

Minnesota Attorney General: Administrative Rules Proceedings

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Version 3
August 20, 2018

Problem - Fees
~~Should they~~ Are they O.K exempt from ~~16A.128~~
MJM 9-21-92

Send letters see page 3

RULE REVIEW CHECKLIST

180-Day Deadline - 14.12

File No. 1951
DATE RECEIVED 9-17-92
REVIEW DATE ~~9-26-92~~ 9-28-92
DUE DATE 10-1-92
(DIS)APPROVED
WITHDRAWN

Docket No. 05 0009 1800
ADOPTED W/O HEARING
EMERGENCY RULE
TO REVISOR ON 9-21-92
REVISOR (DIS)APPROVED 9-25-92
FILED W/SEC. OF STATE 10-1-92
RETURNED TO AGENCY 10-2-92

✓ Rule as adopted (4 copies)

✓ Notice to Solicit Outside Information/Opinion (if applicable)
January 27, 1992 Date published in State Register
Comments

~~Petition for Adoption of a Rule~~

~~Board's Authorizing Resolution~~
Date adopted

✓ Proposed Rule
✓ Revisor's Certificate

✓ Notice of Intent to Adopt Rule
144.05, 144.12 and Statutory Authority 144.661 to 144.665
✓ Small Business Statement
Expenditure of public money statement
July 7, 1992 Signature

✓ Statement of Need and Reasonableness (if applicable)
~~Sept 3, 1992~~ ✓ Small Business Statement
Fees - § 16A.128? - Question

✓ Affidavit of Mailing Notice of Intent to Adopt Rule
July 15, 1992 Dated 30/25 days before adoption
✓ Notice attached indicates it is attached
Copy of rule or summary attached

✓ Publication in State Register
July 27, 1992 Date 30/25 days before adoption

Problem 180-day deadline from:
Effective date of law requiring rule (14.12) (both rules) amendments don't apply
✓ end of comment period (§ 14.26) (rules without hearing)
effective date of statutory authority (§ 14.29) (emergency rules)

~~Resolution Adopting~~
Date adopted

✓ Findings of Fact, Conclusions & Order Adopting
Sept 3, 1992 Date

Written Requests, Submissions or Comments

✓ Declaration of Attorney
Maria Christie Name of SAAG representing agency

~~Notice of Submission to Attorney General (if applicable)~~

~~Affidavit of Mailing Notice to Attorney General (if applicable)~~

Department of Health

Adopted Permanent Rules Relating to Health; Traumatic Brain Injury and Spinal Cord Injury Registry

Rules as Adopted

4643.0010 PURPOSE, SCOPE, AND APPLICABILITY.

The purpose and scope of parts 4643.0010 to 4643.0040 are to prescribe requirements applicable to the statewide traumatic brain injury and spinal cord injury registry, including what information must be reported, who is required to submit reports, when reports must be submitted, the provision of registry data to public and private entities, and fees to be charged for compiling or analyzing registry data.

4643.0015 INCORPORATIONS BY REFERENCE.

The Fourth edition of the International Classification of Diseases, Clinical Modification, 9th Revision, 1991, and corresponding annual updates is incorporated by reference. It is subject to frequent change, is published by the United States Department of Health and Human Services, Health Care Financing Administration, and may be purchased through the Superintendent of Documents, United States Government Printing Office, Washington, D.C. 20402. It is available through the Minitex interlibrary loan system.

4643.0020 DEFINITIONS.

Subpart 1. **Scope.** For purposes of parts 4643.0010 to 4643.0040, the following terms have the meanings given them in this part.

Subp. 2. **Commissioner.** "Commissioner" means the state commissioner of health, or the commissioner's designee.

Subp. 3. **E-Code.** "E-Code" means the ICD-9-CM classification code assigned to describe the environmental events, circumstances, and conditions determined to be the external cause of the injury.

Subp. 4. **Electronic submission of data.** "Electronic submission of data" means the transfer of data from a computer used by a reporting hospital to a computer specified by the commissioner through the use of a modem, magnetic tape, or magnetic disk.

Subp. 5. **Hospital.** "Hospital" means an acute care institution licensed in accordance with Minnesota Statutes, sections 144.50 to 144.581.

Subp. 6. **ICD-9-CM.** "ICD-9-CM" means the International Classification of Diseases, Clinical Modification, 9th Revision, 1991.

Subp. 7. **N-Code.** "N-Code" means the ICD-9-CM classification code assigned to describe the clinical nature of the injury.

Subp. 8. **Spinal cord injury reportable case.** "Spinal cord injury reportable case" means an injury event as defined in Minnesota Statutes, section 144.661, subdivision 3, which results in a hospital acute care inpatient admission or emergency room death, and is assigned one or more of the following N-Codes: 806, 907.2, and 952.

Subp. 9. **Summary registry data.** "Summary registry data" means statistical records and reports derived from registry data on individuals but in which individuals are not identified and from which neither their identities nor any other characteristic that could uniquely identify an individual is ascertainable.

Subp. 10. **Traumatic brain injury reportable case.** "Traumatic brain injury reportable case" means an injury event as defined in Minnesota Statutes, section 144.661, subdivision 2, which results in a hospital acute care inpatient admission or emergency room death, and is assigned one or more of the following N-Codes: 310.2, 348.1, (when used in combination with 994.1 or 994.7), 800, 801, 803, 804, 850, 851, 852, 853, 854, 905.0, 907.0 and 950.

4643.0030 REGISTRY REPORTING REQUIREMENTS.

Subpart 1. **Hospitals required to report.** Hospitals shall

submit to the commissioner reports containing the information items in subpart 2 for all traumatic brain injury and spinal cord injury reportable cases.

Subp. 2. **Report content.** The following information items must be submitted to the commissioner for each reportable case:

A. Patient data including: name, street address, city, county, and state of residence, telephone number, date of birth, gender, race/ethnicity, social security number, type of insurance or payment source, and name of parent or guardian for individuals under the age of 18 years.

B. Injury circumstance data including: date and time of day injury occurred, location where injury occurred (street address, city, county, and state), E-Codes or equivalent information submitted on forms provided by the commissioner, alcohol/drug levels (from toxicology reports), employer name (for work-related injuries), and use of protective equipment.

C. Nature of injury data including: N-Codes and fatality of injury.

D. Reporting source data including: name and address of hospital, name and telephone number of person completing report, date of report, patient medical record number, date of admission, date of discharge or transfer from acute care, place discharged or transferred to (for example home, rehabilitation center, nursing home) and whether the place is located in Minnesota or another state, and name of attending physician.

Subp. 3. **Report format.** Registry information must be submitted on forms provided by the commissioner for that purpose. The commissioner may approve alternative means for providing registry information including the electronic submission of data.

Subp. 4. **Report submission deadline.** A report must be completed and submitted to the commissioner within 60 days of patient death, discharge, or transfer from the acute care setting.

Subp. 5. **Report quality assurance.** A hospital must take all reasonable measures to assure that the registry information

submitted to the commissioner is complete and accurate. A hospital must cooperate with the commissioner in the conduct of registry information validation studies, including providing access to patient medical records.

4643.0040 PROVISION OF REGISTRY DATA.

Subpart 1. **Summary registry data.** Except as provided in Minnesota Statutes, section 144.664, subdivision 3, the commissioner will release only summary registry data.

Subp. 2. **Data compilation or analyses.** The commissioner must provide assistance in response to requests from public or private entities engaged in research regarding the compilation or analyses of summary registry data. The assistance must include interpreting data analysis results and providing recommendations concerning the subsequent use of this information.

Subp. 3. **Fees.** The commissioner may charge fees in accordance with Minnesota Statutes, section 13.03, subdivision 3, to recover all expenses and costs. These costs may include employee hourly wages, employee expenses, electronic data processing costs, duplicating, and clerical charges incurred by the commissioner as a result of requests by public and private entities for summary registry data compilation or analyses under the following conditions:

A. the entity requesting the summary registry data is not a community health services board as defined in Minnesota Statutes, chapter 145A;

B. the request requires more than one person hour of time to complete for an employee of the commissioner who is classified as either a programmer/analyst or higher, or an epidemiologist I or higher; and

C. the estimated total out-of-pocket expenses, regardless of person hours needed to satisfy the request, are greater than $50.

APPROVED AS TO FORM AND LEGALITY
Oct 1 1992
HUBERT H. HUMPHREY, III
ATTORNEY GENERAL
BY N J Murray
SPECIAL ASSISTANT ATTORNEY GENERAL

STATE OF MINNESOTA
DEPARTMENT OF STATE
FILED

OCT 01 1992

Joan Anderson Growe
Secretary of State

4:15 PB
PM

Re 4643.0040 subp 3 C clear

What purpose does the sentence mean "regardless of person hours needed to satisfy the request, are greater than $ 50.

9-21-92 - Talked to Marie about 180 day deadline and lanuage under 4643.0040 sub 3C
Going to write the letter

9-22-92 - send letter see page 3

Problem - 2nd letter see page 3.

end of comment period August 26, 1992

Stat. Authority

144.05 General Duties of Commissioners

144.12

The commissioner may adopt reasonable rules pursuant to chapter 14 for the preservation of the public health

144.664 subd 5

The commissioner shall adopt rules to administer the registry, collect information, and distribute data but are not limited to the following: (attached Statute)

4643.0040 subd 3.C - set fee at greater than $50.

Setting fees - 144.664 sub 5 (6)

gives authority to set fees but doesn't set the amount

should they have gone under 16A.128 - probably no

180 day deadline

14.12 - mandatory commissioner shall adopt rules

left a message to call

State of Minnesota
Department of Health

M E M O R A N D U M

Rec 9-17-92

DATE: September 11, 1992

TO: Patricia Nolte, Legal Assistant
Public Finance Division
Office of the Attorney General
Capitol Office Building

FROM: Mark Kinde, Supervisor MK
Injury Unit

PHONE: (612) 623-5782

SUBJECT: Review of a Rule Adopted Without a Public Hearing Related to the Traumatic Brain Injury and Spinal Cord Injury Registry

Enclosed are the documents required to be submitted under Minnesota Rules, part 2010.0300 for your review of a rule adopted without a public hearing. Please address any questions and your order on this matter to me.

Official documents in this submittal include:

A. A photocopy of the notice of solicitation of outside information or opinions as published in the State Register.

B. A copy of the proposed rule with a certificate of approval as to form by the Revisor of Statutes attached.

C. A copy of the notice of intent to adopt a rule without a public hearing as mailed.

D. A copy of the Statement of Need and Reasonableness in support of the proposed rule complying with part 2010.0700.

E. A copy of the affidavit of mailing the Statement of Need and Reasonableness to the Legislative Commission to Review Administrative Rules.

F. A copy of the certificate and affidavit of mailing the notice of intent to adopt a rule without a public hearing. The certificate states that the mailing list maintained by the Department pursuant to Minnesota Statutes, section 14.14 and 14.22 is accurate, complete, and current and that the notice of intent to adopt the rule was mailed to all persons and groups whose names appear on the list.

G. A photocopy of the notice of intent to adopt the rule without a public hearing as published in the State Register.

STATE OF MINNESOTA

Office of the Attorney General

TO : MARK KINDE
Minnesota Department of Health
Health Promotion and Education Division
717 Southeast Delaware Street
Minneapolis

DATE : October 1, 1992

FROM : MARY JO MURRAY
Special Assistant
Attorney General

PHONE : 296-3258

SUBJECT : In the Matter of the Adopted Rule Relating to Health; Traumatic Brain Injury and Spinal Cord Injury Registry

The above-referenced rule has been approved as to its legality by the Attorney General on October 1, 1992.

Enclosed is your copy of the approved rule. This office has already filed two copies with the Secretary of State, who will forward one copy to the Revisor of Statutes. The fourth is being retained by this division of the Attorney General's Office for its records.

Also enclosed are any petitions, requests, submissions or comments along with any extra copies of documents which you submitted to the Attorney General.

Your next step is to arrange for publication of the Notice of Adoption in the State Register. In a day or two, you should receive from the Revisor's Office three copies of the notice of adoption of your rule. You should submit two copies of the Notice of Adoption to the State Register for publication. A permanent rule without a hearing does not become effective until five days after a notice of adoption is published in the State Register in accordance with Minn. Stat. § 14.27. An emergency rule becomes effective five working days after approval by the Attorney General; however, the agency must publish a notice in the State Register in accordance with Minn. Stat. § 14.34.

If you have any questions in this regard, please contact me.

Enclosures
cc: Maria C. Christu
William Brown, Chief Judge
MaryAnn Hruby

MJM:jj.rules.bb5

H. Four copies of the rule as adopted. Any modification made to the proposed rule is reflected on the rule as adopted and is approved as to form by the Revisor of Statutes.

I. A copy of the Findings of Fact, Conclusions, and Order Adopting the Rule.

J. A copy of all written requests, submissions, or comment on the rule received by the Department except requests solely for copies of the rule or for the Statement of Need and Reasonableness.

K. A copy of the Declaration of Counsel of the Attorney General-Health.

No requests were received to be notified of submission of the rule to the Attorney General.

If you have any questions on this submittal, please call me at 623-5782. Thank you.

MK:djg
Attachments

SF-00006-05 (4/86)

DEPARTMENT : HEALTH

STATE OF MINNESOTA

Office Memorandum

DATE : March 23, 1992

TO : Maryanne V. Hruby, Executive Director
Legislative Commission to Review Administrative Rules

FROM : David R. Abrams, Director D.R.A.
Legal and Policy Affairs

PHONE : 623-5768

SUBJECT : Report required by Minn. Stat. section 14.12 on Adoption of Rules - 1991 Session

Your Staff Report dated February 19, 1992 identifies several statutory provisions enacted in the 1991 session requiring the Minnesota Department of Health (MDH) to make rules. Pursuant to M.S. §14.12, this report addresses the status of the MDH's rulemaking activities under those provisions.

I. Criteria for Family Planning Special Project Grant Funding/Procedures for Conscience Change (Chapter 292, A.1, S.9, Subd. 3)

Proposed rule amendments for family planning special projects, including criteria for grant funding, were published in the State Register on April 1, 1991, pursuant to the MDH's rulemaking authority under M.S. §§144.05, 144.12 and 145.925. Permanent rules, including rules establishing criteria for grant funding, were adopted and published in the State Register for July 29, 1991.

Chapter 292, A.1., s. 9, subd. 3, in addition to calling for rules relating to grant funding criteria, also required the MDH to "develop procedures" regarding "the conscience clause." The MDH has developed such procedures. The application instructions and "Conscience Clause Documentation" form from the grant application package disseminated on August 27, 1991 are attached to this memorandum as Exhibit 1, and show the procedures developed by the MDH pursuant to Chapter 292, A.1, s.9, subd.3.

In short, the MDH has already fully complied with the requirements of Chapter 292, A.1, s.9, subd.3, that it adopt rules and develop procedures.

II. Minimum Standards Regarding Borings, Including Exploratory Borings, M.S. §103I.101, Subd. 5.

Since the initial adoption of Chapter 103I in 1989, including the lengthy list of regulatory responsibilities enumerated in M.S. §103I.101, subd. 5, the MDH has adopted rules on licensing, registration, notices and permits, which were published in the State Register on July 9, 1990. Subsequent to 1990 legislative amendments to chapter 103I, the rules were revised to address dewatering and sealing licensure and variances; the revised rules were published in the State Register on December 24, 1990.

In response to 1991 amendments to chapter 103I, the MDH on November 25, 1991 adopted emergency rules mandated by M.S. §103I.222. The permanent rules mandated by that law were published on March 9, 1992, and will be codified as Minnesota Rule 4725.7605.

As to rules governing "minimum standards for design, location, construction, maintenance, repairs, sealing, safety, and resource conservation regarding borings, including exploratory borings," Chapter 4725 of the Minnesota Rules includes existing rules on well and boring construction, design and location. These rules, parts 4725.1860 to 4725.7605, are now under revision.

The MDH has formed and met with a number of task forces and advisory bodies, including counties and the regulated drilling industry, to discuss new rule provisions and amendments to existing rules. A Notice of Solicitation for Comment was published in the July 22, 1991 State Register. A revisor's draft rule has been prepared. That draft streamlines some existing notices, permitting and record keeping requirements, revises isolation distances, consolidates and hopefully simplifies construction, maintenance and repair standards, includes provisions on sealing, and extends the requirements to environmental boreholes, as well as wells. Work to complete the SNR is underway. The MDH anticipates publication to adopt by May 1992. Staff have presented drafts of the rule revision to statewide industry meetings and

the response so far has been good. Industry representatives have indicated the consolidation, improved format and simplification of the code has been well worth the wait.

III. Rules to Administer the Traumatic Brain Injury and Spinal Chord Injury (TBI/SCI) Registry (M.S. §144.664, Subd. 5)

The enabling legislation for the TBI/SCI Registry was enacted during the 1991 session. M.S. §144.664, subd. 5, directs the commissioner to adopt rules to "...administer the registry, collect information, and distribute data." Section 144.664, subd. 4, requires the commissioner to establish a review committee to assist in the adoption of the rules.

In November 1991, Commissioner Marschall appointed members to the TBI/SCI Review Committee. Meetings of the committee have been held on November 22, 1991, December 19, 1991, January 22, 1992, and February 28, 1992. A fifth meeting is scheduled for March 27, 1992, at which time the review committee will discuss a preliminary draft of the proposed TBI/SCI Registry rules.

A Notice of Solicitation of Outside Information or Opinions was published in the State Register on January 27, 1992.

The MDH anticipates that if the review committee approves a preliminary draft of the proposed rules at its meeting on March 27, 1992, the numerous procedural steps will be completed and the rules adopted by July 1992. If the proposed rules become controversial and substantial revisions need to be made, that timeline will be extended by another 60 to 90 days.

IV. Rules Relating to Residential Care Homes (M.S. §144B.03, Subd. 1; M.S. §144B.06; M.S. §144B.09; M.S. §144B.10)

In February 1992, the MDH submitted "Residential Care Homes: A Report to the 1992

Legislature." The report (a copy is attached to this memorandum as Exhibit 2) discusses the establishment by the MDH of the Residential Care Home Work Group, pursuant to M.S. §144B.17 (1991 amendment); sets forth the content of proposed rules (see pages 9-17); and identifies certain areas as needing additional guidance from the legislature as to matters of policy. Because of the time involved in convening the Residential Care Home Work Group and preparing the report, and given the anticipation that additional statutory developments would come from the 1992 legislative session, the MDH has not yet initiated the procedural steps that would lead to adoption of the rules proposed in the report.

The MDH anticipates working on developing additional proposed rules beginning Spring 1992. The issues to be addressed first are admission to and discharge from residential care homes, and the administering of medications in such homes. The MDH has organized smaller groups of experts to address the admission, discharge and medications issues, and will then bring those issues before the entire Residential Care Home Work Group, in order to develop additional proposed rules concerning those issues.

V. Rules to Adjust Hearing Instrument Dispenser Fees (M.S. §153A.17)

M.S. §153A.17 was amended in the 1991 legislative session to clarify existing law. Prior to that amendment, M.S. §153A.14, subd. 5 had already required the MDH to adopt rules for the permit system. Pursuant to that authority, rules were adopted in November 1989. Those rules are codified as Minn. Rule 4692.0010, et. seq. The 1991 amendments to M.S. §153A.17 do not presently mandate nor necessitate any modification to those existing rules.

Conclusion

I hope that this report answers any questions that the Commission may have concerning the status of MDH rulemaking activities. If not, please let me know. I also hope that the Commission has not been inconvenienced by the additional time that it has taken for this report to be prepared. I assure you that in the future, the MDH will meet the deadline provided in M.S. §14.12.

DRA:crb

Attachments

cc: Governor Arne Carlson
Senator Linda Berglin
Senator Bob Lessard
Senator Don Samuelson
Representative Lee Greenfield
Representative Henry Kalis
Representative Willard Munger
Representative Peter Rodosovich

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

DEPARTMENT OF HEALTH

In the Matter of the Proposed Adoption of Rules Related to the Traumatic Brain Injury and Spinal Cord Injury Registry

FINDINGS OF FACT, CONCLUSIONS, AND ORDER ADOPTING RULES

The Department of Health (hereinafter "Department") initiated the above-captioned rulemaking proceeding to adopt rules without a public hearing pursuant to Minn. Stat., section 14.22 to 14.28 as well as all other provisions of Minn. Stat. ch. 14 applicable to this rulemaking proceeding. The comment period has closed without 25 or more persons requesting that a hearing be held on these proposed rules. Accordingly, the Commissioner of Health (hereinafter "Commissioner") having fully and thoroughly reviewed and considered the record in this matter, and based thereon, makes the following **FINDINGS:**

1. The Department's Notice of Intent to Adopt the above-entitled rules without a public hearing was published in the State Register on July 27, 1992, and was sent by United States mail to all persons on the list maintained by the Department pursuant to Minn. Stat., section 14.14, subd. 1a and 14.22 on July 15, 1992. The Department also sent a copy of the Notice by United States mail to all hospitals which are currently licensed by the Department.

2. The Statement of Need and Reasonableness was prepared before the Notice of Intent to Adopt Rules Without a Public Hearing

was mailed to all persons on the rulemaking mailing list and published in the State Register and was available to the public.

3. All persons were given the opportunity to submit comment on the rules for 30 days after the notice of proposed rulemaking was published and mailed.

4. The Department received no requests for a public hearing on the rules.

5. The Department received no requests to be notified when the rulemaking record is submitted to the office of the Attorney General.

6. T. G. Birkey, M.D, submitted written comments which raised four areas of concern. Dr. Birkey's first area of concern related to the impetus for developing the registry and how the results of the registry are expected to improve the health status of people in Minnesota. Minn. Stat., section 144.662 directs the Commissioner to establish and maintain the registry and describes the two purposes of the registry and the benefits to be derived therefrom. Adding language to the rules to describe the purposes and intended benefits of the registry would be redundant and is unnecessary.

7. Dr. Birkey's second area of concern related the length of time that the registry would be in effect. Minn. Stat., sections 144.661 to 144.665 do not contain a sunset provision. Therefore, the registry will remain in effect until the statutory authority is repealed or a specific sunset provision is added. If in the future it is determined by the Commissioner that the registry is

no longer needed to meet the two purposes stated in Minn. Stat., section 144.662, the Commissioner could recommend to the State Legislature that Minn. Stat., sections 144.661 to 144.665 be amended or repealed.

8. Dr. Birkey's third area of concern related to the setting of a precedent which would lead to the collection of information on injuries other than traumatic brain injury and spinal cord injury. Minn. Stat., sections 144.661 to 144.665 authorizes the Commissioner to collect information only on traumatic brain injuries and spinal cord injuries. The Commissioner's statutory authority would need to be expanded in order to include other types of injury in the registry and the Commissioner has no plans, at this time, to seek such additional statutory authority from the State Legislature.

9. Dr. Birkey's fourth concern related to the lack of monetary compensation for the reporting hospitals. Because the State Legislature did not authorize the Commissioner to reimburse hospitals for the cost of completing registry reports nor appropriate funds for that purpose, special attention was given to creating reporting requirements which would place a minimal burden on reporting hospitals. For example, the information required to be reported is readily available from patient medical records, the time allowed to submit the information is sufficient to assure that the patient medical records will have been completed by the attending physicians, and options are provided for the manner in which certain information (e.g., E-Codes) is submitted. These

provisions assure that the cost to hospitals of submitting registry information is minimized to the extent possible.

10. The Commissioner incorporates herein as findings, the statement of need and reasonableness.

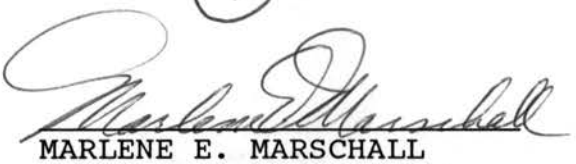
Based upon the above findings, the Commissioner with respect to the above-captioned rules makes the following **CONCLUSIONS:**

1. That all substantive and procedural requirements have been complied with;

2. That the rules are statutorily authorized; and

3. That the rules are both needed and reasonable. (8)

NOW, THEREFORE, IT IS HEREBY ORDERED that the rules identified as In the Matter of the Proposed Adoption of Rules Related to the Traumatic Brain Injury and Spinal Cord Injury Registry are adopted this 3rd day of September, 1992, pursuant to authority vested in the Commissioner by Minn. Stat., sections 144.05, 144.12, and 144.661 to 144.665 (1991). (9)



MARLENE E. MARSCHALL
Commissioner of Health

STATE OF MINNESOTA

DEPARTMENT OF HEALTH

IN THE MATTER OF THE PROPOSED ADOPTION OF RULES OF THE DEPARTMENT OF HEALTH RELATED TO THE TRAUMATIC BRAIN INJURY AND SPINAL CORD INJURY REGISTRY, PARTS 4643.0010 TO 4643.0040

STATEMENT OF NEED AND REASONABLENESS

STATUTORY AUTHORITY

The Minnesota Commissioner of Health (hereinafter "commissioner"), pursuant to Minnesota Statutes, section 14.131 and 14.23 presents facts establishing the need for and reasonableness of proposed rules related to the traumatic brain injury and spinal cord injury registry, parts 4643.0010 to 4643.0040.

The statutory authority of the commissioner to adopt rules related to the traumatic brain injury and spinal cord injury registry is found in Minnesota Statutes, sections 144.05, 144.12, and 144.661 to 144.665. Section 144.664, contains a specific grant of authority to the commissioner to "adopt rules to administer the registry, collect information, and distribute data."

COMPLIANCE WITH PROCEDURAL RULEMAKING REQUIREMENTS

To prepare the proposed rules the Department:

(1) followed the procedures mandated by the Minnesota Administrative Procedures Act and the rules of the State of Minnesota's Office of Administrative Hearings;

(2) published a Notice of Intent to Solicit Outside Opinion concerning the adoption of rules in the State register on Monday, January 27, 1992;

(3) established a review committee to assist in the adoption of rules as required by Minnesota Statutes, section 144.664. This committee included representatives from the following agencies and organizations: Family Physicians of Northfield, Hennepin County Medical Center, Mayo Clinic, Medicus Information Service, Minneapolis Clinic of Neurology, Minnesota Department of Human Services, Minnesota Department of Jobs and Training, Minnesota Head Injury Association, Minnesota Hospital Association, Minnesota Medical Association, Minnesota Medical Records Association, Minnesota Spinal Cord Injury Association/Sister Kenney Institute, North Memorial Medical Center, St. Cloud Hospital, St. Luke's Hospital, St. Mary's Hospital, St. Paul Ramsey Medical Center, and the University of Minnesota's School of Public Health. The committee met once per month from the period of November 1991 through March of 1992 and assisted Department staff by making specific comments

and recommendations concerning all key matters covered by the proposed rules. The committee was particularly helpful in defining what constitutes a reportable case, determining what information should be reported, who should be required to submit reports and how much time should be allowed for the submission of reports. After Department staff prepared a draft of the proposed rules, the draft was reviewed by the committee and additional suggestions were offered. These final recommendations of the review committee were incorporated in the rules as proposed.

As of March 5, 1992, one individual submitted written comments and two individuals submitted oral comments in response to the notice to solicit outside opinion concerning the proposed rules. The written submission and the log of oral comments will be made a part of the rulemaking record pursuant to Minnesota Statutes, section 14.10. These comments were reviewed and considered by the Department when it prepared the proposed rules.

A Notice of Intent to Adopt the Rules Without a Public Hearing, a Notice of Intent to Adopt the Rules With a Public Hearing if 25 or More Persons Request a Hearing, and a Notice of Intent to Cancel a Hearing if Fewer than 25 Persons Request a Hearing will be published in the State Register. Drafts of the proposed rule will be provided to affected parties, other interested individuals and

organizations, and to each person requesting a copy.

IMPACT OF PROPOSED RULES ON SMALL BUSINESS

State agencies are required by Minnesota Statutes, section 14.115, subdivision 2, to consider ways to reduce the impact of proposed rules on small businesses and to discuss those ways in the statement of need and reasonableness. Minnesota Statutes, section 144.663 authorizes the commissioner to designate either the treating hospital, medical facility, or physician as the entity required to report traumatic brain injury and spinal cord injury registry information. The commissioner has decided to designate hospitals as the reporting entity, and because some rural hospitals may meet the definition of small business the impact on small businesses has been considered.

The Department considered each of the methods specified in Minnesota Statutes, section 14.115, subdivision 2 for reducing the impact of the rules on small businesses. With regard to less stringent compliance or reporting requirements, it was decided to allow hospitals to submit equivalent information in lieu of E-Codes because some smaller hospitals do not currently assign E-Codes as part of their medical records coding process (see detailed justification for part 4643.0030, subp. 2, item B). When establishing the report submission deadline (see detailed justification for part 4643.0030, subp. 4), a time period was selected that was considered to be reasonable for all hospitals

including those with small numbers of medical records personnel. In order to simplify the submission of reports for small hospitals, several methods of information transfer are made possible (see detailed justification for part 4643.0030, subp. 3) and small hospitals will be able to select the method that works best for them. Since the proposed rules do not contain any design or operational standards, performance standards could not be substituted for them. Because the registry is intended to include traumatic brain injury and spinal cord injury events that occur throughout Minnesota, it is not possible to exclude small hospitals from the reporting requirements.

Given the above considerations, all reasonable efforts have been taken to minimize the impact on small businesses and still fulfill the intent of the authorizing statute.

STATEMENT OF NEED

The commissioner has been authorized by Minnesota Statutes, sections 144.661 through 144.665 to design and establish a traumatic brain injury and spinal cord injury registry. Minnesota Statutes, section 144.664 authorizes the commissioner to adopt rules to administer the registry, collect information, and distribute data. The rules must include at least those items specified in Minnesota Statutes, section 144.664, subdivision 5.

In order to establish a traumatic brain injury and spinal cord

injury registry that can be effectively and efficiently administered, the commissioner has proposed rules that define reportable cases; specify who is required to report, the content of the report, the format of the report and when the report must be submitted; and provide for the release of registry summary data and fees to be charged for compilation or analyses of registry data. These rules are necessary to develop and operate a registry capable of satisfying the two purposes stated in Minnesota Statutes, section 144.662.

GENERAL STATEMENT OF REASONABLENESS

The proposed rules are intended to establish a traumatic brain injury and spinal cord injury registry which will provide the information necessary to fulfill the purposes set forth in Minnesota Statutes, section 144.662 without creating an undue hardship for the reporting hospitals. The data items to be reported have been limited to those which are required to meet the registry's statutory purpose and the report submission deadline was selected because it allows a reasonable amount of time for hospitals to abstract the information from patient medical records. Fees for registry data compilation or analyses are limited to actual expenses and no fee is charged for very minor requests.

The rule by rule justification which follows provides a further basis for a determination of reasonableness.

RULE BY RULE JUSTIFICATION

Part 4643.0010 describes the purpose, scope and applicability of the proposed rules related to the statewide traumatic brain injury and spinal cord injury registry. This part lists all of the key subject areas addressed by the rules.

Part 4643.0015 incorporates the Fourth Edition of the International Classification of Diseases, Clinical Modification, 9th Revision, 1991 (and corresponding annual updates) by reference. This part includes information concerning where the document may be purchased and through which interlibrary loan system it may be obtained. Classification codes described in the document are used to define traumatic brain injury and spinal cord injury reportable cases (see part 4643.0020, subparts 6,8 and 10).

Part 4643.0020, Subp. 1 makes it clear that, for purposes of the rules related to the traumatic brain injury and spinal cord injury registry, the terms that follow are defined in a certain way.

Part 4643.0020, Subp. 2 defines the term "commissioner" to mean the state commissioner of health, or the commissioner's designee. This makes it possible to use the term "commissioner" throughout the rules even though most of the specific tasks will be carried out by authorized Department of Health staff members.

Part 4643.0020, Subp. 3 defines the term "E-Code." This term is

used to describe one of the key data elements that must be included in the registry reports submitted to the commissioner. A specific series of E-Codes are included in the Fourth Edition of the International Classification of Diseases, Clinical Modification, 9th Revision, 1991 for describing the environmental events, circumstances, and conditions determined to be the external cause of injury. Justification for including this data element will be addressed under Part 4643.0030, Subp. 2.

Part 4643.0020, Subp. 4 defines the term "electronic submission of data." This term is used in Part 4643.0030, Subp. 3 regarding the format used for submitting registry reports to the commissioner. Although registry reports will be able to be submitted on paper report forms provided by the commissioner for this purpose, some hospitals may find it easier to submit the data in an electronic manner and this term is defined to make it clear that the use of a computer modem, magnetic tape, or magnetic disk could be considered as alternative methods for submitting registry reports.

Part 4643.0020, Subp. 5 defines the term "hospital." This term must be defined because the commissioner has decided to designate hospitals as the entity required to submit registry reports. The term is defined to include any acute care institution licensed by the commissioner as a hospital facility.

Part 4643.0020, Subp. 6 defines the term "ICD-9-CM." The Fourth

Edition of the International Classification of Diseases, Clinical Modification, 9th Revision, 1991 is a detailed coding system used to describe morbidity data. It is used for purposes of indexing medical records, medical care review, third party reimbursement and basic health statistics. ICD-9-CM codes are used by all hospitals because they are required for purposes of submitting claims for third party reimbursement. A special series of ICD-9-CM codes are used to describe the clinical nature (N-Codes) of injuries as well as their external cause (E-Codes). ICD-9-CM is the most recent revision of this universally accepted morbidity coding system.

Part 4643.0020, Subp. 7 defines the term "N-Code." This term is used to describe those medical conditions which will constitute reportable traumatic brain injury or spinal cord injury cases. A specific series of N-Codes are included in the Fourth Edition of the International Classification of Diseases, Clinical Modification, 9th Revision, 1991 for describing the clinical nature of injuries (e.g., code number 800 is a fracture of the vault of the skull). Minnesota Statutes, section 144.664, subdivision 5, clause (1) requires the commissioner to identify the specific ICD-9 codes to be used to define traumatic brain injury and spinal cord injury.

Part 4643.0020, Subp. 8 defines the term "spinal cord injury reportable case." Only those spinal cord injuries that are fatal events or severe enough to require hospitalization will be

reportable. Deaths that occur in non-hospital settings will be identified through the existing death certificate reporting system. Given the clinical nature of spinal cord injuries, most (if not all) such injuries require some period of acute inpatient medical care in a hospital setting. Consistent with recommendations of the Review Committee established in accordance with Minnesota Statutes, section 144.664, subdivision 4, no attempt will be made to collect information on the few (if any) spinal cord injuries which do not require hospitalization. This decision is based on the fact that there are hundreds of private clinical practices in Minnesota and most of them do not have medical records personnel with the level of training of those in hospital facilities. Therefore, the quality of the information submitted from these clinical practices would be in question and, given the large number of such practices, it would be impossible for the Department to provide training and do information validation studies in a timely manner. The specific N-Codes that will be used for identifying reportable cases are the following:

806 Fracture of vertebral column with spinal cord injury;

907.2 Late effect of spinal cord injury; and

952 Spinal cord injury without evidence of spinal bone injury.

These specific N-Codes were selected based on the recommendations of the Review Committee established in accordance with Minnesota Statutes, section 144.664, subdivision 4.

Part 4643.0020, Subd. 9 defines the term "summary registry data." Minnesota Statutes, section 144.664, subdivision 2 authorizes the commissioner to provide summary registry data to public and private entities to conduct research studies. Minnesota Statutes, section 144.665 classifies registry data collected on individuals as "private data" as defined in section 13.02, subdivision 12. This term is defined to clearly distinguish the difference between "private data on individuals" and "summary registry data" by incorporating language that is consistent with the definition of "summary data" contained in Minnesota Statutes, section 13.02, subdivision 19.

Part 4643.0020, Subp. 10 defines the term "traumatic brain injury reportable case." Only those traumatic brain injuries that are fatal events or severe enough to require hospitalization will be reportable. Deaths that occur in non-hospital settings will be identified through the existing death certificate reporting system. Consistent with recommendations of the Review Committee established in accordance with Minnesota Statutes, section 144.664, subdivision 4, no attempt will be made to collect information on the less severe traumatic brain injuries which do not require hospitalization. This decision is based on the fact that there are hundreds of private clinical practices in Minnesota and most of them do not have medical records personnel with the level of training of those in hospital facilities. Therefore, the quality of the information submitted from these clinical practices would

be in question and, given the large number of such practices, it would be impossible for the Department to provide training and do information validation studies in a timely manner. However, the Department intends to conduct special studies in the future to determine if it is feasible to collect accurate information on traumatic brain injuries that require only outpatient care. The specific N-Codes that will be used for identifying reportable cases are the following:

310.2 Postconcussion syndrome;

348.1 Anoxic brain damage, when used in combination with 994.1 (drowning and nonfatal submersion) or 994.7 (asphyxiation and strangulation);

800 Fracture of vault of skull;

801 Fracture of base of skull;

803 Other and unqualified skull fractures;

804 Multiple fractures involving skull or face with other bones;

850 Concussion;

851 Cerebral laceration and contusion;

852 Subarachnoid, subdural, and extradural hemorrhage, following injury;

853 Other and unspecified intracranial hemorrhage, following injury;

854 Intracranial injury of other and unspecified nature;

905.0 Late effect of fracture of skull and face bones;

907.0 Late effect of intracranial injury without

mention of skull fracture; and

950 Injury to optic nerve and pathways.

These specific N-Codes were selected based on the recommendations of the Review Committee established in accordance with Minnesota Statutes, section 144.664, subdivision 4.

Part 4643.0030, Subp. 1 designates hospitals as the entity required to submit registry information to the commissioner. Minnesota Statutes, section 144.663, subdivision 1 authorizes the commissioner to designate either the treating hospital, medical facility, or physician as the reporting entity. Minnesota Statutes, section 144.664, subdivision 5, clause (4) directs the commissioner to adopt rules that include specification of the persons and facilities required to report. Because the commissioner, in consultation with the Review Committee, has determined that traumatic brain injury and spinal cord injury reportable cases include only those that are fatal events or severe enough to require hospitalization, it is logical to designate hospitals as the reporting entity because the information the commissioner seeks is contained in hospital medical records. Furthermore, the assignment of N-Codes is done by hospital medical records personnel and these codes are subsequently used to determine which cases are reportable. Although treating physicians have access to patient medical records, they do not have the time necessary to abstract the required information, complete the registry reports, and submit the information to the commissioner.

It is not necessary to designate other medical facilities, such as physician clinics, as reporting entities because less severe injuries that require treatment only on an outpatient basis are not required to be reported to the commissioner.

Part 4643.0030, Subp. 2, Item A specifies the "patient" data elements that must be included in registry reports. Minnesota Statutes, section 144.663, subdivision 2, clause (1) specifies that registry reports must contain the name, age, and residence of the injured person. Clause (4) authorizes the commissioner to require information in addition to that specified in clauses (1) through (3). The patient's name, address, telephone number and the name of parent or guardian for individuals under the age of 18 are necessary for the commissioner to comply with the notification requirement contained in Minnesota Statutes, section 144.664, subdivision 3 which requires the provision of patient identifying information to the commissioner of jobs and training. This information is used by the commissioner of jobs and training to carry out the responsibilities specified in Minnesota Statutes, section 268A.03, clause (o). County of residence is included to make it possible for the commissioner to analyze registry data on a county basis without needing to convert patient addresses to county of residence. Date of birth is included as a substitute for age because it is more likely to be reported accurately and is easier to abstract from the medical record. Gender and race/ethnicity are included to make it possible for the

commissioner to analyze the distribution of injury events among these basic demographic variables. Social security number and payment source are included to make it possible to match registry and medical assistance files in order for the commissioner to analyze the financial impact of these injuries and determine the need for additional treatment and rehabilitation services.

Part 4643.0030, Subp. 2, Item B specifies the "injury circumstance" data elements that must be included in registry reports. Minnesota Statutes, section 144.663, subdivision 2, clause (2) specifies that registry reports must contain information regarding the date and cause of the injury. The date and time of day of injury are necessary for the commissioner to analyze the temporal distribution of these events. Location where the injury occurred is necessary to analyze the geographic distribution of events. E-Codes are required because they provide very specific information on the external cause of injury (e.g., E813 is a motor vehicle accident involving a collision with another vehicle). Because some hospitals do not currently assign E-Codes as part of their medical records coding process, the commissioner will provide forms that make it possible for these hospitals to provide the information necessary for the commissioner to determine the appropriate E-Code designations. If toxicology tests have been conducted, alcohol and drug analysis data are to be reported because of the known association between chemical substance use/abuse and the occurrence of injuries. Employer name (for work related injuries) is

necessary in order for the commissioner to determine the type of industry and analyze the distribution of work related injury events. Information concerning the use of protective equipment is necessary to analyze the frequency of use and effectiveness of such equipment. All of these data elements are necessary for the commissioner to identify the causal relationships that are essential to facilitate the development of injury prevention programs referred to in the statement of the registry's purpose, Minnesota Statutes, section 144.662, clause (1).

Part 4643.0030, Subp. 2, Item C specifies the "nature of injury" data elements that must be included in registry reports. Minnesota Statutes, section 144.663, clause (3) specifies that registry reports must contain information regarding the initial diagnosis. This information will be obtained by requiring hospitals to provide the N-Code(s) that describe the nature of a patient's injury (e.g., code number 800 is a fracture of the vault of the skull). All hospitals currently assign N-Codes as part of their medical records coding process because these codes must be used to obtain reimbursement from third party payment sources. The commissioner will use N-Code and fatality information to analyze the relationship between the external cause of the injury and the type and severity of the injury sustained. The results of this analysis will assist in establishing priorities for the development of injury prevention programs referred to in the statement of the registry's purpose specified in Minnesota Statutes, section

144.662, clause (1). The requirement that this information be provided is reasonable because it can be abstracted from the patient medical record.

Part 4643.0030, Subp.2 Item D specifies the "reporting source" data elements that must be included in registry reports. Minnesota Statutes, section 144.663, clause (4) authorizes the commissioner to require information in addition to that specified in clauses (1) through (3). The name and address of the hospital, the name and telephone number of the person completing the report, and the date of the report are necessary for the commissioner to conduct follow-up on reports that are submitted with incomplete or inconsistent information. The patient medical record number is required in order to make it possible for the commissioner to do registry information validation studies (see detailed justification for Subp. 5). Dates of admission and discharge (or transfer) from acute care are necessary for the commissioner to be able to calculate patient length of stay which can be used as a proxy for severity of injury. The place that the patient is discharged or transferred to (e.g., home, rehabilitation center, nursing home) can also be used as a proxy for severity of injury sustained. Knowledge of whether the place of discharge or transfer is located in Minnesota or another state is useful in determining the need for Minnesota based rehabilitation or long term care facilities. Name of the attending physician is necessary so that the commissioner can consult with the patient's personal physician to obtain

approval to contact the patient directly if additional information concerning the circumstances of the injury event is required.

Part 4643.0030, Subp. 3 specifies that registry information must be submitted on forms provided by the commissioner for that purpose. Minnesota Statutes, section 144.663, subdivision 2 states that the registry report must be submitted on forms provided by the department. In addition to submitting the information on paper report forms, the proposed rule allows the commissioner to approve alternative means of providing registry information including the electronic submission of data. This flexibility is allowed because some hospitals may (now or in the future) find it easier to submit the information through a computer modem, magnetic tape or magnetic disk. These alternative methods of submission would not compromise the quality of the data submitted and could reduce the amount of time necessary to submit data to the commissioner or for the subsequent entry of the information into the registry data base.

Part 4643.0030, Subp. 4 specifies that registry reports must be completed and submitted to the commissioner within 60 days of patient death, discharge or transfer from the acute care setting. Minnesota Statutes, section 144.664, subdivision 5, clause (4) authorizes the commissioner to establish in rule the time period in which reports must be submitted. The commissioner considered and rejected the establishment of a two-stage reporting system which would require the submission of two separate registry reports

for each patient. Under a two-stage system, a report would be submitted at the time of initial diagnosis and another report at the time of patient death, discharge or transfer from acute care. Based on recommendations of the Review Committee established in accordance with Minnesota Statutes, section 144.664, subdivision 4, the commissioner determined that there were no significant advantages associated with a two-stage reporting system and that requiring the submission of two separate reports for each patient would create an undue hardship for hospitals. The number of days allowed for submission of registry reports was also based on recommendations of the Review Committee which took into consideration the amount of time that is usually required before all patient information is collected within a hospital and included in the medical record. In addition, consideration was given to the amount of time necessary to abstract the required information from medical records and the fact that some hospitals have a small medical records staff.

Part 4643.0030, Subp. 5 addresses the issue of assuring the quality of registry information submitted to the commissioner by hospitals. Minnesota Statutes, section 144.664, subdivision 5, clause (3) authorizes the commissioner to establish standards for reporting specific types of data. The basic standard established by this proposed rule is to require that the information be as complete and accurate as possible. The commissioner has decided not to prescribe specific internal verification procedures for hospitals

to follow in order to make it possible for them to continue to use their existing mechanisms for assuring that information abstracted from medical records is complete and accurate. However, the commissioner intends to conduct registry information validation studies to ascertain the quality of the data that is being submitted. These studies will be carried out by drawing a random sample of registry reports and, with the cooperation of the reporting hospitals, conduct an on-site review of the pertinent patient medical records to identify errors that may exist in abstracting and reporting registry data elements. Depending upon the nature and extent of any problems identified through these validation studies, the commissioner will determine the most appropriate means of addressing the problems including possible changes in report format or the provision of additional training to hospital medical records personnel who complete the registry reports.

Part 4643.0040, Subp. 1 specifies that, except as provided for in Minnesota Statutes, section 144.664, subdivision 3, the commissioner will release only summary registry data. Section 144.664, subdivision 2 directs the commissioner to provide summary data to public and private entities to conduct studies using data collected by the registry. However, section 144.664, subdivision 3 directs the commissioner to provide patient identifying information to the commissioner of jobs and training. Section 144.665 classifies such identifying information as private data on

individuals as defined in section 13.02, subdivision 12.

Part 4643.0040, Subp. 2 specifies that the commissioner will provide assistance to public and private entities engaged in research regarding the compilation, analyses and interpretation of summary registry data. Minnesota Statutes, section 144.664, subdivision 5, clause (5) authorizes the commissioner to prescribe in rule criteria relating to the use of registry data by public and private entities engaged in research. By its very definition, summary registry data will not include information that could lead to the identification of any individual who is the subject of the data and, therefore, the commissioner does not need to be concerned with the subsequent disclosure of private data on individuals. However, scientifically invalid inferences could be drawn from an analysis of summary registry data which would inaccurately characterize the nature or magnitude of the public health significance of traumatic brain and spinal cord injuries. The inadvertent use of seriously flawed interpretations could result in inappropriate decisions being made concerning the allocation of public resources for injury prevention, treatment, and rehabilitation programs. This unfortunate outcome would be contrary to the registry purpose stated in Minnesota Statutes, section 144.662, clause (1). Because it is not possible to prescribe a specific set of criteria for use of registry data that will prevent scientifically invalid interpretations of summary registry data from being made, the commissioner proposes to provide

assistance with the interpretation of data analysis results and to make recommendations concerning the subsequent use of this information. This approach will assure that public and private entities engaged in research have an opportunity to fully benefit from the commissioner's expertise related to the analyses and interpretation of summary registry data. It will also provide an opportunity for the commissioner to advise against the use of summary registry data in a manner which could lead to the development of scientifically invalid conclusions. This approach is reasonable because it fully provides the summary registry data to requesting parties while ensuring that they also receive appropriate information concerning the use of the data.

Part 4643.0040, Subp. 3 specifies fees to be charged to recover expenses and costs associated with requests by public or private entities for summary registry data compilation or analyses. Minnesota Statutes, section 144.664, subdivision 5, clause (6) authorizes the commissioner to prescribe these fees in rule. The fees are intended to offset expenses related to employee hourly wages, employee expenses, electronic data processing costs, duplicating, and clerical charges incurred by the commissioner as a result of such requests. The fees would not be charged to community health service boards because they receive a state subsidy administered by the commissioner and charging a fee to them would have the net result of reducing the amount of their subsidy. Fees would not be charged for requests from other entities that

require a minimal amount of professional staff time or total expense because the cost of collecting and depositing the fee would be greater than the fee amount. The provisions proposed in this rule for charging fees are identical to those contained in the commissioner's existing rules related to the cancer surveillance system (see Minnesota Rules, part 4606.3309).

STATE OF MINNESOTA
DEPARTMENT OF HEALTH

Dated: July 6, 1992

Marlene E. Marschall
Commissioner of Health

Department of Health

Proposed Permanent Rules Relating to Health; Traumatic Brain Injury and Spinal Cord Injury Registry

Rules as Proposed (all new material)

4643.0010 PURPOSE, SCOPE, AND APPLICABILITY.

The purpose and scope of parts 4643.0010 to 4643.0040 are to prescribe requirements applicable to the statewide traumatic brain injury and spinal cord injury registry, including what information must be reported, who is required to submit reports, when reports must be submitted, the provision of registry data to public and private entities, and fees to be charged for compiling or analyzing registry data.

4643.0015 INCORPORATIONS BY REFERENCE.

The Fourth edition of the International Classification of Diseases, Clinical Modification, 9th Revision, 1991, and corresponding annual updates is incorporated by reference. It is subject to frequent change, is published by the United States Department of Health and Human Services, Health Care Financing Administration, and may be purchased through the Superintendent of Documents, United States Government Printing Office, Washington, D.C. 20402. It is available through the Minitex interlibrary loan system.

4643.0020 DEFINITIONS.

Subpart 1. **Scope.** For purposes of parts 4643.0010 to 4643.0040, the following terms have the meanings given them in this part.

Subp. 2. **Commissioner.** "Commissioner" means the state commissioner of health, or the commissioner's designee.

Subp. 3. **E-Code.** "E-Code" means the ICD-9-CM classification code assigned to describe the environmental events, circumstances, and conditions determined to be the external cause of the injury.

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Subp. 4. **Electronic submission of data.** "Electronic submission of data" means the transfer of data from a computer used by a reporting hospital to a computer specified by the commissioner through the use of a modem, magnetic tape, or magnetic disk.

Subp. 5. **Hospital.** "Hospital" means an acute care institution licensed in accordance with Minnesota Statutes, sections 144.50 to 144.581.

Subp. 6. **ICD-9-CM.** "ICD-9-CM" means the International Classification of Diseases, Clinical Modification, 9th Revision, 1991.

Subp. 7. **N-Code.** "N-Code" means the ICD-9-CM classification code assigned to describe the clinical nature of the injury.

Subp. 8. **Spinal cord injury reportable case.** "Spinal cord injury reportable case" means an injury event as defined in Minnesota Statutes, section 144.661, subdivision 3, which results in a hospital acute care inpatient admission or emergency room death, and is assigned one or more of the following N-Codes: 806, 907.2, and 952.

Subp. 9. **Summary registry data.** "Summary registry data" means statistical records and reports derived from registry data on individuals but in which individuals are not identified and from which neither their identities nor any other characteristic that could uniquely identify an individual is ascertainable.

Subp. 10. **Traumatic brain injury reportable case.** "Traumatic brain injury reportable case" means an injury event as defined in Minnesota Statutes, section 144.661, subdivision 2, which results in a hospital acute care inpatient admission or emergency room death, and is assigned one or more of the following N-Codes: 310.2, 348.1, (when used in combination with 994.1 or 994.7), 800, 801, 803, 804, 850, 851, 852, 853, 854, 905.0, 907.0 and 950.

4643.0030 REGISTRY REPORTING REQUIREMENTS.

Subpart 1. **Hospitals required to report.** Hospitals shall

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submit to the commissioner reports containing the information items in subpart 2 for all traumatic brain injury and spinal cord injury reportable cases.

Subp. 2. **Report content.** The following information items must be submitted to the commissioner for each reportable case:

A. Patient data including: name, street address, city, county, and state of residence, telephone number, date of birth, gender, race/ethnicity, social security number, type of insurance or payment source, and name of parent or guardian for individuals under the age of 18 years.

B. Injury circumstance data including: date and time of day injury occurred, location where injury occurred (street address, city, county, and state), E-Codes or equivalent information submitted on forms provided by the commissioner, alcohol/drug levels (from toxicology reports), employer name (for work-related injuries), and use of protective equipment.

C. Nature of injury data including: N-Codes and fatality of injury.

D. Reporting source data including: name and address of hospital, name and telephone number of person completing report, date of report, patient medical record number, date of admission, date of discharge or transfer from acute care, place discharged or transferred to (for example home, rehabilitation center, nursing home) and whether the place is located in Minnesota or another state, and name of attending physician.

Subp. 3. **Report format.** Registry information must be submitted on forms provided by the commissioner for that purpose. The commissioner may approve alternative means for providing registry information including the electronic submission of data.

Subp. 4. **Report submission deadline.** A report must be completed and submitted to the commissioner within 60 days of patient death, discharge, or transfer from the acute care setting.

Subp. 5. **Report quality assurance.** A hospital must take all reasonable measures to assure that the registry information

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submitted to the commissioner is complete and accurate. A hospital must cooperate with the commissioner in the conduct of registry information validation studies, including providing access to patient medical records.

4643.0040 PROVISION OF REGISTRY DATA.

Subpart 1. **Summary registry data.** Except as provided in Minnesota Statutes, section 144.664, subdivision 3, the commissioner will release only summary registry data.

Subp. 2. **Data compilation or analyses.** The commissioner must provide assistance in response to requests from public or private entities engaged in research regarding the compilation or analyses of summary registry data. The assistance must include interpreting data analysis results and providing recommendations concerning the subsequent use of this information.

Subp. 3. **Fees.** The commissioner may charge fees in accordance with Minnesota Statutes, section 13.03, subdivision 3, to recover all expenses and costs. These costs may include employee hourly wages, employee expenses, electronic data processing costs, duplicating, and clerical charges incurred by the commissioner as a result of requests by public and private entities for summary registry data compilation or analyses under the following conditions:

A. the entity requesting the summary registry data is not a community health services board as defined in Minnesota Statutes, chapter 145A;

B. the request requires more than one person hour of time to complete for an employee of the commissioner who is classified as either a programmer/analyst or higher, or an epidemiologist I or higher; and

C. the estimated total out-of-pocket expenses, regardless of person hours needed to satisfy the request, are greater than $50.

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Office of the Revisor of Statutes

Administrative Rules

TITLE: Proposed Permanent Rules Relating to Health; Traumatic Brain Injury and Spinal Cord Injury Registry

AGENCY: Department of Health

MINNESOTA RULES: Chapter 4643

INCORPORATION BY REFERENCE:

Part 4643.0015: The fourth edition of the International Classification of Diseases, Clinical Modification, 9th Revision, 1991, and corresponding annual updates.

The attached rules are approved for publication in the State Register

Marie O'Neill

Marie E. O'Neill
Assistant Revisor

8/10

The Minnesota

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General, or who wish to receive a copy of the adopted rule must submit a written request to Ms. Milligan.

Dated: 16 June 1992

State of Minnesota
Elton Redalen, Commissioner
Department of Agriculture

Rules as Proposed (all new material)

1502.0027 ADVOCATE SERVICES FEES.

As allowed in *Minnesota Statutes*, section 17.03, subdivision 9, the Department of Agriculture shall charge $15 per hour following a free two-hour consultation for farm advocate services. The department shall waive the fees upon proof that the farm advocate's client has a reportable federal adjusted gross income of $15,000 or less and a debt to asset ratio of greater than 50 percent.

Department of Health

Proposed Permanent Rules Relating to Health; Traumatic Brain Injury and Spinal Cord Injury Registry

Notice of Intent to Adopt Rules Without a Public Hearing, Notice of Intent to Adopt Rules With a Public Heaing if 25 or More Persons Request a Hearing, and Notice of Intent to Cancel Hearing if Fewer Than 25 Persons Request a Hearing

I.

EXPLANATION OF ALTERNATIVE NOTICES.

The Minnesota Department of Health (hereinafter "Department") **is hereby giving notice** of its intent to adopt rules without a public hearing under the noncontroversial rulemaking procedure of *Minnesota Statutes* §§ 14.22 to 14.28 (1990). However, in case 25 or more persons request a hearing, thus necessitating that one be held pursuant to *Minnesota Statutes* § 14.25 (1990), and in order to expedite the rulemaking process should that occur, the Department is at the same time hereby giving notice of the hearing on the proposed rules pursuant to *Minnesota Statutes* §§ 14.131 to 14.20 (1990). The hearing will be cancelled if 25 or more people do not request that one be held. The hearing will also be cancelled if a sufficient number of people withdraw their requests for a hearing. With the comment period closing on August 26, 1992, there will be 14 days before the scheduled hearing date which is September 9, 1992. This 14-day period will give interested persons ample time to contact the Department to find out whether the hearing will be cancelled and to plan accordingly.

II.

NOTICE OF INTENT TO ADOPT RULES WITHOUT A PUBLIC HEARING.

NOTICE IS HEREBY GIVEN that the Minnesota Department of Health (hereinafter "Department") proposes to adopt the above-captioned rules without a public hearing unless 25 or more persons submit written requests for a public hearing. The Department has determined that the proposed rules will be noncontroversial in nature and has elected to follow procedures set forth in *Minnesota Statutes* §§ 14.22 to 14.28 (1990).

Interested persons shall have until August 26, 1992 to submit comments in support of or in opposition to the proposed rules. Comment is encouraged. Each comment should identify the portion of the proposed rules being addressed, the reason for the comment, and any change proposed to the rules by the comment. The proposed rules may be modified if the modifications are supported by the data and views submitted to the Department and do not result in a substantial change in the proposed language.

In addition to submitting comments, interested persons may request in writing, during the comment period, that a hearing be held on the proposed rules. Any person requesting a hearing should state his or her name, address, and telephone number and is encouraged to identify the portion of the proposed rules addressed, the reason for the request, and any changes they want made to the proposed rules. If a person desires that a hearing be held on only a portion of the proposed rules, it is requested that the Department be informed of the specific rules on which a hearing is being requested at the time that the hearing request is made. This will enable the Department to limit the hearing, if one is held, to the specific issues of concern. A public hearing will be held only if 25 or more persons submit in writing requests for a hearing on the proposed rules or a portion thereof by August 26, 1992. If a hearing is required, it will be held in accordance with the provisions of *Minnesota Statutes* §§ 14.131 to 14.20 (1990) and the hearing notice provided in Part III below.

Comments or written requests for a public hearing should be submitted to: Mark Kinde, Minnesota Department of Health, Health Promotion and Education Division, 717 Southeast Delaware Street, P.O. Box 9441, Minneapolis, MN 55440, (612) 623-5782.

The statutory authority of the Department to adopt the proposed rules is contained in *Minnesota Statutes* §§ 144.05, 144.12, and 144.661 to 144.665.

If adopted, the proposed rules will establish a statewide traumatic brain injury and spinal cord injury registry. A copy of the proposed rules is attached to this Notice. The proposed rules will also be published in the *State Register* issue of July 27, 1992, and a free copy of the rules may be obtained from the Department by writing or telephoning Mark Kinde at the address or telephone number listed above.

A STATEMENT OF NEED AND REASONABLENESS that describes the need for and reasonableness of each provision of the proposed rules and identifies the data and information relied upon to support the proposed rules has been prepared and may be obtained from the Department by writing or telephoning Mark Kinde at the address or telephone number listed above.

Promulgation of the proposed rules will not result in the expenditure of more than $100,000 in public monies by local public bodies for the two years immediately following adoption of the rules nor have an impact on agricultural land; therefore, no further information need be provided under *Minnesota Statutes* § 14.11 (1990).

It is the position of the Department that it is subject to *Minnesota Statutes* § 14.115 (1990) regarding small business considerations in rulemaking. The basis for this position, and the Department's evaluation of the applicability of the methods contained in *Minnesota Statutes* § 14.115, subd. 2 (1990), for reducing the impact of the proposed rules, are addressed in the statement of need and reasonableness.

Pursuant to *Minnesota Statutes* § 14.115, subd. 4 (1990), the Department will mail a copy of this notice to every licensed hospital in the State of Minnesota in order to assure that small businesses have an opportunity to participate in the rulemaking process. In addition, the Department included representation from the Minnesota Hospital Association on the review committee that was established to assist with the adoption of the rules. If a hearing is held on these proposed rules, testimony will be received on the impact of them on small businesses.

If no hearing is required, upon adoption of the rules, the rules as proposed, this notice, the statement of need and reasonableness, all written comments received, the rules as adopted, and a statement explaining any differences between the rules as proposed and as adopted will be delivered to the Attorney General for review as to form and legality, including the issue of substantial change. Persons who wish to be advised of the submission of this material to the Attorney General or who wish to receive a copy of the rules as adopted should submit a written request to Mark Kinde at the address listed above.

III.

NOTICE OF INTENT TO ADOPT RULES WITH A PUBLIC HEARING IF 25 OR MORE PERSONS REQUEST A HEARING

PLEASE NOTE THAT IF 25 OR MORE PERSONS SUBMIT WRITTEN REQUESTS FOR A PUBLIC HEARING WITH RESPECT TO THE ABOVE-CAPTIONED RULES WITHIN THE COMMENT PERIOD PURSUANT TO THE NOTICE GIVEN IN PART II ABOVE, A HEARING WILL BE HELD ON SEPTEMBER 9, 1992, IN ACCORDANCE WITH THE FOLLOWING NOTICE OF PUBLIC HEARING.

NOTICE IS HEREBY GIVEN that a public hearing in the above-captioned matter will be held pursuant to *Minnesota Statutes* § 14.131 to 14.20 (1990), and *Minnesota Rules*, parts 1400.0200 to 1400.1200 (1991) in the Chesley Room of the Minnesota Department of Health Building, 717 Delaware Street Southeast, Minneapolis, Minnesota on September 9, 1992, commencing at 9 a.m.

All interested or affected persons, including representatives of associations or other interested groups, will have an opportunity to participate. Such persons may present their views either orally at the hearing or in writing at any time prior to the close of the hearing record. All evidence presented should be pertinent to the matter at hand. Written material not submitted at the time of hearing which is to be included in the hearing record may be mailed to Howard L. Kaibel, Administrative Law Judge, Office of Administrative Hearings, 100 Washington Square, Suite 1700, Minneapolis, Minnesota 55401-2138, telephone (612) 341-7600. Unless a longer period not to exceed 20 calendar days is ordered by the administrative law judge at the hearing, the hearing record will remain open for the inclusion of written material for five working days after the hearing ends. Written material received during this period will be available for reveiw at the Office of Administrative Hearings. The Department and interested persons may respond in writing within three business days after the submission period ends to any new information submitted. Any written material or responses submitted must be received at the office no later than 4:30 p.m. on the final day. No additional evidence may be submitted during the three-day

KEY: PROPOSED RULES SECTION — Underlining indicates additions to existing rule language. ~~Strike outs~~ indicate deletions from existing rule language. If a proposed rule is totally new, it is designated "all new material." **ADOPTED RULES SECTION** — Underlining indicates additions to proposed rule language. ~~Strike outs~~ indicate deletions from proposed rule language.

period. This rule hearing procedure is governed by *Minnesota Statutes* §§ 14.131 to 14.20 (1990) and by *Minnesota Rules* pts. 1400.0200 to 1400.1200 (1991). Questions about procedure may be directed to the administrative law judge.

If adopted, the rules will establish a statewide traumatic brain injury and spinal cord injury registry. A copy of the proposed rules is attached to this Notice. The proposed rules will also be published in the *State Register* issue of July 27, 1992, and a free copy of the rules may be obtained from the Department by writing or telephoning Mark Kinde at the address and telephone number listed above in Part II of this notice.

The statutory authority of the Department to adopt the proposed rules is contained in *Minnesota Statutes* §§ 144.05, 144.12, and 144.661 to 144.665.

The proposed rules may be modified as a result of the rule hearing process. Those who are potentially affected in any manner by the substance of th proposed rules are therefore advised to participate in the process.

Minnesota Statutes ch. 10A requires each lobbyist to register with the Ethical Practices Board. Questions should be directed to the Ethical Practices Board, 625 North Robert Street, St. Paul, Minnesota 55101-2520, telephone: (612) 296-5148.

NOTICE IS HEREBY GIVEN that **A STATEMENT OF NEED AND REASONABLENESS** is now available for review at the Department and at the Office of Administrative Hearings. This statement of need and reasonableness includes a summary of all the evidence which the Department anticipates presenting at the hearing justifying both the need for and the reasonableness of the proposed rules. Copies of the statement of need and reasonablenss may be reviewed at the Department or the Office of Administrative Hearings and copies may be obtained from the Office of Administrative Hearings at the cost of reproduction.

Please note that any person may request notification of the date on which the administrative law judge's report will be available, after which date the Department may not take any final action on the rules for a period of five working days. If you desire to be so notified, you may so indicate at the hearing. After the hearing, you may request notification by sending a written request to the administrative law judge. Any person may request notification of the date on which the rules are adopted and filed with the Secretary of State. The notice must be mailed on the same day that the rules are filed. If you want to be so notified, you may so indicate at the hearing or send a request in writing to the Department at any time prior to the filing of the rules with the Secretary of State.

Promulgation of these proposed rules will not result in the expenditure of more than $100,000 in public monies by local public bodies for the two years immediately following adoption of the rules nor have any impact on agricultural land; therefore, no further information need be provided under *Minnesota Statutes* § 14.11 (1990).

It is the position of the Department that it is subject to *Minnesota Statutes* § 14.115 (1990) regarding small business considerations in rulemaking. The basis for this position, and the Department's evaluation of the applicability of the methods contained in *Minnesota Statutes* § 14.115, subd. 2 (1990) for reducing the impact of the proposed rules are addressed in the statement of need and reasonableness.

Pursuant to *Minnesota Statutes* § 14.115, subd. 4 (1990), the Department will mail a copy of this notice to every licensed hospital in the State of Minnesota in order to assure that small businesses have an opportunity to participate in the rulemaking process. In addition, the Department included representation from the Minnesota Hospital Association on the review committee that was established to assist with the adoption of the rules. At the hearing on these rules, testimony will be received on the impact of them on small businesses.

IV.

NOTICE OF INTENT TO CANCEL HEARING IF FEWER THAN 25 PERSONS REQUEST A HEARING.

PLEASE NOTE THAT THE HEARING, NOTICE OF WHICH IS GIVEN IN PART III ABOVE, WILL BE CANCELLED IF FEWER THAN 25 PERSONS REQUEST A HEARING IN RESPONSE TO THE NOTICE GIVEN IN PART II ABOVE. ALSO, THE HEARING WILL BE CANCELLED IF A SUFFICIENT NUMBER OF PEOPLE WITHDRAW THEIR REQUEST FOR A HEARING IN RESPONSE TO PROPOSED REVISIONS OF THE PROPOSED RULES BY THE DEPARTMENT.

To be informed whether the hearing noticed in Part III above will be held, please telephone Mark Kinde at the telephone number listed above in Part II of this Notice before September 4, 1992, and leave your name, address, and telephone number. You will be notified if the hearing has been cancelled. You may also telephone Mark Kinde after September 4, 1992, for oral confirmation regarding the scheduled hearing.

Dated: 7 July 1992

Marlene E. Marschall
Commissioner of Health

Rules as Proposed (all new material)

4643.0010 PURPOSE, SCOPE, AND APPLICABILITY.

The purpose and scope of parts 4643.0010 to 4643.0040 are to prescribe requirements applicable to the statewide traumatic brain

injury and spinal cord injury registry, including what information must be reported, who is required to submit reports, when reports must be submitted, the provision of registry data to public and private entities, and fees to be charged for compiling or analyzing registry data.

4643.0015 INCORPORATIONS BY REFERENCE.

The Fourth edition of the International Classification of Diseases, Clinical Modification, 9th Revision, 1991, and corresponding annual updates is incorporated by reference. It is subject to frequent change, is published by the United States Department of Health and Human Services, Health Care Financing Administration, and may be purchased through the Superintendent of Documents, United States Government Printing Office, Washington, D.C. 20402. It is available through the Minitex interlibrary loan system.

4643.0020 DEFINITIONS.

Subpart 1. **Scope.** For purposes of parts 4643.0010 to 4643.0040, the following terms have the meanings given them in this part.

Subp. 2. **Commissioner.** "Commissioner" means the state commissioner of health, or the commissioner's designee.

Subp. 3. **E-Code.** "E-Code" means the ICD-9-CM classification code assigned to describe the environmental events, circumstances, and conditions determined to be the external cause of the injury.

Subp. 4. **Electronic submission of data.** "Electronic submission of data" means the transfer of data from a computer used by a reporting hospital to a computer specified by the commissioner through the use of a modem, magnetic tape, or magnetic disk.

Subp. 5. **Hospital.** "Hospital" means an acute care institution licensed in accordance with *Minnesota Statutes*, sections 144.50 to 144.581.

Subp. 6. **ICD-9-CM.** "ICD-9-CM" means the International Classification of Diseases, Clinical Modification, 9th Revision, 1991.

Subp. 7. **N-Code.** "N-Code" means the ICD-9-CM classification code assigned to describe the clinical nature of the injury.

Subp. 8. **Spinal cord injury reportable case.** "Spinal cord injury reportable case" means an injury event as defined in *Minnesota Statutes*, section 144.661, subdivision 3, which results in a hospital acute care inpatient admission or emergency room death, and is assigned one or more of the following N-Codes: 806, 907.2, and 952.

Subp. 9. **Summary registry data.** "Summary registry data" means statistical records and reports derived from registry data on individuals but in which individuals are not identified and from which neither their identities nor any other characteristic that could uniquely identify an individual is ascertainable.

Subp. 10. **Traumatic brain injury reportable case.** "Traumatic brain injury reportable case" means an injury event as defined in *Minnesota Statutes*, section 144.661, subdivision 2, which results in a hospital acute care inpatient admission or emergency room death, and is assigned one or more of the following N-Codes: 310.2, 348.1, (when used in combination with 994.1 or 994.7), 800, 801, 803, 804, 850, 851, 852, 853, 854, 905.0, 907.0 and 950.

4643.0030 REGISTRY REPORTING REQUIREMENTS.

Subpart 1. **Hospitals required to report.** Hospitals shall submit to the commissioner reports containing the information items in subpart 2 for all traumatic brain injury and spinal cord injury reportable cases.

Subp. 2. **Report content.** The following information items must be submitted to the commissioner for each reportable case:

A. Patient data including: name, street address, city, county, and state of residence, telephone number, date of birth, gender, race/ethnicity, social security number, type of insurance or payment source, and name of parent or guardian for individuals under the age of 18 years.

B. Injury circumstance data including: date and time of day injury occurred, location where injury occurred (street address, city, county, and state), E-Codes or equivalent information submitted on forms provided by the commissioner, alcohol/drug levels (from toxicology reports), employer name (for work-related injuries), and use of protective equipment.

C. Nature of injury data including: N-Codes and fatality of injury.

D. Reporting source data including: name and address of hospital, name and telephone number of person completing report, date of report, patient medical record number, date of admission, date of discharge or transfer from acute care, place discharged or transferred to (for example home, rehabilitation center, nursing home) and whether the place is located in Minnesota or another state, and name of attending physician.

KEY: PROPOSED RULES SECTION — Underlining indicates additions to existing rule language. ~~Strike outs~~ indicate deletions from existing rule language. If a proposed rule is totally new, it is designated "all new material." **ADOPTED RULES SECTION** — Underlining indicates additions to proposed rule language. ~~Strike outs~~ indicate deletions from proposed rule language.

Subp. 3. **Report format.** Registry information must be submitted on forms provided by the commissioner for that purpose. The commissioner may approve alternative means for providing registry information including the electronic submission of data.

Subp. 4. **Report submission deadline.** A report must be completed and submitted to the commissioner within 60 days of patient death, discharge, or transfer from the acute care setting.

Subp. 5. **Report quality assurance.** A hospital must take all reasonable measures to assure that the registry information submitted to the commissioner is complete and accurate. A hospital must cooperate with the commissioner in the conduct of registry information validation studies, including providing access to patient medical records.

4643.0040 PROVISION OF REGISTRY DATA.

Subpart 1. **Summary registry data.** Except as provided in *Minnesota Statutes*, section 144.664, subdivision 3, the commissioner will release only summary registry data.

Subp. 2. **Data compilation or analyses.** The commissioner must provide assistance in response to requests from public or private entities engaged in research regarding the compilation or analyses of summary registry data. The assistance must include interpreting data analysis results and providing recommendations concerning the subsequent use of this information.

Subp. 3. **Fees.** The commissioner may charge fees in accordance with *Minnesota Statutes*, section 13.03, subdivision 3, to recover all expenses and costs. These costs may include employee hourly wages, employee expenses, electronic data processing costs, duplicating, and clerical charges incurred by the commissioner as a result of requests by public and private entities for summary registry data compilation or analyses under the following conditions:

A. the entity requesting the summary registry data is not a community health services board as defined in *Minnesota Statutes*, chapter 145A;

B. the request requires more than one person hour of time to complete for an employee of the commissioner who is classified as either a programmer/analyst or higher, or an epidemiologist I or higher; and

C. the estimated total out-of-pocket expenses, regardless of person hours needed to satisfy the request, are greater than $50.

Adopted Rules

The adoption of a rule becomes effective after the requirements of Minn. Stat. §14.14-14.28 have been met and five working days after the rule is published in *State Register*, unless a later date is required by statutes or specified in the rule.

If an adopted rule is identical to its proposed form as previously published, a notice of adoption and a citation to its previous *State Register* publication will be printed.

If an adopted rule differs from its proposed form, language which has been deleted will be printed with strikeouts and new language will be underlined. The rule's previous *State Register* publication will be cited.

An emergency rule becomes effective five working days after the approval of the Attorney General as specified in Minn. Stat. §14.33 and upon the approval of the Revisor of Statutes as specified in §14.36. Notice of approval by the Attorney General will be published as soon as practicable, and the adopted emergency rule will be published in the manner provided for adopted rules under §14.18.

Department of Agriculture

Adopted Permanent Rules Relating to Waste Pesticide Collection

The rules proposed and published at *State Register*, Volume 16, Number 44, pages 2366-2368, April 27, 1992 (16 SR 2366), are adopted with the following modifications:

Rules as Adopted

1509.0020 DEFINITIONS.

Subp. 8. **Waste pesticide.** "Waste pesticide" means ~~an unusable pesticide including: suspended, canceled, or degraded pesticide. Waste pesticide does not include other materials contaminated with pesticide formulations~~ a pesticide that the pesticide end user considers a waste. A waste pesticide can be a canceled pesticide, an unusable pesticide, or a usable pesticide.

3/10/92

The Minnesota

State Register

Department of Administration—Print Communications Division

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Rules edition
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(Tuesday if Monday is a holiday)

Monday 27 January 1992

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Minnesota State Department of Health

Health Promotion and Education Division

Notice of Solicitation of Outside Information or Opinions Regarding Proposed New Rules Governing the Establishment of a Traumatic Brain Injury and Spinal Cord Injury Registry

NOTICE IS HEREBY GIVEN that the State Department of Health is seeking information or opinions from sources outside the agency in preparing to propose new rules governing the establishment of a Traumatic Brain Injury and Spinal Cord Injury Registry. The adoption of the new rules is authorized by *Minnesota Statutes* section 144.664, subdivision 5 (Supplement 1991) which permits the Commissioner of Health to adopt rules to administer the registry, collect information, and distribute data. The rules must include, but are not limited to the following:

(1) the specific ICD-9 procedure codes included in the definition of "traumatic brain injury" and "spinal cord injury";

(2) the type of data to be reported;

(3) standards for reporting specific types of data;

(4) the persons and facilities required to report and the time period in which reports must be submitted;

(5) criteria related to the use of registry data by public and private entities engaged in research; and

(6) specification of fees to be charged for the provision of data or data analysis to public and private entities.

The State Department of Health requests information and opinions concerning the subject matter of the proposed new rules. Interested persons or groups may submit data or views on the subject matter of concern in writing or orally. Written statements should be addressed to: Mark Kinde, Minnesota Department of Health, Health Promotion and Education Division, 717 SE Delaware, P.O. Box 9441, Minneapolis, Minnesota 55440. Oral statements will be received during regular business hours over the telephone by Mark Kinde at 612/623-5782 and in person at the above address.

It is anticipated that State Department of Health staff will begin preparing a draft of the rules in March, 1992. Therefore, it is recommended that all statements of information and opinions be submitted by March 1, 1992. However, statements of information and opinions will be accepted until the formal rulemaking process is commenced. Any written material received by the State Department of Health shall become part of the rulemaking record to be submitted to the Attorney General or Administrative Law Judge if the rules are adopted.

Dated: 15 January 1992

Marlene E. Marschall
Commissioner of Health

Department of Labor and Industry

Labor Standards Division

Notice of Solicitation of Outside Information or Opinions Regarding Proposed Rule Governing Prevailing Wages

NOTICE IS HEREBY GIVEN that the State Department of Labor and Industry is seeking information or opinions from sources outside the agency in preparing to propose the amendment of the rules governing the payment of prevailing wages on state-funded projects pursuant to *Minnesota Statutes*, section 177.41-177.44 (1990).

The adoption of the rule is authorized by *Minnesota Statutes*, section 175.171 (2) (1990) and 177.41-177.44 (1990) which permits the agency to adopt reasonable and proper rules regarding implementation of the prevailing wage law. The proposed rule may include provisions setting forth:

1) The method of setting the prevailing wage rate, including the geographic division of survey areas (counties, districts or other unit), the appropriate classes of labor and equipment subject to survey, and methods to determine whether work or equipment falls within a particular class;

2) Differentiation between the respective roles of the Minnesota Department of Transportation, Minnesota Department of Labor and Industry, and the Minnesota Department of Administration in enforcement of the prevailing wage laws;

3) Application of the truck rental rate rule: when the truck rental rate applies and to whom, and recordkeeping requirements for independent truck owner-operators on state-funded projects; and

MINNESOTA DEPARTMENT OF HEALTH
MINNESOTA INJURY PREVENTION PROGRAM

Log of Comments Received by Telephone Regarding the Establishment of a TBI and SCI Registry During the 30 day Formal Comment Period July 27 - August 26, 1992

Date & Name	Address	Substance of Comment
1. 7/31/92 Christopher Chute, MD Mayo Clinic Rochester, MN 55905 **507.284.5506**	Rochester, MN	Christopher asked Dave Giese for a copy of the proposed rules.
2. 8/3 and 20/92 Colleen Simcoe	Twin Cities McGladrey & Pullen **376.9338**	Colleen was referred to us by Craig Rushmeyer (see above); she works for a CPA consulting firm that has been doing some feasibility work for the Community Home Program. She was wondering what kind of data I had about length of stay in rehab, the numbers of private pay vs. assisted care, etc. I referred her to the CDC and to Cynthia Harrison in Michigan.

3. 8/6/92 Montevideo, MN
Dr. Tom Birkey **612.269.6435**
Montevideo Clinic
908 N. 11th St.
Montevideo, MN 56265

Dr. Birkey serves as chief of staff and head of the ER dept. at the local hospital. He had several concerns and, after discussing them by phone, he decided he would log them in a letter to me. I have responded to that letter; Dr. Birkey's letter, along with my response, are a part of the official log.

Chippewa County-Montevideo Hospital
824 NORTH 11TH STREET
MONTEVIDEO, MN 56265
612-269-8878

August 6, 1992



Mark Kinde, MPH, Supervisor
Minnesota Injury Prevention Program
Minnesota Department of Health
717 Deleware St., S.E.
Minneapolis, MN 55440-9441

Dear Mr. Kinde:

Thank you for spending the time on the phone today regarding the letter you sent to hospital administrations regarding a proposed MDH rules related to the development of a traumatic brain injury and spinal cord injury registry. As we developed in our conversation, I have several concerns regarding this matter. They are:

1. What was the original impetus for developing such a proposal and what good will the results of the registry be to the health status of the people of Minnesota?
2. How long will the registry be in effect? (i.e. is there a sunset provision for the registry and the mandatory reporting?)
3. Does this proprosal start a worrisome precedent? In other words, this time it is concern about head injuries, perhaps next time it will be about chest injuries or extremity injuries, etc.
4. Fees. Fees are discussed with regard to the commissioner charging fees for expenses incurred regarding this registry, but how about the reporting hospitals being compensated for their work and documentation.

Unless these questions are answered satisfactorily I believe I am rather against the proprosal. Health care people apparently feel inundated with paper work and this just adds another piece of paper work. I would want to have reassurances that this had more definite benefits, had definite limitations, did not start a new precedent for reporting forms and that there be some compensation for the paper work before I would be in favor of such a proposal.

Thank you for your consideration.

Sincerely,

T.G. Birkey, M.D.

TGB:jlm

Minnesota Department of Health
717 Delaware Street Southeast
P.O. Box 9441
Minneapolis, MN 55440-9441
(612) 623-5000

August 24, 1992

T. G. Birkey, MD
Chippewa County-Montevideo Hospital
824 North 11th Street
Montevideo, MN 56265

Dear Dr. Birkey:

Thank you for your letter dated August 6, 1992. I appreciate your time in outlining your questions and concerns. I will attempt to briefly respond; also, I will share your letter with Department staff so they are aware of your concerns as well. Also, I will enclose a copy of the originating legislation, a copy of the SONAR (Statement of Need and Reasonableness), and a list of advisory committee members who are serving with me in the development and implementation process.

I believe the original impetus for developing this registry came from the Minnesota Head Injury Association, representing the needs of people who sustain a traumatic brain injury (TBI) in Minnesota and who may end up not receiving the rehabilitative services they need, simply because the injured people are unaware of the provisions available in Minnesota. Thus, the concept of a service registry was to inform those persons who sustain a TBI of services available to or for them. The involvement of the State Health Department brings a focus on primary prevention. Thus, while I am concerned about secondary and tertiary prevention and rehabilitation issues, my primary emphasis and experience lies with the epidemiology of injury and with implementing primary prevention strategies. With that emphasis, the data I propose to collect is minimal, readily available and is being collected with a bias for action. Thus, I think the registry will improve the health status of Minnesotans by suggesting strategies that communities and individuals may utilize to reduce their risk of sustaining a traumatic brain or spinal cord injury.

Your second question addressed the concern about the length or duration of the registry. At this point, there is not a sunset provision, either for the registry or for the mandatory reporting on the part of hospitals. While the treating physician's name is queried, we were careful to create a data collection system that would not need to involve direct physician participation. It certainly does allow for physicians to serve as primary reporters. However,

we recognize the limits on time and therefore wanted to create a form that can be completed by medical records personnel or in fact by a data entry clerk. I would anticipate that, if the registry provides data that are deemed useful by the State of Minnesota, the legislature would want the registry to continue. However, if, in their estimation, the registry is not providing data which are useful, then I believe the legislature would not want to fund the registry in an ongoing manner.

I think that the collection of information about brain and spinal cord injury is important because of the magnitude of the problem as we currently understand it. And, the picture as we have it now is rather incomplete. I believe the registry will help to further define the extent of the problem, including the economic and human suffering factors. It may be that, in the years to come, this state may move to the development of an all-trauma registry. If that does happen, it will be at the behest of reporting institutions and not at the direction of the state. I would imagine that we would be invited to participate but I do not believe that in the immediate future we (the state) will be requesting or demanding that Minnesota develop an all-trauma registry.

During the initial meetings of the advisory committee, compensatory fees for participating institutions were discussed. At this point, there are not monies adequate to recompense institutions for their participation. It may be that this could be an option pursued in subsequent legislative sessions, in particular if the funding strategy is expanded to garner additional funds for the operation of the registry.

In addition to the other enclosures previously described, I have enclosed a draft of the proposed data collection form. My staff will also be developing an electronic mechanism so that data could be transferred via modem or diskette.

Again, thank you for your letter. I trust my comments have helped clarify the background and genesis of this effort and I look forward to working with you and the people of your community as, together, we try to prevent brain and spinal cord injury in Minnesota.

Sincerely,

Mark R. Kinde

Mark R. Kinde, MPH, Supervisor
Minnesota Injury Prevention Program

MRK:bks

cc: David Giese, MPH, Chair, TBI/SCI Advisory Committee

enclosures

MINNESOTA DEPARTMENT OF HEALTH
MINNESOTA INJURY PREVENTION PROGRAM

Log of Comments Received by Telephone Regarding the Notice of Solicitation of Outside Information or Opinions For Proposed New Rules Governing the Establishment of a TBI and SCI Registry.

Date & Name	Address	Substance of Comment
1. 2/14/92 Chris Peterson	U of MN Hospital Box 601 Mpls., MN 55455 **626-3353**	Chris requested a copy of the legislation. Also, queried about reimbursement to hospitals for participating; wanted us to know that data collection is difficult for Med Records while the person is still hospitalized. Less labor intensive and less costly to collect data post discharge.
2. 2/28/92 Patty C. Garvey	Care Providers 2850 Metro Drive, Suite 200 Bloomington, MN 55425 **854-2844**	Represents nursing homes in MN; wanted to know who was going to be responsible for reporting. Hoped it would not be nursing homes! Suggested that Jim Sims, MDH QAR, could give us good prevalence data, since they collect diagnostic categories when they inspect and license facilities.

3.	6/8/92 Diane Monkmen	Northern MN **218.283.4481**	Diane called in with some questions on TBI/SCI reporting; I returned her call three times, each time waiting a number of minutes while she was paged before leaving a message for her. I was not able to make direct contact with her.
4.	6/11/92 Jan Culliton (also, 7/24/92)	St. Mary's Medical Center 407 E. Third St. Duluth, MN 55805 **218.726.4479**	Jan serves as the neuroscience and orthopedic/rehab coordinator for St. Mary's; she is new to this position. Her first call was really information seeking, wanting to know more about the genesis of the registry and what the impact would be on hospitals. In July, she called back wondering if the goal of the MDH was to perform outcome studies; if the registry was just a precursor for regionalization of hospital providers and distribution of grant awards; and what exactly we meant by "validation studies" on page 4, line 3 of the rules. I believe I addressed, to her comfort, each of her concerns.

5.	7/2/92 Warren Bloomquist	Twin Cities **789.9456**	Warren had some questions about the TBI program; he called from his home initially on 7/2, and again on 7/10. I returned his calls X 2; leaving messages on his answering machine each time with my name and work and home phone numbers. Warren may be an individual who serves with me on the DHS TBI Program Advisory Committee; however, I have not yet been able to determine this for certain.
6.	7/15/92 Craig Rushmeyer	Twin Cities **339.7789**	Craig serves with a group that is attempting to meet the needs of persons who have sustained a TBI, by building community living centers, etc. He wondered if we had statistical information available describing the magnitude of the problem in MN, and in the Twin Cities. I sent him copies of some of the background material I have collected.
7.	7/16/92 Dr. Bob Fitzgerald	Twin Cities **827.3583** 133 W. Lake St. Mpls, MN 55408	Dr. Bob Fitzgerald called representing the chiropractic interest in spinal cord injury. He wondered whether or not we expected

			chiropractors to report injuries; I suggested that initially, in keeping with the intent of a severe injury reporting system, that probably would not be the case. In the future, I laid the groundwork for chiropractic participation. Bob was concerned about the history of non-cooperation between his colleagues and traditional medical practitioners.
8.	7/21/92 Ellie Hands	Twin Cities **644.1121**	Ellie just called to see if we had received any requests for a hearing at this point in time.

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

DEPARTMENT OF HEALTH

In the Matter of the Proposed Adoption of Rules of the Department of Health Related to the Traumatic Brain Injury and Spinal Cord Injury Registry

ALTERNATIVE NOTICES

NOTICE OF INTENT TO ADOPT RULES WITHOUT A PUBLIC HEARING, NOTICE OF INTENT TO ADOPT RULES WITH A PUBLIC HEARING IF 25 OR MORE PERSONS REQUEST A HEARING, AND NOTICE OF INTENT TO CANCEL HEARING IF FEWER THAN 25 PERSONS REQUEST A HEARING

I.

EXPLANATION OF ALTERNATIVE NOTICES.

The Minnesota Department of Health (hereinafter "Department") is hereby giving notice of its intent to adopt rules without a public hearing under the noncontroversial rulemaking procedure of Minn. Stat. SS 14.22 to 14.28 (1990). However, in case 25 or more persons request a hearing, thus necessitating that one be held pursuant to Minn. Stat. S 14.25 (1990), and in order to expedite the rulemaking process should that occur, the Department is at the same time hereby giving notice of the hearing on the proposed rules pursuant to Minn. Stat. SS 14.131 to 14.20 (1990). The hearing will be cancelled if 25 or more people do not request that one be held. The hearing will also be cancelled if a sufficient number of people withdraw their requests for a hearing. With the comment period closing on August 26, 1992, there will be 14 days before the scheduled hearing date which is September 9, 1992. This 14-day period will give interested persons

ample time to contact the Department to find out whether the hearing will be cancelled and to plan accordingly.

II.

NOTICE OF INTENT TO ADOPT RULES WITHOUT A PUBLIC HEARING.

NOTICE IS HEREBY GIVEN that the Minnesota Department of Health (hereinafter "Department") proposes to adopt the above-captioned rules without a public hearing unless 25 or more persons submit written requests for a public hearing. The Department has determined that the proposed rules will be noncontroversial in nature and has elected to follow procedures set forth in Minn. Stat. SS 14.22 to 14.28 (1990).

Interested persons shall have until August 26, 1992 to submit comments in support of or in opposition to the proposed rules. Comment is encouraged. Each comment should identify the portion of the proposed rules being addressed, the reason for the comment, and any change proposed to the rules by the comment. The proposed rules may be modified if the modifications are supported by the data and views submitted to the Department and do not result in a substantial change in the proposed language.

In addition to submitting comments, interested persons may request in writing, during the comment period, that a hearing be held on the proposed rules. Any person requesting a hearing should state his or her name, address, and telephone number and is encouraged to identify the portion of the proposed rules addressed, the reason for the request, and any changes they want made to the

proposed rules. If a person desires that a hearing be held on only a portion of the proposed rules, it is requested that the Department be informed of the specific rules on which a hearing is being requested at the time that the hearing request is made. This will enable the Department to limit the hearing, if one is held, to the specific issues of concern. A public hearing will be held only if 25 or more persons submit in writing requests for a hearing on the proposed rules or a portion thereof by August 26, 1992. If a hearing is required, it will be held in accordance with the provisions of Minn. Stat. SS 14.131 to 14.20 (1990) and the hearing notice provided in Part III below.

Comments or written requests for a public hearing should be submitted to: Mark Kinde, Minnesota Department of Health, Health Promotion and Education Division, 717 Southeast Delaware Street, P.O. Box 9441, Minneapolis, MN 55440, (612) 623-5782.

The statutory authority of the Department to adopt the proposed rules is contained in Minn. Stat. SS 144.05, 144.12, and 144.661 to 144.665.

If adopted, the proposed rules will establish a statewide traumatic brain injury and spinal cord injury registry. A copy of the proposed rules is attached to this Notice. The proposed rules will also be published in the State Register issue of July 27, 1992, and a free copy of the rules may be obtained from the Department by writing or telephoning Mark Kinde at the address or telephone number listed above.

A statement of need and reasonableness that describes the

need for and reasonableness of each provision of the proposed rules and identifies the data and information relied upon to support the proposed rules has been prepared and may be obtained from the Department by writing or telephoning Mark Kinde at the address or telephone number listed above.

(13) Promulgation of the proposed rules will not result in the expenditure of more than $100,000 in public monies by local public bodies for the two years immediately following adoption of the rules nor have an impact on agricultural land; therefore, no further information need be provided under Minn. Stat. § 14.11 (1990).

(14) It is the position of the Department that it is subject to Minn. Stat. § 14.115 (1990) regarding small business considerations in rulemaking. The basis for this position, and the Department's evaluation of the applicability of the methods contained in Minn. Stat. § 14.115, subd. 2 (1990), for reducing the impact of the proposed rules, are addressed in the statement of need and reasonableness.

Pursuant to Minn. Stat. § 14.115, subd. 4 (1990), the Department will mail a copy of this notice to every licensed hospital in the State of Minnesota in order to assure that small businesses have an opportunity to participate in the rulemaking process. In addition, the Department included representation from the Minnesota Hospital Association on the review committee that was established to assist with the adoption of the rules. If a hearing is held on these proposed rules, testimony will be received on the

impact of them on small businesses.

(9) If no hearing is required, upon adoption of the rules, the rules as proposed, this notice, the statement of need and reasonableness, all written comments received, the rules as adopted, and a statement explaining any differences between the rules as proposed and as adopted will be delivered to the Attorney General for review as to form and legality, including the issue of substantial change. Persons who wish to be advised of the submission of this material to the Attorney General or who wish to receive a copy of the rules as adopted should submit a written request to Mark Kinde at the address listed above.

III.

NOTICE OF INTENT TO ADOPT RULES WITH A PUBLIC HEARING IF 25 OR MORE PERSONS REQUEST A HEARING

PLEASE NOTE THAT IF 25 OR MORE PERSONS SUBMIT WRITTEN REQUESTS FOR A PUBLIC HEARING WITH RESPECT TO THE ABOVE-CAPTIONED RULES WITHIN THE COMMENT PERIOD PURSUANT TO THE NOTICE GIVEN IN PART II ABOVE, A HEARING WILL BE HELD ON SEPTEMBER 9, 1992, IN ACCORDANCE WITH THE FOLLOWING NOTICE OF PUBLIC HEARING.

NOTICE IS HEREBY GIVEN that a public hearing in the above-captioned matter will be held pursuant to Minn. Stat. S 14.131 to 14.20 (1990), and Minnesota Rules, parts 1400.0200 to 1400.1200 (1991) in the Chesley Room of the Minnesota Department of Health Building, 717 Delaware Street Southeast, Minneapolis, Minnesota on September 9, 1992, commencing at 9 a.m.

All interested or affected persons, including representatives of associations or other interested groups, will

have an opportunity to participate. Such persons may present their views either orally at the hearing or in writing at any time prior to the close of the hearing record. All evidence presented should be pertinent to the matter at hand. Written material not submitted at the time of hearing which is to be included in the hearing record may be mailed to Howard L. Kaibel, Administrative Law Judge, Office of Administrative Hearings, 100 Washington Square, Suite 1700, Minneapolis, Minnesota 55401-2138, telephone (612) 341-7600. Unless a longer period not to exceed 20 calendar days is ordered by the administrative law judge at the hearing, the hearing record will remain open for the inclusion of written material for five working days after the hearing ends. Written material received during this period will be available for review at the Office of Administrative Hearings. The Department and interested persons may respond in writing within three business days after the submission period ends to any new information submitted. Any written material or responses submitted must be received at the office no later than 4:30 p.m. on the final day. No additional evidence may be submitted during the three-day period. This rule hearing procedure is governed by Minn. Stat. SS 14.131 to 14.20 (1990) and by Minn. Rules pts. 1400.0200 to 1400.1200 (1991). Questions about procedure may be directed to the administrative law judge.

If adopted, the rules will establish a statewide traumatic brain injury and spinal cord injury registry. A copy of the proposed rules is attached to this Notice. The proposed rules will also be published in the State Register issue of July 27,

1992, and a free copy of the rules may be obtained from the Department by writing or telephoning Mark Kinde at the address and telephone number listed above in Part II of this notice.

The statutory authority of the Department to adopt the proposed rules is contained in Minn. Stat. **SS** 144.05, 144.12, and 144.661 to 144.665.

The proposed rules may be modified as a result of the rule hearing process. Those who are potentially affected in any manner by the substance of the proposed rules are therefore advised to participate in the process.

Minn. Stat. ch. 10A requires each lobbyist to register with the Ethical Practices Board. Questions should be directed to the Ethical Practices Board, 625 North Robert Street, St. Paul, Minnesota 55101-2520, telephone: (612) 296-5148.

Notice is hereby given that a statement of need and reasonableness is now available for review at the Department and at the Office of Administrative Hearings. This statement of need and reasonableness includes a summary of all the evidence which the Department anticipates presenting at the hearing justifying both the need for and the reasonableness of the proposed rules. Copies of the statement of need and reasonableness may be reviewed at the Department or the Office of Administrative Hearings and copies may be obtained from the Office of Administrative Hearings at the cost of reproduction.

Please note that any person may request notification of the date on which the administrative law judge's report will be

available, after which date the Department may not take any final action on the rules for a period of five working days. If you desire to be so notified, you may so indicate at the hearing. After the hearing, you may request notification by sending a written request to the administrative law judge. Any person may request notification of the date on which the rules are adopted and filed with the Secretary of State. The notice must be mailed on the same day that the rules are filed. If you want to be so notified, you may so indicate at the hearing or send a request in writing to the Department at any time prior to the filing of the rules with the Secretary of State.

Promulgation of these proposed rules will not result in the expenditure of more than $100,000 in public monies by local public bodies for the two years immediately following adoption of the rules nor have any impact on agricultural land; therefore, no further information need be provided under Minn. Stat. S 14.11 (1990).

It is the position of the Department that it is subject to Minn. Stat. S 14.115 (1990) regarding small business considerations in rulemaking. The basis for this position, and the Department's evaluation of the applicability of the methods contained in Minn. Stat. S 14.115, subd. 2 (1990) for reducing the impact of the proposed rules are addressed in the statement of need and reasonableness.

Pursuant to Minn. Stat. S 14.115, subd. 4 (1990), the Department will mail a copy of this notice to every licensed

hospital in the State of Minnesota in order to assure that small businesses have an opportunity to participate in the rulemaking process. In addition, the Department included representation from the Minnesota Hospital Association on the review committee that was established to assist with the adoption of the rules. At the hearing on these rules, testimony will be received on the impact of them on small businesses.

IV.

NOTICE OF INTENT TO CANCEL HEARING IF FEWER THAN 25 PERSONS REQUEST A HEARING.

PLEASE NOTE THAT THE HEARING, NOTICE OF WHICH IS GIVEN IN PART III ABOVE, WILL BE CANCELLED IF FEWER THAN 25 PERSONS REQUEST A HEARING IN RESPONSE TO THE NOTICE GIVEN IN PART II ABOVE. ALSO, THE HEARING WILL BE CANCELLED IF A SUFFICIENT NUMBER OF PEOPLE WITHDRAW THEIR REQUEST FOR A HEARING IN RESPONSE TO PROPOSED REVISIONS OF THE PROPOSED RULES BY THE DEPARTMENT.

To be informed whether the hearing noticed in Part III above will be held, please telephone Mark Kinde at the telephone number listed above in Part II of this Notice before September 4, 1992, and leave your name, address, and telephone number. You will be notified if the hearing has been cancelled. You may also telephone Mark Kinde after September 4, 1992, for oral confirmation regarding the scheduled hearing.

Dated: July 7, 1992

Marlene E. Marschall
Commissioner of Health

approved by the state fire marshal. The licensee shall also provide additional space and physical plant accommodations appropriate for the number and age of children residing in the facility. For purposes of license capacity, each child residing in the facility shall be considered to be a resident.

[For text of subd 7, see M.S.1990]

History: *1991 c 286 s 3*

144.653 RULES; PERIODIC INSPECTIONS; ENFORCEMENT.

[For text of subds 1 to 4, see M.S.1990]

Subd. 5. **Correction orders.** Whenever a duly authorized representative of the state commissioner of health finds upon inspection of a facility required to be licensed under the provisions of sections 144.50 to 144.58 that the licensee of such facility is not in compliance with sections 144.411 to 144.417, 144.50 to 144.58, 144.651, or 626.557, or the applicable rules promulgated under those sections, a correction order shall be issued to the licensee. The correction order shall state the deficiency, cite the specific rule violated, and specify the time allowed for correction.

[For text of subds 6 to 9, see M.S.1990]

History: *1991 c 286 s 4*

TRAUMATIC BRAIN AND SPINAL CORD INJURIES

144.661 DEFINITIONS.

Subdivision 1. **Scope.** For purposes of sections 144.661 to 144.665, the following terms have the meanings given them.

Subd. 2. **Traumatic brain injury.** "Traumatic brain injury" means a sudden insult or damage to the brain or its coverings caused by an external physical force which may produce a diminished or altered state of consciousness and which results in the following disabilities:

(1) impairment of cognitive or mental abilities;

(2) impairment of physical functioning; or

(3) disturbance of behavioral or emotional functioning.

These disabilities may be temporary or permanent and may result in partial or total loss of function. "Traumatic brain injury" does not include injuries of a degenerative or congenital nature.

Subd. 3. **Spinal cord injury.** "Spinal cord injury" means an injury that occurs as a result of trauma which may involve spinal vertebral fracture and where the injured person suffers an acute, traumatic lesion of neural elements in the spinal canal, resulting in any degree of temporary or permanent sensory deficit, motor deficit, or bladder or bowel dysfunction. "Spinal cord injury" does not include intervertebral disc disease.

History: *1991 c 292 art 2 s 5*

144.662 TRAUMATIC BRAIN INJURY AND SPINAL CORD INJURY REGISTRY; PURPOSE.

The commissioner of health shall establish and maintain a central registry of persons who sustain traumatic brain injury or spinal cord injury. The purpose of the registry is to:

(1) collect information to facilitate the development of injury prevention, treatment, and rehabilitation programs; and

(2) ensure the provision to persons with traumatic brain injury or spinal cord injury of information regarding appropriate public or private agencies that provide rehabilitative services so that injured persons may obtain needed services to alleviate

injuries and avoid secondary problems, such as mental illness and chemical dependency.

History: *1991 c 292 art 2 s 6*

144.663 DUTY TO REPORT.

Subdivision 1. **Establishment of reporting system.** The commissioner shall design and establish a reporting system which designates either the treating hospital, medical facility, or physician to report to the department within a reasonable period of time after the identification of a person with traumatic brain injury or spinal cord injury. The consent of the injured person is not required.

Subd. 2. **Information.** The report must be submitted on forms provided by the department and must include the following information:

(1) the name, age, and residence of the injured person;

(2) the date and cause of the injury;

(3) the initial diagnosis; and

(4) other information required by the commissioner.

Subd. 3. **Reporting without liability.** The furnishing of information required by the commissioner shall not subject any person or facility required to report to any action for damages or other relief, provided that the person or facility is acting in good faith.

History: *1991 c 292 art 2 s 7*

144.664 DUTIES OF COMMISSIONER.

Subdivision 1. **Studies.** The commissioner shall collect injury incidence information, analyze the information, and conduct special studies regarding traumatic brain injury and spinal cord injury.

Subd. 2. **Provision of data.** The commissioner shall provide summary registry data to public and private entities to conduct studies using data collected by the registry. The commissioner may charge a fee under section 13.03, subdivision 3, for all out-of-pocket expenses associated with the provision of data or data analysis.

Subd. 3. **Notification.** Within five days of receiving a report of traumatic brain injury or spinal cord injury, the commissioner shall notify the commissioner of jobs and training. The notification shall include the person's name and other identifying information.

Subd. 4. **Review committee.** The commissioner shall establish a committee to assist the commissioner in the adoption of rules under subdivision 5 and in the review of registry activities. The committee expires as provided in section 15.059, subdivision 5.

Subd. 5. **Rules.** The commissioner shall adopt rules to administer the registry, collect information, and distribute data. The rules must include, but are not limited to, the following:

(1) the specific ICD-9 procedure codes included in the definitions of "traumatic brain injury" and "spinal cord injury";

(2) the type of data to be reported;

(3) standards for reporting specific types of data;

(4) the persons and facilities required to report and the time period in which reports must be submitted;

(5) criteria relating to the use of registry data by public and private entities engaged in research; and

(6) specification of fees to be charged under section 13.03, subdivision 3, for out-of-pocket expenses.

History: *1991 c 292 art 2 s 8*

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'UBLIC HEALTH SERVICES.

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85 c 248 s 70

(2) Empowers and directs the commissioner to cooperate with the federal children's bureau to carry out the purposes of such acts; and

(3) Appoints the state treasurer as custodian of all moneys given to the state by the United States under the authority of such acts and such money shall be paid out in the manner provided by such acts for the purposes therein specified.

History: *(5344) 1921 c 392 s 5; 1977 c 305 s 45*

144.092 COORDINATED NUTRITION DATA COLLECTION.

The commissioner of health may develop and coordinate a reporting system to improve the state's ability to document inadequate nutrient and food intake of Minnesota's children and adults and to identify problems and determine the most appropriate strategies for improving inadequate nutritional status. The board on aging may develop a method to evaluate the nutritional status and requirements of the elderly in Minnesota. The commissioner of health and the board on aging may report to the legislature on each July 1, beginning in 1988, on the results of their investigation and their recommendations on the nutritional needs of Minnesotans.

History: *1986 c 404 s 6; 1987 c 209 s 3*

144.10 FEDERAL AID FOR MATERNAL AND CHILD WELFARE SERVICES; CUSTODIAN OF FUND; PLAN OF OPERATION; LOCAL APPROPRIATIONS.

The state treasurer is hereby appointed as the custodian of all moneys received, or which may hereafter be received, by the state by reason of any federal aid granted for maternal and child welfare service and for public health services, including the purposes as declared in Public Law Number 725 enacted by the 79th Congress of the United States, Chapter 958-2d Session and all amendments thereto, which moneys shall be expended in accordance with the purposes expressed in the acts of congress granting such aid and solely in accordance with plans to be prepared by the state commissioner. The plans so to be prepared by the commissioner for maternal and child health service shall be approved by the United States Children's Bureau; and the plans of the commissioner for public health service shall be approved by the United States Public Health Service. Such plans shall include the training of personnel for both state and local health work and conform with all the requirements governing federal aid for these purposes. Such plans shall be designed to secure for the state the maximum amount of federal aid which is possible to be secured on the basis of the available state, county, and local appropriations for such purposes. The commissioner shall make reports, which shall be in such form and contain such information as may be required by the United States Children's Bureau or the United States Public Health Service, as the case may be; and comply with all the provisions, rules, and regulations which may be prescribed by these federal authorities in order to secure the correction and verification of such reports.

History: *(5391-1) Ex1936 c 70 s 1; 1947 c 485 s 1; 1977 c 305 s 45*

144.11 RULES.

The commissioner may make such reasonable rules as may be necessary to carry into effect the provisions of section 144.10 and alter, amend, suspend, or repeal any of such rules.

History: *(5391-2) Ex1936 c 70 s 2; 1977 c 305 s 45; 1985 c 248 s 70*

144.12 REGULATION, ENFORCEMENT, LICENSES, FEES.

Subdivision 1. **Rules.** The commissioner may adopt reasonable rules pursuant to

(2) The business of scavengering and the disposal of sewage;

(3) The location of mortuaries and cemeteries and the removal and burial of the dead;

(4) The management of boarding places for infants and the treatment of infants in them;

(5) The pollution of streams and other waters and the distribution of water by persons for drinking or domestic use;

(6) The construction and equipment, in respect to sanitary conditions, of schools, hospitals, almshouses, prisons, and other public institutions, and of lodging houses and other public sleeping places kept for gain;

(7) The treatment, in hospitals and elsewhere, of persons suffering from communicable diseases, including all manner of venereal disease and infection, the disinfection and quarantine of persons and places in case of those diseases, and the reporting of sicknesses and deaths from them;

Neither the commissioner nor any board of health as defined in section 145A.02, subdivision 2, nor director of public health may adopt any rule or regulation for the treatment in any penal or correctional institution of any person suffering from any communicable disease or venereal disease or infection, which requires the involuntary detention of any person after the expiration of the period of sentence to the penal or correctional institution, or after the expiration of the period to which the sentence may be reduced by good time allowance or by the lawful order of any judge or the department of corrections;

(8) The prevention of infant blindness and infection of the eyes of the newly born by the designation, from time to time, of one or more prophylactics to be used in those cases and in the manner that the commissioner directs, unless specifically objected to by a parent of the infant;

(9) The furnishing of vaccine matter; the assembling, during epidemics of smallpox, with other persons not vaccinated, but no rule of the board or of any public board or officer shall at any time compel the vaccination of a child, or exclude, except during epidemics of smallpox and when approved by the local board of education, a child from the public schools for the reason that the child has not been vaccinated; any person required to be vaccinated may select for that purpose any licensed physician and no rule shall require the vaccination of any child whose physician certifies that by reason of the child's physical condition vaccination would be dangerous;

(10) The accumulation of filthy and unwholesome matter to the injury of the public health and its removal;

(11) The collection, recording, and reporting of vital statistics by public officers and the furnishing of information to them by physicians, undertakers, and others of births, deaths, causes of death, and other pertinent facts;

(12) The construction, equipment, and maintenance, in respect to sanitary conditions, of lumber camps, migratory or migrant labor camps, and other industrial camps;

(13) The general sanitation of tourist camps, summer hotels, and resorts in respect to water supplies, disposal of sewage, garbage, and other wastes and the prevention and control of communicable diseases; and, to that end, may prescribe the respective duties of agents of a board of health as authorized under section 145A.04; and all boards of health shall make such investigations and reports and obey such directions as the commissioner may require or give and, under the supervision of the commissioner, enforce the rules;

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STATE OF MINNESOTA

COUNTY OF HENNEPIN

In the Matter of the Proposed Adoption of Rules Related to the Traumatic Brain Injury and Spinal Cord Injury Registry

BEFORE THE MINNESOTA

DEPARTMENT OF HEALTH

AFFIDAVIT OF MAILING THE STATEMENT OF NEED AND REASONABLENESS

STATE OF MINNESOTA)
)ss.
COUNTY OF HENNEPIN)

Brenda Sayler, being duly sworn says:

That on the 7th day of July, 1992, at the City of Minneapolis, County of Hennepin, State of Minnesota, I mailed the attached Statement of Need and Reasonableness, pursuant to Minnesota Statutes, section 14.23, by depositing in the Department of Health's Central Mail System for United States mailing a copy thereof, with postage prepaid, to Maryanne V. Hruby, Executive Director, Legislative Commission to Review Administrative Rules, State Office Building, Room 55, 100 Constitution Avenue, St. Paul, Minnesota 55155.

Brenda Sayler

Subscribed and sworn to before me
this 7th day of July, 1992.

Joan M. Osell
NOTARY PUBLIC

JOAN M. OSELL
NOTARY PUBLIC-MINNESOTA
HENNEPIN COUNTY
MY COMMISSION EXPIRES MARCH 6, 1997

minnesota department of health
717 s.e. delaware st. p.o. box 9441 minneapolis 55440
(612) 623-5000

July 7, 1992

Ms. Maryanne Hruby
State Office Building Room 55
100 Constitution Avenue
St. Paul, MN 55155

RE: In the Matter of the Proposed Adoption of Rules of the Department of Health Related to the Traumatic Brain Injury and Spinal Cord Injury Registry.

Dear Ms. Hruby:

Pursuant to Minnesota Statutes, sections 14.23, I am enclosing a copy of the Department's Statement of Need and Reasonableness with respect to the above subject rulemaking proceeding. I am also enclosing for your convenience a copy of the proposed rules.

The rule making notice will be published in the July 27, 1992 issue of the State Register. The comment period will close on August 26, 1992. If a hearing is required, it will be held on September 9, 1992 in the Chesley Room of the Minnesota Department of Health Building, starting at 9 a.m.

If you have any questions, please feel free to contact me at 623-5782.

Sincerely,

Mark Kinde /bps

Mark Kinde, Supervisor
Injury Control Unit

MK:djg
Enclosure
cc: D. Welch
D. Giese
D. Bishop

an equal opportunity employer

Celebrate MINNESOTA 1990

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ADMINISTRATIVE
HEARINGS

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA DEPARTMENT OF HEALTH

In the Matter of the Proposed Adoption of Rules Related to the Traumatic Brain Injury and Spinal Cord Injury Registry

AFFIDAVIT OF MAILING THE NOTICE OF INTENT TO ADOPT RULES WITHOUT A PUBLIC HEARING, NOTICE OF INTENT TO ADOPT RULES WITH A PUBLIC HEARING IF 25 OR MORE PERSONS REQUEST A HEARING, NOTICE OF INTENT TO CANCEL HEARING IF FEWER THAN 25 PERSONS REQUEST A HEARING AND CERTIFICATE OF MAILING LIST

STATE OF MINNESOTA)
)ss.
COUNTY OF HENNEPIN)

Brenda Saylor, being duly sworn says:

I hereby certify that the list of persons and associations who have requested, pursuant to Minnesota Statutes, section 14.14, subd. 1a, and 14.22 or 14.30, that their names be placed on the Department of Health rulemaking list is accurate, complete, and current as of this 15th day of July, 1992. This list is attached to this affidavit as Exhibit A and made a part hereof.

That on the 15th day of July, 1992, at the City of Minneapolis, County of Hennepin, State of Minnesota, I mailed the attached Notice of Intent to Adopt Rules Without a Public Hearing, Notice of Intent to Adopt Rules With a Public Hearing if 25 or More Persons Request a Hearing and Notice of Intent to Cancel Hearing if Fewer Than 25 Persons Request a Hearing by depositing in the Department of Health's Central Mail System for United States mailing a copy thereof, with postage prepaid, to all persons and associations on the mailing list attached as Exhibit A as well as

to all hospitals which are currently licensed by the Department, the names and addresses of which are attached as Exhibit B and made a part hereof.

Brenda Sayler

Subscribed and sworn to before me
this 15th day of July, 1992.

Joan M. Osell
NOTARY PUBLIC

JOAN M. OSELL
NOTARY PUBLIC-MINNESOTA
HENNEPIN COUNTY
MY COMMISSION EXPIRES MARCH 6, 1997

EXHIBIT A

Michael J. Ahern
Moss & Barnett
4800 Norwest Center
90 So. Seventh St.
Minneapolis, MN 55402

Walter A. Baldus
Woodvale Management
Services Inc.
P.O. Box 1047
Austin, MN 55912

Lester Block
School of Public Health
C309 Mayo - 97 UMHC
University of Minnesota
Minneapolis, MN 55455

William E. Bond
Minnesota Pharmacists
Association
2550 University Avenue
West #320N
St. Paul, MN 55114

Marge Scudder Brchan
Morrison County Public
Health Services
200 E. Broadway
Little Falls, MN 56345

Mark J. Brunner
MN Manufactured Housing
Association
555 Park Street, Ste 400
St. Paul, MN 55103

Marcia B. Bryan, Ed. D.
A.R.R.M.
26 E. Exchange St. #503
St. Paul, MN 55101

Wm. R. Carter III
Board of Peace Office
Standards & Training
1600 University Avenue
Suite 200
St. Paul, MN 55104

Rebecca A. Comstock
Dorsey & Whitney
2200 First Bank Place East
Minneapolis, MN 55402

Bill Conley
114 Mackubin Street
St. Paul, MN 55102

D.E.F.F.B.A.M.
P.O. Box 11855
St. Paul, MN 55111

Judith S. Douglas
The Phoenix Residence,
Inc.
135 Colorado St. E.
St. Paul, MN 55107

John E. Drawz
Fredrikson & Byron, PA
1100 International Centre
900 Second Avenue South
Mpls, MN 55402-3397

Michael J. Duffy, Dir.
Community Health Board
325 Lake Ave So/Rm.510-B
Duluth, MN 55802

Sandra DuVander
Anoka County Community
Health/Environment Srvcs
325 E. Main - Courthouse
Anoka, MN 55303

Ernest K Lehmann & Assoc.
Attn: Land Department
430 First Avenue North
Suite 790
Mpls., MN 55401-1727

Doug Ewald
Ewald Consulting Group
26 E. Exchange St., #507
St. Paul, MN 55101

Matthew Felker
Scott-Levin Associates
60 Blacksmith Road
Newtown, PA 18940

Carol Fielders, PHN Dir.
St. Louis Cty Health Dept
222 East Superior Street
Duluth, MN 55802-2134

Bob Fitzgerald, D.C.
133 W. Lake Street
Minneapolis, MN 55405

Pamela A. Foster
Supervising Sanitarian
City of Crystal
4141 Douglas Drive N.
Crystal, MN 55422

Iris C. Freeman
Minnesota Alliance for
Health Care Consumers
5609 Lyndale Avenue South
Minneapolis, MN 55419

Cynthia R. Fremgord
QSS, Inc.
P.O. Box 838
Faribault, MN 55021

Patti Cullen Garvey
Care Providers of MN
2850 Metro Drive
Suite 200
Bloomington, MN 55425

Mr. Robert A. Harder
Minnesota Dental Assoc.
2236 Marshall Avenue
St. Paul, MN 55104

Brian Heinen
Assisi Residences, Inc.
P.O. Box 454
Blue Earth, MN 56013

Elisabeth Hennessey
Arc Olmsted County
903 West Center Street
Rochester, MN 55902

John W. Henrich
Bergerson-Caswell, Inc.
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STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

DEPARTMENT OF HEALTH

In the Matter of the
Proposed Adoption of
Rules Related to the
Traumatic Brain Injury
and Spinal Cord Injury
Registry

DECLARATION OF COUNSEL

I, Maria C. Christu, Special Assistant Attorney General, do hereby declare that I have examined the above-captioned rules and the supporting rulemaking record and that, based on my examination, the Administrative Procedure Act and Minn. Rules ch. 2010 have been followed. Any exceptions are listed below. For Attorney General billing purposes, the four-digit docket client code is: 1800

Dated: 9/16, 1992.

Maria C. Christu

MARIA C. CHRISTU
Special Assistant Attorney General