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."

Laws 1991

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