STATE OF MINNESOTA

DEPARTMENT OF PUBLIC SAFETY
DRIVER AND VEHICLE SERVICES DIVISION

STATEMENT OF NEED AND REASONABLENESS

In the matter of the proposed permanent rules relating to driver's license requirements of persons with diabetes.

GENERAL STATEMENT

The above-entitled rules govern the department's administration of Minnesota Statutes, sections 171.04, 171.13 and 171.14. Such statutes pertain to the examination of driver's license applicants and the cancellation, suspension and denial of driving privileges. Minnesota Statutes, section 171.04, provides that the department of public safety (department) shall not issue a driver's license to a person who is afflicted with or suffering from a physical disability or disease which will affect the person in a manner that prevents the person from exercising reasonable and ordinary control over a motor vehicle while operating the vehicle upon the highways. Minnesota Statutes, section 171.14, works in conjunction with section 171.04 and provides that the commissioner of public safety (commissioner) has authority to cancel the driver's license of any person who, at the time of the cancellation, would not have been entitled to receive a license under the provisions of 171.04.

Minnesota Statutes, section 171.13, provides that the commissioner may require an examination of a licensed driver to determine if any physical disability or disease might prevent the driver from exercising reasonable and ordinary control over a motor vehicle. If the commissioner believes that the driver cannot safely operate a motor vehicle upon the public highways, the commissioner may cancel the driver's license of the person.

The above statutory mandates have led to the development and adoption of the rules relating to driver's license requirements for persons with diabetes. The rules set forth procedures for monitoring persons with diabetes who experience a loss of consciousness or voluntary control due to hypoglycemia or hyperglycemia. The risk of a diabetic person experiencing a loss of consciousness or voluntary control while operating a motor vehicle warrants the monitoring of the person's diabetic condition in the interest of public safety.

The extent to which the department should monitor a person's diabetic condition and under what circumstances a diabetic's driver's license should be cancelled has been an issue of debate between the department and the public since the initial adoption of the rules in 1981. In 1988, when the rules were last amended, many of the public's comments on the rules centered around the rules being too strict on the licensing of diabetics in light of the advances in medical technologies. Subsequent to the 1988 rule amendments, the department has continued to receive requests for changes in department policies with respect to the licensing of diabetics.

In response to the comments received at the 1988 hearing and subsequent comments from the American Diabetes Association (ADA), members of the public and the medical community, the department is proposing amendments to the diabetes rules. In developing the amendments, the department has worked extensively on the amendments with the Minnesota affiliate of the ADA and the Minnesota Diabetes Steering Committee (Steering Committee). The Steering Committee is composed of approximately 20 individuals who work in the diabetes area. Steering committee members include physicians, nurses, certified diabetes educators, dietitians, and other individuals from various diabetic programs and organizations.

The proposed amendments to the rules are a product of negotiation and compromise between the department and the various organizations and individuals. The department has strived to improve the existing system for the regulation of drivers with diabetes while at the same time balancing the interests of public safety. Individual facts, supporting literature and discussions with regard to each specific rule are contained in the rule-by-rule analysis.

STATUTORY AUTHORITY

The statutory authority for the promulgation of rules for driving privileges as they relate to individuals with a physical disease, such as diabetes, is set forth in Minnesota Statutes, section 299A.01, subdivision 6, and section 14.06 of the Administrative Procedure Act.

Minnesota Statutes, section 299A.01, subdivision 6, provides that the commissioner of public safety shall have the power to promulgate such rules pursuant to chapter 14, as are necessary to carry out the duties of the commissioner. Section 14.06 of the Administrative Procedure Act gives the department of public safety general rulemaking authority. Under section 14.06, the commissioner of public safety has the authority to promulgate rules that directly affect the rights of and procedures available to the public.

These rules, which administer the various provisions under Minnesota Statues, Chapter 171, directly affect the diabetic public who have a driver's license or who apply for a driver's license. Therefore, when such policies and procedures of the department directly affect the public, the procedures must be adopted through the formal rulemaking process. The rulemaking process gives the public the opportunity to comment and participate in the development of the procedures and policies of the department.

SMALL BUSINESS CONSIDERATIONS

Minnesota Statutes, section 14.115, subdivision 2, requires the department, when proposing rules, to consider the impact such rules will have on small businesses. The department is to consider the following methods for reducing the impact of the rules on small businesses:

(a) the establishment of less stringent compliance or reporting requirements for small businesses;
(b) the establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses;

(c) the consolidation or simplification of compliance or reporting requirements for small businesses;

(d) the establishment of performance standards for small businesses to replace design or operational standards required in the rule; and

(e) the exemption of small businesses from any or all requirements of the rule.

Minnesota Statutes, section 14.115, subdivision 3, requires agencies to incorporate into proposed rules any of the above methods "that it finds to be feasible, unless doing so would be contrary to the statutory objectives that are the basis of the proposed rulemaking."

These rules directly regulate a diabetic person's driving privileges and do not directly regulate businesses. However, the rules do have an indirect effect on physicians who are required to complete and submit a physician's statement under part 7410.2610, subpart 3a. Some of these physicians operate small businesses. To the extent that these rules affect small businesses the department has attempted to establish less stringent reporting and deadline requirements in the submission of the physician's statement in accordance with factors (a), (b) and (c) above. The amendments in part 7410.2610, subparts 3 and 3a will reduce the amount of paperwork that a physician will have to complete by consolidating the reporting requirements. (See subparts 3 and 3a for more details on the amendments.)

Paragraph (d) above requires the agency to establish performance standards for small businesses to replace design or operational standards required in the rule. The rules do not contain performance standards that businesses are required to follow. Paragraph (e) relating to the exemption of small businesses from the requirements of the rules is not feasible because businesses are not required to follow specific requirements under the rules. All the requirements are written to regulate the individual. However, the businesses that do become involved in the medical diagnosis of an individual are a necessary part of the effectiveness of administering the rules and could not be exempted.

There may also be an indirect effect upon small businesses caused by an employee's withdrawal of driving privileges. However, the effect on the small business is outweighed by the interests of the public in keeping the roads and highways safe.

OTHER STATUTORY REQUIREMENTS

Minnesota Statutes, section 16A.128, subdivisions 1a and 2a, do not apply because the rules do not fix fees. Minnesota Statutes, section 14.11, subdivision 1, does not apply because adoption of these rules will not result in additional spending by local public bodies in excess of $100,000 per year for the first two years following adoption of the rules. Minnesota Statutes, section 14.11, subdivision 2, does not apply because adoption of these rules will not have an impact on agricultural land. Minnesota Statutes, sections 115.43, subdivision 1, 116.07, subdivision 6, and 144A.29, subdivision 4, do not apply to these rules.

WITNESSES

If these rules go to a public hearing, the following individuals may testify on behalf of the department of public safety in support of the need for and reasonableness of the rules:

Rollie Hunter, Supervisor, Driver Evaluation Unit, Driver and Vehicle Services Division, Department of Public Safety, 151 Transportation Bldg., 395 John Ireland Blvd., St. Paul, MN 55155.

Paul Johnson, Assistant Supervisor, Driver Evaluation Unit, Driver and Vehicle Services Division, Department of Public Safety, 108 Transportation Bldg., 395 John Ireland Blvd., St. Paul, MN 55155.

Laura Nehl-Trueman, Rulewriter, Driver and Vehicle Services Division, Department of Public Safety, 208 Transportation Bldg., 395 John Ireland Blvd., St. Paul, MN 55155

Other employees of the Department of Public Safety.

If the rules go to a public hearing, it is anticipated that the agency will call expert witnesses. If a hearing is required, a list of expert witnesses will be attached to this Statement of Need and Reasonableness and will be sent to all persons who requested a copy of the Statement of Need and Reasonableness.

RULE-BY-RULE ANALYSIS

7410.2600 DIABETES DIAGNOSIS. [See repealer.]

Part 7410.2600 currently sets forth regulations regarding persons who have been diagnosed as having diabetes. The part describes different methods of reporting a diabetic condition depending on whether the person's diabetes is treated with insulin or not. All of part 7410.2600 has been repealed. The parts of the rule dealing with the reporting of the diagnosis of individuals with diabetes who are not treated with insulin will no longer be required. However, the requirements of the rule dealing with the diagnosis and reporting of insulin-treated diabetes have been incorporated into part 7410.2610.

Therefore, there will now only be one rule part regulating the licensing of drivers with insulin-treated diabetes. Based on the recommendation of the ADA and the Steering Committee, the department will no longer require medical information from an individual whose diabetes is controlled solely by diet or oral medication. (Insulin is not administered orally) Only individuals whose diabetes is treated with insulin will be included under the proposed rule. This amendment is further explained in subpart 2 below. Having one rule part that sets forth the requirements of licensure of people with insulin-treated diabetes will streamline the rules and provide better guidance for the public.

Subpart 1. Scope. Subpart 1 has been repealed. The scope of rules dealing with the licensing and regulation of insulin-treated diabetic drivers is contained in part 7410.2610.

Subpart 2. Reports required. Currently, under part 7410.2600, subpart 2, an individual is required to report a diagnosis of diabetes, even if the diabetes is not treated with insulin. Upon informing the department of such a diagnosis the person is required to have his or her physician fill out a medical form with respect to the person's medical condition. When the form is returned to the department, the person's name and status of their diabetic condition is entered into the department's computer system and no further action is taken with regard to the person unless the condition changes to require the use of insulin.

Because the department does not take further action on non-insulin treated diabetics, the department is proposing the elimination of this reporting requirement and the repeal of subpart 2. The reporting requirement unnecessarily places a burden on the individuals and physicians who are affected by the regulation. By eliminating this reporting process we can reduce the paperwork for both the non-insulin treated diabetic and the physician.

The elimination of this reporting requirement for non-insulin treated diabetics is reasonable because if a person's condition does change to require the use of insulin, the person will be required to report that change of their diabetic condition to the department under part 7410.2610, subpart 3. Further, the department's repeal of the reporting requirement for the non-insulin treated diabetic is reasonable because not all individuals with diabetes are subject to severe hypoglycemic reactions.

As specified in recent medical literature, "[h]ypoglycemia is most apt to occur in insulin-treated patients with type I [diabetes] (ie, insulin dependent diabetes mellitus (IDDM)), particularly those who have labile or `brittle' diabetes or who are controlled too tightly." E. N. Ehrlich, MD, Diabetes and the License to Drive, Wisconsin Medical Journal, p. 116, March 1991. "Hypoglycemia does not occur in people with diabetes who require only diet for treatment. Except in elderly or chronically ill individuals or in association with prolonged fasting, severe hypoglycemia is unlikely to occur when appropriate doses of oral medications are used to manage blood glucose." Hypoglycemia and Employment/Licensure, Diabetes Care, Vol. 14, Suppl. 2, p. 47, March 1991.

Therefore, if an individual is not subject to hypoglycemic reactions, there is no reason why the department should continue to require a physician's statement from non-insulin treated diabetics. If a diabetic who is treated with oral medication or diet does have an episode he or she will still be subject to the rules under part 7410.2500 which regulates other types of loss of consciousness or voluntary control. Individuals whose diabetes is treated with insulin will continue to be monitored by the department and will have to report the status of their diabetic condition under the requirements of part 7410.2610, subpart 3.

Subpart 3. Failure to Report; Misrepresentation. Subpart 3 is repealed. A person will no longer be required to report a diagnosis of non-insulin treated diabetes. Therefore, there will be no cancellation of a person's driver license for failure to report such diagnosis. However, the portion of the rule that pertains to the withdrawal of a person's driver's license for failure to report a diagnosis of insulin-treated diabetes is still required and is now incorporated into part 7410.2610, subpart 3.

Subpart 4. Cancellation. Subpart 4 regarding cancellation of a person's driver's license based upon the recommendation of the physician is repealed and the requirements are now located in part 7410.2610, subpart 5a, item A.

Subpart 5. Reinstatement. Subpart 5 regarding the reinstatement requirements for a person whose driver's license was cancelled upon the advice of a physician under subpart 4 has been repealed. The reinstatement requirements located in part 7410.2610, subpart 6 will apply for an insulin-treated diabetic whose license has been denied, cancelled or suspended.

7410.2610 Insulin-Treated Diabetes Mellitus.

The headnote of part 7410.2610 has been changed from "Diabetes Related Loss of Consciousness or Voluntary Control" to "Insulin-Treated Diabetes Mellitus". Although the headnote is not part of the rule it does provide guidance to the public as to who and what the rule pertains to. The change in the headnote reflects the scope of the proposed amendments. Part 7410.2610 no longer deals exclusively with diabetes related loss of consciousness or voluntary control but now also includes rules on reporting of a diagnosis of insulin-treated diabetes which were previously set forth in part 7410.2600.

Subpart 1. Scope. The language of this subpart has been amended to state that the scope of the rule refers to the broader category of insulin-treated diabetes and not just diabetes related loss of consciousness or voluntary control. The amendment is necessary because of the addition of rule requirements regarding the reporting requirements of insulin-treated diabetes that were previously set forth in part 7410.2600.

Subpart 2. Definitions. Five new definitions have been added to this subpart. The terms "Commissioner" and "Department" under items B and C have been added for clarification and for public guidance. These definitions were not previously provided in part 7410.2610. While it may be obvious that these are rules of the department of public safety, not everyone is aware of that fact. Therefore, it is reasonable to define these terms for a more complete rule.

The term "applying", under item A has been added because the term is used in the rule without adequate definition. As the definition of the word "applying" points out, a person is making an application for a driver's license when they seek their initial license, as well as when they renew their license or when they complete a duplicate driver's license application. The definition of "applying" will accurately inform people as to when they are required to report a diagnosis of insulin-treated diabetes.

Under item D, the term "driving-related episode" has been defined as an "episode that occurred while the person was driving, operating, or in physical control of a motor vehicle." Instead of repeating this entire phrase throughout the rule the term "driving-related episode" will allow for a less cumbersome and therefore more understandable rule.

The phrase "while the person was driving, operating, or in physical control of a motor vehicle," is the same standard that is used in Minnesota Statutes, section 169.121, subdivision 1. Section 169.121 is the statute regarding drivers who operate a motor vehicle under the influence of alcohol or a controlled substance. The above phrase is used in this rule because the same issues of operation and physical control are likely to arise in the implementation of this rule. The issue of whether a person was "driving, operating, or in physical control of a motor vehicle" has been litigated in connection with section 169.121. The litigation and subsequent court decisions will provide helpful guidance for the department in determining the issues of operation and control in these rules as well. (See State of Minnesota v. Starfield, 481 N.W.2d 834, (Minn. App. 1992) for a discussion of the issue of "physical control.")

The term "episode" under item E has been defined to streamline the rules. Currently, the rules refer to the single term of "episode" or the longer phrase of "episode of loss of consciousness or loss of voluntary control due to insulin reaction or acidosis." Use of the word "episode" will provide for consistency within the rules and for a less cumbersome and more understandable rule.

In addition, the definition of episode uses the terminology of "hypoglycemia or hyperglycemia" instead of "insulin reaction or acidosis." The change in wording from

"insulin reaction or acidosis" to "hypoglycemia or hyperglycemia" was made in response to a recommendation contained in the 1988 Administrative Law Judge's report. The Administrative Law Judge report was issued as a result of an administrative hearing that was held to determine whether the amendments made to the rules in 1988 were necessary and reasonable.

The Administrative Law Judge wrote in her 1988 report:

> Part 7410.2610, subpart 1 is all new language and describes the scope of this rule part. It specifies that the rule part applies to drivers and applicants for driving privileges who experience a loss of consciousness or voluntary control due to insulin reaction or acidosis. Bruce R. Zimmerman, M.D., an endocrinologist from the Mayo Clinic suggested that the reference to the loss of voluntary control as due to an `insulin reaction' is not accurate. He suggests that it should provide loss of voluntary control due to `hypoglycemia', because patients treated for their diabetes with sulfonylureas may also have hypoglycemia and loss of voluntary control. He also points out that loss of voluntary control from diabetic ketoacidosis is extremely unusual, as the unconsciousness and mental clouding of acidosis is a very gradual onset. He suggests that the term `acidosis' be eliminated from the rule....

Report of the Administrative Law Judge, p. 11-12, DPS-88-002-PR, August 12, 1988.

In response to Dr. Zimmerman's suggestion, the Administrative Law Judge wrote,

> The purpose of rules is to notify the public intended to be regulated what is expected of them to comply. One of the principles of foremost importance in rule drafting is that the rule should be clear and understandable to the public and to persons affected by the rule. The language of a proposed rule should focus on the reader's ability to understand the rule. It should be written so that it can be read and understood by people of average education. Technical terms should be kept at a minimum. Beck, Bakken and Muck, Minnesota Administrative Procedure, 331 (1987). If the rule was being written for more specialized audiences, such as doctors, the rule could then reflect a more technical orientation and could utilize language of that group. In this case, describing the scope of this rule part to apply to drivers and applicants who experience a loss of consciousness or voluntary control due to insulin reaction or acidosis leaves little room for misinterpretation. However, the agency did not respond to the suggestion of Dr. Zimmerman and it is suggested that the agency review Dr. Zimmerman's proposed changes and consider their adoption.

Administrative Law Judge Report, p. 11-12.

The department is now adopting the recommendation of Dr. Zimmerman and the Administrative Law Judge. Therefore, the words, "insulin reaction or acidosis" have been stricken and replaced with the terms "hypoglycemia or hyperglycemia" under the definition of episode. They more accurately describe the targeted behavior and are familiar to and easily understood by diabetics who are the focus of this rule.

Subpart 3. Reporting diagnosis of insulin-treated diabetes or episode. Subpart 3 contains the requirements for reporting to the department a diagnosis of insulin-treated diabetes or an episode. Reporting of a diagnosis of insulin-treated diabetes was previously required under part 7410.2600, subpart 2, which has been repealed. The reporting requirement for a diagnosis has not changed and is now located under item A of this subpart.

Items B and C contain the reporting requirements for an episode. Item B provides for reporting of a driving-related episode to the department within 30 days after the episode and on a regularly scheduled physician's statement as required in subpart 3a. Item C provides for reporting of a non-driving-related episode to the department on a regularly scheduled physician's statement as required in subpart 3a.

Under the proposed reporting requirements a distinction has been made between episodes that occur while a person is driving and those that occur outside of driving, such as in a person's home. The driving/non-driving distinction has been made in light of recent advances in medical technology in the control of diabetes and upon the recommendations of the medical community and the diabetic public. (For more discussion on the driving/non-driving distinction see subpart 5a).

Currently, an individual is required to report every episode, driving and non-driving, to the department when applying for a driver's license and within 30 days after the episode. Under item C of the proposed rule the requirements for reporting of a non-driving-related episode on the application and within 30 days of the episode would be eliminated.

Elimination of the 30 day reporting requirement and the reporting on an application for non-driving-related episodes is necessary because non-driving episodes will not normally result in a cancellation without the recommendation of the physician. Therefore, if a person's driver's license will not likely be cancelled for a non-driving episode, the reporting of such episodes within 30 days or upon the application is not warranted. Elimination of the reporting requirements is reasonable because the person will still be required to report all non-driving related episodes to the physician and the department on the regularly scheduled physician's statement as required under subpart 3a.

A person who is experiencing non-driving episodes will have to submit a physician's statement to the department every six months, annually, or every four years or more often, as recommended by the person's physician. If a person is experiencing episodes, the physician will have an opportunity to examine that person, determine the cause of the episodes and make a determination as to whether the person's medical condition warrants a cancellation of the person's driver's license or just continued monitoring of the person's condition.

In the past, there has been a problem with people not accurately reporting all episodes because of the fear of having their license cancelled upon reporting of the episode. Hopefully, without the fear of cancellation, people will be more willing to report such episodes not only to the department, but more importantly to their physician who needs the information to adequately assess the persons' medical condition.

The most important aspect is that the person continues to cooperate in the treatment and avoid driving if they are prone to hypoglycemic episodes. If a person is cooperating in treatment and being responsible in driving, there is no reason for the department to have more frequent reports to the department. Those that are unable to control their diabetic condition while driving or choose not to cooperate in treatment and continue to drive will be subject to more stringent reporting requirements and cancellation of their driver's licenses under subpart 5a.

Under item B, the department will continue to require that a person report a driving-related episode within 30 days and on the physician's statement. Driving-related episodes pose a risk to the safety of the public upon the streets and highways. If a person does have an episode while operating a motor vehicle the department will forward a physician's statement to the individual to have the physician fill out. Review of a person's diabetic condition after a driving-related episode by a physician may indicate that the

person's condition is not under control or it may indicate that the person is not taking the necessary responsibility to monitor their diabetic condition before operating a motor vehicle. Such a condition will warrant that the person's driver's license be cancelled under subpart 5a.

The final amendment in subpart 3 is the inclusion of the provision for failing to report a diagnosis of insulin-treated diabetes or a driving-related episode as required under this subpart. The requirements regarding the failure to report an episode or diagnosis are not new. The rule provisions were previously set forth in parts 7410.2600, subpart 3 and 7410.2610, subpart 4 and have been incorporated with amendments in this subpart as part of the reorganization of the rules.

The provision relating to the failure to report also makes the distinction between driving and non-driving-related episodes. Under the current rules, a failure to report any episode could result in a cancellation of the person's driver's license. To be consistent with the other amendments in this subpart, the proposed rules only require a suspension of a person's driver's license in cases of failing to report a diagnosis of insulin-treated diabetes and episodes occurring while the person was driving, operating, or in physical control of a motor vehicle.

Therefore, there will no longer be a cancellation of a person's driver's license for the failure to report non-driving related episodes. This is reasonable because of the elimination of requiring a person to report a non-driving-related episode within 30 days. The emphasis is being placed on driving-related episodes. Since we will not be taking action in most cases on non-driving related episodes, there should be no withdrawal of the person's driver's license for failure to report.

If a person does fail to meet the reporting requirement for a diagnosis or a driving-related episode the person's driver's license will be subject to suspension. The current rule requires a cancellation for failure to report. However, the amendment to the rule was made to conform to 1991 legislation which gives the commissioner the authority to suspend in such cases. Minnesota Statutes, section 171.18, subdivision 11, provides: "The commissioner may suspend the license of a driver without preliminary hearing upon a showing by department records or other sufficient evidence that the licensee:...(11) has failed to report a medical condition that, if reported, would have resulted in cancellation of driving privileges." Therefore, with the change in statutory authority, a cancellation will not be required. Also, the suspension of a person's license will give the person the opportunity to apply for a limited license under Minnesota Statutes, section 171.30.

Subpart 3a. Physician's statement required. As previously stated, subpart 3a contains the requirements for submission of a physician's statement. Item A requires a physician's statement upon reporting of a diagnosis of insulin-treated diabetes to the department. This requirement was previously set forth in part 7410.2600, subpart 2. Item A also requires the submission of a physician's statement after a report to the department of a driving-related episode.

Under item B, further physician's statements will be required every six months until the person has been episode free for a year, then annually until the person has been episode free for four years, then every four years, and additionally, as recommended by the physician or by the department. The requirement of additional physician's statements every six months or annually is currently found in part 7410.2610 subpart 3, as it relates to the reporting of episodes. The requirement of such additional physician's statements as it relates to the reporting of a diagnosis was not previously stated in rule. Part 7410.2600, subpart 2, states that "A driver who uses insulin to control diabetes shall submit a

physician's statement, in a form prescribed by the commissioner, every four years upon license renewal unless the physician recommends more frequent reports."

However, if a person was experiencing episodes at the time of the reporting of the diagnosis, the doctor would have to recommend more frequent reports because of the wording on the physicians statement, which required a six month or annual review until the person was episode free for four years. Therefore, in practice, if a person is experiencing episodes, the person will be reporting regularly every six months or on an annual basis. This procedure of having a person submit a physician's statement every six months or annually until the person has been episode free for four years either after a report of an episode or after a report of a diagnosis of insulin-treated will now be set forth in this subpart. Having the policy stated in rule and not just on the physician's statement will provide for a more complete and understandable rule.

A new paragraph has been inserted which informs the person that the six month, one year or four year reporting period will start from the date the most recent physician's statement has been received and approved by the department. A person is also informed that if a person's driver's license is suspended or cancelled under this part, no additional physician's statements will be required until the period of withdrawal is over. Once the period of withdrawal is over, a physician's statement will be required and a new six month or one year period will begin. This is not a new department policy but one that has not been previously set forth in rule.

This subpart also provides that if a person fails to return a physician's statement within 30 days from the date the physician's statement was mailed, the commissioner shall cancel the person's driver's license until such statement is submitted to the department. This cancellation procedure was previously set forth on the department's notice to the person that accompanied the physician's statement but not previously provided for in rule.

Under Minnesota Statutes, section 171.13, subdivision 3, the commissioner may require an examination of any licensed driver to determine incompetency, physical or mental disability or disease, or any other condition which might affect the driver from exercising reasonable and ordinary control over a motor vehicle. Subdivision 4 of section 171.13 provides that if a licensee does not submit to a required examination, the commissioner may cancel the driver's license of that person.

This rule requires a person to submit the physician's statement to the department within 30 days after the department mails the statement out to the person. The thirty-day time period to submit the physician's statement to the department has been shown over time to be a reasonable time period that the public is able to comply with. Therefore, the time period of 30 days will remain the same.

It is necessary and reasonable to set forth in rule these additional policies of the department. The public needs to be put on notice of the regulations that will affect them. Furthermore, having a complete rule will provide better guidance to the public which will lead to more effective administration of the program.

Subpart 4. Failure to Report; misrepresentation. Repealed. As previously stated, this requirement has now been incorporated into subpart 3.

Subpart 5. Cancellation. Repealed. Subpart 5 has been repealed and rewritten as subpart 5a. See subpart 5a for an explanation of amendments regarding the cancellation procedures.

Subpart 5a. Cancellation or Denial. Revision of this subpart, pertaining to the cancellation of a person's driver's license for an episode, has been given considerable attention by the department. The amendments in this subpart are based on research, meetings with the Steering Committee and ADA and comments from the public.

Item A provides that a person's driver's license will be cancelled or denied if the commissioner receives a physician's statement that indicates a person is not medically qualified to exercise reasonable and ordinary control over a motor vehicle. While it has been a policy of the department to rely on the judgment of the physician, this policy was not previously stated in the rule. Specifically stating that the department will cancel based upon the physician's recommendation is necessary to provide adequate notice to the public of the department's policies.

Item B is an amendment to the rules with regard to cancellation for episodes of loss of consciousness or voluntary control due to hypoglycemia or hyperglycemia. The current cancellation provision provides that if a driver or applicant experiences and reports an episode, driving or non-driving, the commissioner shall cancel or deny the person's driving privileges until six months have elapsed since the episode, and until the person submits a physician's statement that indicates the person is cooperating in the treatment of the condition and is medically qualified to exercise reasonable and proper control over a motor vehicle on the public roads. However, a person's driver's license would not be cancelled if one of three listed exceptions applied.

The department is proposing that the rule be amended to provide for a distinction between episodes that occur while the person is driving, operating, or in physical control of a motor vehicle and those episodes that are not related to driving. As previously stated, in deciding to institute a distinction between driving and non-driving episodes the department relied on the opinions and recommendations submitted by the ADA and the Steering Committee.

With regard to the driving/non-driving distinction, the ADA submitted to the department a Position Statement on Driver's License Regulations. The position statement recommended that "non-driving-related hypoglycemic episodes should not be considered as cause for cancellation unless information is provided by the driver's physician indicating a clear case of `uncontrolled' diabetes." In support of its position, the association stated:

> Contrary to common misconception, occasional hypoglycemic episodes do not indicate `uncontrolled' diabetes.
>
> Most people with diabetes can perceive when their blood glucose levels are falling and will take precautions at the first signs of a hypoglycemic episode and therefore, will not represent a threat on Minnesota roadways.
>
> For those individuals who have not taken the necessary precautions to prevent driving related hypoglycemic episodes, we strongly recommend cancellation according to due process....

In addition, the department believes that a comment made with regard to the 1988 rule hearing accurately expresses the opinions of a majority of the medical community and public with respect to the cancellation of a person's driver's license.

> From a patient standpoint and from my viewpoint, I think the real issue is whether or not the patient is cooperating with treatment and, as best possible, attempting to

avoid hypoglycemia while driving. If the patient is measuring their blood glucose in circumstances where hypoglycemia is likely while driving and if they are maintaining an adequate pattern of food intake when driving, then I do not believe it is reasonable to restrict a patient's driving privileges. Restriction of driving privileges, unfortunately, has major implications on patients' employment and their general social well-being in our society and driving privileges should only be withdrawn when there is good evidence that the patient represents a serious threat to their own life and the life of others because of potential incompetence while driving.

Letter of B. R. Zimmerman, M.D., Endocrinology and Internal Medicine, Mayo Clinic, Rochester, Minnesota, June 6, 1988.

The comments expressed by the public demonstrate that there is a need for the department to reexamine the issue surrounding hypoglycemic episodes and the risk such episodes have in the safe operation of a motor vehicle. A reasonable solution that was worked out with the interested parties was to make the distinction between driving and non-driving-related episodes. This solution was reasonable based upon the department's research of various studies that have been conducted with regard to the rate of traffic accidents among diabetics, the advanced medical technologies in the control of diabetes and the role of education for the prevention of hypoglycemic reactions. Some of the research that the department discovered in each of the above areas is presented in the following discussion.

There have been several studies with regard to diabetes and traffic accidents. While the results of those studies have been less than consistent, such results still provide useful data with regard to diabetes and traffic accidents. The studies seem to suggest that diabetes can be one factor among many that may play a role in traffic accidents.

A study that evaluated the number of accidents reported by a case-control population reported that "[o]verall, IDDM [insulin-dependent diabetes mellitus] cases had slightly more accidents per 100 drivers than did the nondiabetic controls..., but the degree of increase was not significant.... Tendencies for accidents were seen among younger, unmarried, and high-mileage drivers but were not significant in either the cases or the controls." T. J. Songer, et al, Motor vehicle Accidents and IDDM, Diabetes Care, Vol 11, No. 9, p. 704, October, 1988. The study conducted by Songer and others came to the conclusion that "there is little evidence regarding the motor vehicle accident risk of the driver with IDDM. Our data suggest that, overall, drivers with IDDM do not have an increased accident risk." Id., p. 706.

In addition to the increased number of studies that have been conducted, medical advances in the control of diabetes have also seen a dramatic increase over the last few years. The medical advances that have been developed have had a direct impact on the control of hypoglycemic reactions. One of the latest and perhaps most important medical advance is in self blood glucose monitoring.

Self blood glucose monitoring is a way for a person to know what is happening on a day-to-day basis and helps the person make the daily adjustments required to achieve good long-term results. If several blood glucose tests are done each day, an accurate and clear picture of diabetes control is available. Self blood glucose tests can be a basis for adjusting insulin doses. With the advancement of blood testing, people are able to "take control" of their diabetes. A person can determine their metabolic status immediately. With blood testing diabetics are a part of the treatment and management team, rather then being passive participants. L. Krall, M.D. & R. Beaser, M.D., Joslin Diabetes Manual 12th ed., pgs. 133-139, (1989).

Furthermore, it is reported that

> [s]elf monitoring is the key to achieving excellent control of blood glucose levels in a safe and effective manner, allowing careful tailoring of dosages of insulin or oral agents to the needs of each person. It is especially useful when insulin therapy is used. A proper self monitoring program combined with a thoughtfully designed treatment plan can eliminate the frequent, severe hypoglycemia of years past while achieving excellent control. The old fears that "tight control means alot of hypoglycemic reactions" are no longer valid if self monitoring is used. The success of a self monitoring program is dependent primarily upon the motivation of the self-tester. Better, safer diabetes control is the reward for these efforts. Any anticipated change in diet, exercise, or stress can be immediately compensated for by an increase in insulin or glucose depending upon the circumstances.

Id., Joslin Diabetes Manual, p. 153.

The role of education in the prevention of hypoglycemic reactions is another important factor in the safe operation of a motor vehicle. Physicians and other health care professionals who are educating patients must be aware of the risks and recommend that the person not drive if their diabetic condition is not under control.

> Every diabetic patient should be made aware of the potential seriousness of an insulin reaction while driving.... The importance of neither missing nor postponing meals while driving and of having a source of carbohydrate always available in the car should be stressed. The young driver with IDDM, who exhibits wide swings in blood sugar and indifferent compliance, needs special counseling regarding the avoidance of hypoglycemia while driving, and if it has occurred, how to avoid a repetition....
>
> The only real solution to prevention of the motor vehicle accident due to hypoglycemia rests in the proper education of the diabetic driver.

E.M. Lasche, M.D., The Diabetic Driver, Diabetes Care, Vol. 8, No. 2, p. 191, March-April, 1985.

The safe operation of a motor vehicle places a significant amount of responsibility on examining physicians, diabetic educators and the diabetic patient. However, all must work together to ensure a successful treatment. "Physicians must assume responsibility for instructing patients who take blood glucose-lowering agents about risks of hypoglycemia and ensure that they have acquired self-management practices needed to minimize this risk." E.N. Ehrlich, Diabetes and the License to Drive, Wisconsin Medical Journal, p. 118, March 1991.

"Accordingly, in exercising their privilege to drive, diabetics must assume personal responsibility for managing their diabetes in such a manner as to avoid hypoglycemia while driving. Control of hyperglycemia may have to be comprised in the interest of public safety." Id., Wisconsin Medical Journal, p. 118, March 1991. Therefore, in addition to the education received, a diabetic must have the ability, willingness, and commitment to self-monitoring and control of his or her disease.

Even though insulin reactions can be prevented, hypoglycemia can still cause an automobile accident. People with diabetes must be careful to risk neither their own lives and property nor those of others. Physicians and educators can instruct a person on proper self-care and how to avoid hypoglycemia, but it is the responsibility of each person with diabetes to follow these instructions. Driving while hypoglycemic is a serious violation and will result in cancellation of the person's driver's license.

In examining the relevant research in this area, it is evident that the medical advances justify cancellation for only driving-related episodes, unless otherwise recommended by the physician. The tools are available to adequately control and monitor a person's diabetic condition. Education and cooperation in the treatment plan are other factors that will enhance a person's successful treatment of diabetes.

The proposed rules allow for more of an individualized assessment of a person's ability to safely operate a motor vehicle. The effect of the proposed rules will be to provide for a more workable and fair system of regulating the licensing of persons with diabetes. However, if a person does not control the diabetic condition, or cannot control their diabetes while operating a motor vehicle, then the cancellation of the person's driver's license is warranted.

Another amendment under this subpart has been the deletion of the exceptions to cancellation. Because the department will not cancel for the majority of non-driving episodes there will be substantially fewer cancellations of diabetic drivers. Therefore, the drivers who are cancelled because of an episode while operating a motor vehicle and those who are cancelled upon a physician's recommendation provide the greatest risk to public safety and will have their driver's licenses cancelled. It is reasonable to delete the exceptions, because these limited number of individuals pose the greatest risk to public safety.

Furthermore, if a person's driver's license is cancelled under this part the person has a right to a review of their case. A person may apply for a variance before the medical review board under Minnesota Rules, part 7410.3000. Under part 7410.3000 "A variance, other than from statutory standards, shall be granted to any person who establishes, under the individual circumstances in that person's case, that the person can operate a motor vehicle safely, with reasonable and ordinary control, and without posing a danger inimical to public safety or welfare."

Under subpart 5a the cancellation period remains the same. If a person has an episode while driving, operating or in physical control of a motor vehicle, the cancellation period will be for six months from the date of the episode with a favorable physician's statement upon reinstatement.

Item C is a rewritten version of the previous exception D relating to cancellation for episodes of loss of consciousness or voluntary control due to alcohol. The item has been updated to reflect the change that the cancellation will result from episodes that occurred while the person was driving, operating, or in physical control of a motor vehicle. Non-driving episodes that involve alcohol will not result in cancellation unless recommended by the physician. The cancellation period will remain the same as in the current rule.

Subpart 5b. Notice. A notice provision has been added to make the rules more complete. The department has had a policy of notifying people of the action that is being taken with regard to their driver's licenses. However, these procedures were not previously set forth in rule. By having a notice provision in the rules, it will better inform the public as to what information they are to receive. The notice provision is the same as notice provisions in other department rules dealing with the suspension or revocation of a driver's license.

Subpart 6. Reinstatement or issuance. The reinstatement section has been amended to list additional requirements which the department follows but were not previously stated in rule. Under Item A the period of suspension must have expired before

reinstatement. Under item B the person must pay the suspension reinstatement fee as required by Minnesota Statutes, section 171.20. Under item C there must be no outstanding withdrawal of a person's driver's license.

Under item D, the requirements that resulted in cancellation or denial must be completed. For example, if a person's license was cancelled for failure to return a physician's statement within the required time period, the statement would have to be submitted to the department before the license would be reinstated. These provisions are consistent with reinstatement requirements in other rules dealing with driver's license issuance. See Minnesota Rules, parts 7409.4100 and 7409.4200.

CONCLUSION

Based on the forgoing, the department's proposed rule amendments are both necessary and reasonable.

8-27-92
Date

Thomas H. Frost, Commissioner
Department of Public Safety