservative treatment modalities, intractable pain secondary to a disease state with objective documentation of pathology, further surgical intervention is not indicated, psychological evaluation unequivocally states that the pain is not psychological in origin, and a temporary trial has been successful prior to permanent implantation as defined by a 50-70% reduction in pain.
Evidence-based clinical practice guideline for interdisciplinary rehabilitation of chronic non-malignant pain syndrome patients	Guide	Given the continued absence of quality research, however, the current guidelines do not recommend using implantable infusion pumps or spinal cord stimulators with chronic non-malignant pain syndrome patients.
Intrathecal drug delivery for the management of pain and spasticity in adults: recommendations for best clinical practice	Guide	Intrathecal drug delivery can be an effective method of pain control. Patient selection is important, particularly when used for CNMP. It must be carried out by a multi-professional team with a comprehensive understanding of the physical, psychological and rehabilitation aspects of the patient's condition.

5. Complications occur in 1/3 or more of cases. Most are side effects of the medication delivered by the system, are dose-dependent, and sometimes improve with continued administration. Catheter, procedure and device related complications are relatively uncommon.

Clin J Pain 2007 Feb 23(2) 180-95	SysRev	The most commonly reported permanent IDDS drug side effects were nausea/vomiting (mean rate weighted by sample size=33%), urinary retention (24%), and pruritus (26%). Catheter problems were also reported commonly. Rare but serious complications included intrathecal catheter tip granulomas.
Pain Physician 2007 Mar 10(2) 357-66	SysRev	Most side effects of intrathecal morphine therapy are dose dependent and mediated by opioid receptors. Common ones include nausea, vomiting, pruritus, urinary retention, constipation, sexual dysfunction, and edema. Less common ones include respiratory depression, and hyperalgesia. Catheter tip inflammatory mass formation is a less common complication that may not be mediated by opioid receptors. Treatment usually involves the utilization of opioid receptor antagonist, such as naloxone.
Eur J Anaesthesiol 2006 Jul 23(7) 605-10	RCT	The incidence of nausea and vomiting was higher at 2- and 4-h observation times, and decreased 24 h after intrathecal injection. No urinary retention was observed in the control group, while 2 h after intrathecal injection urinary retention was observed in 20—40% of cases, and decreased to less than 10% 24 h after spinal injection without differences among the four doses.

Anesth Analg 2000 Dec 91(6) 1493-8	RCT	The most common side effects after morphine administration in those with SCI were pruritus, oxygen desaturation, sedation, nausea, and hypotension (>15% decrease in blood pressure) . The most common side effects after clonidine administration were hypotension, nausea, sedation, oxygen desaturation, and dry mouth. Of those who received saline, 13% experienced sedation and 13% had oxygen desaturation. The most common side effects after the administration of the mixture were hypotension, oxygen desaturation, pruritus, dry mouth, and sedation. Using the mixture did not result in a marked reduction in the incidence of side effects.
J Pain Symptom Manage 2006 May 31(5) 393-406	RCT	Significant adverse events reported in the ziconotide group were dizziness, confusion, ataxia, abnormal gait, and memory impairment. Discontinuation rates for AEs and serious AEs were comparable for both groups.
JAMA 2004; 291:63-70	RCT	Nine types of adverse events (fever, hypotension, nausea, vomiting, confusion, dizziness, somnolence, abnormal gait, and urinary retention) occurred with significantly greater frequency in the ziconotide group compared with the placebo group, but starting at the lower dosage, usingsmaller dose increments, and increasing the interval between dose titrations tended to reduce this frequency.
Pain Physician. 2007 Jan;10(1):7-111	Guide	The complications include post-dural puncture headache, infection, nausea, urinary retention, pruritus, catheter and pump failure, pedal edema, hormonal changes, granuloma formation, and decreased libido.
Guidelines For Longterm Intrathecal Infusions (PM6)	Guide	Intrathecal drug administration can result in significant undesirable side effects, and has the possibility of morbidity and mortality.
Complex Regional Pain Syndrome type 1 Guidelines	Guide	The main side-effects of the screening process and continuous administration of ITB are post-puncture headache, diminished consciousness and urine retention.
Intrathecal drug delivery for the management of pain and spasticity in adults; recommendations for best clinical practice	Guide	Minor complications are common. In a population of cancer patients, catheter, procedure, device-related and illness-associated adverse incidents occurred at a rate of 0.45 events per patient year. Neurological deficits can occur from the procedure and from inflammatory mass development at catheter tip. There are reports of neurotoxicity and permanent neurologic al damage following intrathecal infusions of local anaesthetics. Possible infections include meningitis, epidural abscess, pump pocket infection or pump reservoir infection. Cerebrospinal fluid leaks, hygromas and post dural puncture headaches have all been reported. Device-related complications include catheter kinking, disconnection, dislodgement or pump failure, program error and overfill or incorrect refill.
Pain Med 2004 5 6-13.	Registry	Adverse events were reported in 23 patients receiving an IDDS implant. Of these, 21 required some surgery to correct the problem. Adverse events included: Infection (2.2%), dislodgment/ migration (1.5%), and cerebrospinal fluid leak (0.7%). The most common adverse event over 12 months was reaction to medication, which occurred in 5.1% of patients. Other, rarely reported events included catheter kinking in 1.5% and catheter fracture in 0.7% of patients.

6. Trial screening periods in the reported case series and clinical trials have lasted from a single injection up to 10 days, with most being 24 hours or less. There is no information to judge whether the length of the trial period influences the reported efficacy of implanted intrathecal drug delivery systems.

Health Technology Assessment 2000; Vol. 4: No. 32	SysRev	In those studies reporting a trial, 23 used a single injection and 7 an infusion for more than 24 hours - of those 6 lasted for more than 48 hours
Guidelines For Longterm Intrathecal Infusions (PM6)	Guide	Prior to the insertion of long term delivery systems …Intrathecal trials should be undertaken to assess appropriate drugs, doses and efficacy of the drug or drug combinations. Testing with temporary catheter systems allows investigation of the potential side effects of the proposed procedure and medication.

Treatment in Workers' Compensation 2006	Guide	The specific criteria include ... a temporary trial has been successful prior to permanent implantation.
Intrathecal drug delivery for the management of pain and spasticity in adults; recommendations for best clinical practice	Guide	A trial of intrathecal therapy should always be performed. This can be by means of bolus or infusion but the former give limited information. There is no ideal screening method.
Neuromodulation 2007 10(4) 300-328	Guide	The panelists felt that trial procedure should be left up to the physician performing them. The panelists felt that until there are data that suggest that trials are unnecessary, trials should be performed before placing IT delivery agents through an IDDS. Trials can be performed with monotherapy or with polyanalgesia.
Pain Med 2004 5 6-13.	Registry	Trialing methodologies were: Continuous epidural infusion (53%), continuous intrathecal infusion (25%), single intrathecal bolus injection (14%), and multiple intrathecal bolus injections (8%). The majority of patients (81.1%) were trialed with morphine only. The mean duration of the trial was 3.5 ± 5.4 days.

7. The most common measure of success in the trial period was relief of pain and the most common criteria was pain relief of at least 50%.

Health Technology Assessment 2000; Vol. 4: No. 32	SysRev	Those studies reporting a criteria for judging success used 50% relief of pain.
Guidelines For Longterm Intrathecal Infusions (PM6)	Guide	Base line levels of pain, function and Quality of Life should be recorded.
Treatment in Workers' Compensation 2006	Guide	Defined by a 50-70% reduction in pain

8. There is limited evidence to support the use of morphine, hydromorphone and ziconotide as first line agents in intrathecal drug delivery systems.

(a) There is no evidence to support the use of other medications as first line agents.
(b) There is no reliable evidence on which medications are indicated when morphine, hydromorphone and ziconotide are not effective or become ineffective.

reference	***type***	***author's conclusions***
Guidelines For Longterm Intrathecal Infusions (PM6)	Guide	There is level II evidence for efficacy in treating neuropathic pain with intrathecal clonidine; neuropathic pain following spinal cord injury with morphine and clonidine combined; neuropathic pain with ziconotide.
Complex Regional Pain Syndrome type 1 Guidelines	Guide	Intrathecal baclofen has no place in the treatment of patients with CRPS-I.
Neuromodulation 2007 10(4) 300-328	Guide	The first-line agents are morphine, hydromorphone, and ziconotide. Second line agents include 1) the combination of morphine or hydromorphone and bupivacaine or clonidine; 2) the combination of morphine or hydromorphone and ziconotide; or 3) fentanyl alone. Third-line approaches are: 1) clonidine alone; 2) a combination of morphine/ hydromorphone/ fentanyl/ bupivacaine plus clonidine and ziconotide.

J Pain Symptom Manage 2000 Aug 20(2) S12-36	SysRev	Intrathecal morphine appears to be safe at clinical concentrations, and has favorable efficacy data. Limited information on the other opioid classes also appears favorable, although published literature supporting this is very limited. Based on the currently available literature, both clinical efficacy and toxicology for bupivicaine and clonidine appear favorable. The efficacy of combinations of different drug classes such as opioids/local anesthetics, opioids/ clonidine, and opioids/local anesthetics/ clonidine appears favorable, but is based largely on case studies and retrospective analysis. No information is available on the long-term compatibility of these combinations.
Anesth Analg 2000 Dec 91(6) 1493-8	RCT	Intrathecal morphine resulted in a mean reduction in pain to 80% of the baseline pain before drug administration. Intrathecal administration of clonidine resulted in a mean reduction in pain levels to 83% of the baseline pain. These reductions in pain levels were not significantly different from the relief obtained after saline administration. Intrathecal administration of the mixture of morphine and clonidine resulted in a mean reduction in pain levels to 63% of the baseline pain. There was a significant difference in the relief obtained with the mixture of morphine and clonidine compared with placebo ($P = 0.0084$).
JAMA 2004; 291:63-70	RCT	Mean VASPI scores improved 53.1% (95% C], 44.0%-62.2%) in the ziconotide group and 18.1% (95% CI, 4.8%-31.4%) in the placebo group (P .001), with no loss of efficacy of ziconotide in the maintenance phase. Pain relief was moderate to complete in 52.9% of patients in the ziconotide group compared with 17.5% in the placebo group (P .001). Five patients receiving ziconotide achieved complete pain relief, and 50.0% of patients receiving ziconotide responded to therapy compared with 17.5% of those receiving placebo (P=.001).
Ann Pharmacother 2006 Jul-Aug 40(7-8) 1293-300	SysRev	In double-blind, placebo-controlled studies, ziconotide significantly improved patient perception of pain from baseline to the end of the study periods, which ranged from 11 to 21 days.

Appendix C: Glossary of Terms:

AE: "adverse event"; an unintended negative consequence of a treatment

CI: "confidence interval"; the range of numerical values in which we can be confident (to a computed probability, such as 90 or 95%) that the population value being estimated will be found.

EBM: a process of systematically reviewing, appraising and synthesizing research findings from the medical literature

IDDS: An "Intrathecal Drug Delivery Systems" is a medical device for delivering medication directly to the intrathecal space surrounding the spinal cord. It consists of a pump implanted into the abdominal area and a catheter from the pump to the intrathecal space.

RCT: "randomized controlled trial"; study design where treatments, interventions, or enrollment into different study groups are assigned by random allocation rather than by conscious decisions of clinicians or patients. If the sample size is large enough, this study design avoids problems of bias and confounding variables by assuring that both known and unknown determinants of outcome are evenly distributed between treatment and control groups.

SCS: A "Spinal Cord Stimulator" is a medical device for delivering low voltage stimulation to the spinal nerves to block the sensation of pain. It consists of a pulse generator implanted into the abdominal area and electrical wires from the pulse generator to the spinal nerves.