

NORTH DAKOTA LEGISLATIVE COUNCIL

Minutes of the

ADMINISTRATIVE RULES COMMITTEE

Thursday, September 14, 2006
Roughrider Room, State Capitol
Bismarck, North Dakota

Representative William R. Devlin, Chairman, called the meeting to order at 9:00 a.m.

Members present: Representatives William R. Devlin, LeRoy G. Bernstein, Randy Boehning, Pat Galvin, Ronald A. Iverson, Kim Koppelman, Sally M. Sandvig, Margaret Sitte, Blair Thoreson, Dwight Wrangham; Senators John M. Andrist, Richard L. Brown, Tom Fischer, Jerry Klein, Gary A. Lee, Constance Triplett

Members absent: Representatives Duane DeKrey, Mary Ekstrom, Rod Froelich, Jon O. Nelson; Senators Dennis Bercier, April Fairfield, Layton W. Freborg

Others present: See Appendix A

Representative Lois Delmore, member of the Legislative Council, was also in attendance

It was moved by Senator Brown, seconded by Senator Klein, and carried on a voice vote that the minutes of the June 13, 2006, committee meeting be approved as distributed.

DEPARTMENT OF PUBLIC INSTRUCTION

Chairman Devlin called on Dr. Gary Gronberg, Assistant Superintendent of Public Instruction, for testimony relating to English language learner rules carried over from the previous committee meeting. A copy of Dr. Gronberg's prepared testimony is attached as Appendix B.

Dr. Gronberg said two sentences were carried over from North Dakota Administrative Code Section 67-28-01-08 from the previous committee meeting. He said it appears there was some confusion among committee members about whether these sentences would allow schools adequate flexibility to assess students for English language proficiency in the spring of 2007. He said the department has consulted with the State English Language Learner Advisory Committee to address concerns over transition to a new test instrument for student assessment for English language proficiency.

Dr. Gronberg said a new proficiency test will be used beginning in the spring of 2007 and schools are receiving training from the department on how to administer the test. He said the department and the State English Language Learner Advisory Committee have jointly developed a timeline to phase in use of the new test. He said the language in the rule in question provides schools flexibility to prepare December 1 applications in using either fall of the

current school year results or results from spring of the preceding school year.

In response to a question from Representative Koppelman, Dr. Gronberg said the existing rules provisions do allow the flexibility requested by a representative of the State English Language Learner Advisory Committee at the previous meeting. Representative Koppelman asked whether the existence of that flexibility has been communicated to concerned parties. Dr. Gronberg said concerned parties are aware of the flexibility in the rules and that was one of the reasons for collaboration by the department with the State English Language Learner Advisory Committee.

In response to a question from Representative Delmore, Dr. Gronberg said December 1 is the date for reporting by schools of English language learner program enrollment and applications for state aid.

STATE DEPARTMENT OF HEALTH

Chairman Devlin called on Mr. David Glatt, State Department of Health, for testimony relating to revisions to standards of quality for waters of the state. A copy of the State Department of Health prepared testimony is attached as Appendix C. Mr. Glatt said North Dakota has had water quality rules since 1975. He said the Environmental Protection Agency requires review and revision of water quality rules every three years. He said the department received comments from the North Dakota Game and Fish Department, the North Dakota State Water Commission, and the United States Fish and Wildlife Service. He said Mr. Mike Sauer of the State Department of Health would review the changes to the water quality standards.

Mr. Sauer said water quality standards consist of three parts. He said the three components consist of designated use of the waters, numeric criteria necessary to support the use, and antidegradation criteria.

Senator Triplett said the rules add limits for E. coli to the existing limits for fecal coliform and she asked why the change was made. Mr. Sauer said E. coli tracking is an Environmental Protection Agency requirement and it is a scientifically sound requirement because E. coli affects humans.

Representative Boehning said the arsenic content level for water in the rules is reduced. He said he has heard that the Environmental Protection Agency may

raise that level again and asked if Mr. Sauer has heard discussion of that issue. Mr. Sauer said the arsenic content levels may be adjusted again based on further scientific studies but the level in the rules is the current level required by the Environmental Protection Agency.

Representative Delmore said the rules require Lake Sakakawea to maintain a specified minimum volume of water and a maximum temperature of 59 degrees. She asked whether the current drought conditions affect the temperature of the lake. Mr. Sauer said the drought does affect the water level and temperature of Lake Sakakawea but a bigger impact is caused by the Corps of Engineers management of the lake level. He said if the lake level is reduced too much, this temperature and volume standard cannot be maintained.

RULEMAKING STATISTICS

Chairman Devlin called on committee counsel for review of a memorandum entitled [Administrative Rulemaking Statistics 2004-06](#). Committee counsel said the committee reviewed 1,353 rules sections and 1,920 pages of rules that were changed from December 2004 to October 2006. He said these amounts are a substantial reduction from the volume of rules reviewed during the previous two-year rules review cycle. He said the volume of rules continues a general decline in rules reviewed that has occurred since about 1998.

NEXT MEETING DATE

Chairman Devlin said the next committee meeting is tentatively scheduled for December 14 but he will investigate with staff the possibility of holding the December meeting on the final day of the organizational session. He said there are a number of factors to consider in scheduling the meeting for that day, including coordination with other events and the number of rules requiring committee consideration.

SECRETARY OF STATE

Chairman Devlin called on Ms. Mary Feist, Director, Licensing Administration Division, Secretary of State's office, for testimony relating to mixed fighting style competition rules adopted by the Secretary of State. A copy of prepared testimony of Secretary of State Alvin A. Jaeger is attached as Appendix D. Ms. Feist reviewed the prepared testimony.

Ms. Feist said the prepared testimony indicates that no written or oral public comments were offered on the proposed rules. She said it is important to point out that the hearings involved participation of interested parties and groups and they had significant input to the content of the rules.

Representative Thoreson said North Dakota Administrative Code Section 72-02.2-02-11(1) provides that a ticket to a mixed fighting style competition may not be sold for more than the price

printed on the ticket. He said he recalls that the Legislative Assembly considered and killed legislation that would have imposed the same limitation on all ticket sales so he does not think North Dakota has a limit on ticket sales prices like this in state law. He asked if this is a new precedent. Ms. Feist said she is not certain whether state law contains a provision like this. She said during meetings with representatives of the Bismarck Civic Center, concerns were raised regarding this provision with regard to service fees charged by Ticketmaster and similar organizations. She said this language limiting ticket purchase prices was drawn from the existing rules of the Secretary of State governing boxing.

Representative Delmore asked Ms. Feist to describe the problems that did not allow the Secretary of State to meet the nine-month deadline for adoption of these rules. Ms. Feist said the Secretary of State requested and obtained an extension of time to adopt rules from the Administrative Rules Committee. She said the Secretary of State's office was new to the regulation of mixed fighting style competition so it took time to develop the rules and gain an understanding of other states' regulations on mixed fighting style competitions.

ATTORNEY GENERAL GAMING DIVISION

Chairman Devlin called on Mr. Keith Lauer, Director, Gaming Division, Attorney General's office, for presentation of testimony relating to games of chance rules adopted by the Gaming Commission. A copy of prepared testimony from Mr. James P. Wang, Chairperson, State Gaming Commission, is attached as Appendix E. Mr. Lauer reviewed the prepared testimony.

Senator Klein asked Mr. Lauer to review the discussion of the internal controls issue during the rulemaking process. Mr. Lauer said a statutory change in 2005 required that requirements for internal controls be prescribed by administrative rules. He said administrative rules governing internal controls have existed for several years but the rules provisions were adjusted. He said the procedure that has been followed and will continue to apply is that if the Attorney General determines that a system of internal controls is inadequate, a notice will be sent to the organization pointing out the inadequacy. He said the rule previously required that the organization must remedy the inadequacy and the rule has been changed to require that the organization shall address the inadequacy.

Senator Triplett said it appears the authority governing internal controls has been reduced and she asked what it means to require an agency to address an inadequacy in internal controls systems. Mr. Lauer said the requirement to address an inadequacy does not force the organization to change its policy but if the organization does not provide a satisfactory response regarding the inadequacy, the Gaming Commission may consider further action, possibly including changes to the administrative rules.

Representative Wrangham said it appears the overall effect of the rules changes was to make the charitable gaming rules more user-friendly, especially for smaller organizations. Mr. Lauer said that is correct.

WORKFORCE SAFETY AND INSURANCE

Chairman Devlin said the committee held over consideration of a rule adopted by Workforce Safety and Insurance that would allow coverage for a branded equivalent of a generically available medication only after prior approval by the organization when documentation exists that the injured worker had an adverse response to the generic medication. He said some members of the committee believe that this requirement interferes with a treating physician's discretion and a similar consideration under Department of Human Services programs resulted in a legislative compromise that appeared to satisfy concerned groups and legislators. He said Workforce Safety and Insurance and the North Dakota Medical Association were requested to review the rule in question and report to the committee at this meeting.

Chairman Devlin called on Dr. Harvey Hanel, Director of Pharmacy, Workforce Safety and Insurance, for testimony relating to the rule governing medication coverage. A copy of Dr. Hanel's prepared testimony is attached as Appendix F.

Dr. Hanel said the rule as adopted by Workforce Safety and Insurance is intended to provide customers personal and cost-effective services while not reducing levels of care. He said the rule has the potential to save more than \$700,000 each year in medication costs for Workforce Safety and Insurance.

Dr. Hanel said the rule as adopted is not intended to provide a lower level of care for customers or remove the appropriate authority from treating physicians. He said the rule, as written, proposes prior authorization requirements for brand name drugs if a generic equivalent is available. If an adverse response or inferior response to the generic drug is experienced and documented, Workforce Safety and Insurance would allow access to the brand name drug.

Dr. Hanel listed additional considerations to support the rule as adopted. He said generic medications are manufactured and tested to meet Food and Drug Administration strict bioequivalency requirements. He said prescriptions are written for medications, such as oxycontin, in which the generic is manufactured by the same company using the same formulation. He said the Bureau of Criminal Investigation has informed Workforce Safety and Insurance that brand name prescription drugs are the most valuable in illegal trade on the street. He said "dispense as written" medications composed a higher percentage of prescriptions covered by Workforce Safety and Insurance than for another major payer. He said the rule, as adopted, was presented to the Workforce Safety and Insurance Medical Guidance

Council, comprised of physicians who regularly treat injured workers, for independent review and input. He said the consensus of the council was that the rule would not unnecessarily interfere with the way in which physicians treat injured workers.

Senator Andrist asked Dr. Hanel for a description of how generic and brand name medications differ. Dr. Hanel said when a patent for a brand name medication is about to expire, companies do testing in hopes of bringing a generic alternative to market. He said there are many requirements imposed on generic medication alternatives in addition to the requirement of the same chemical compounds. He said generic medications must dissolve at the same rate as brand name medications and must be substantially equivalent in most respects. He said the most significant differences between brand name and generic drugs may exist in the binders and fillers used.

Representative Koppelman said Dr. Hanel's testimony indicated two primary points, which include basic equivalence of brand name and generic drugs and the opportunity for substantial cost-savings for Workforce Safety and Insurance. He said Dr. Hanel also mentioned that brand name drugs are valuable on the street. He asked how Workforce Safety and Insurance gained an understanding that illegal street traffic in these drugs occurs. Dr. Hanel said discussions with Bureau of Criminal Investigation agents have convinced Workforce Safety and Insurance that brand name drugs are being sold on the street illegally and that some of these illegal drug sales can be traced back to medications provided to injured workers. He said the potential street value of brand name pain medications may give patients an incentive to convince a physician that they need a brand name medication. He said Workforce Safety and Insurance is requesting a limit on physicians' discretion to give in to these requests by requiring documentation of the reason for prescribing a brand name medication over a generic alternative.

Senator Triplett said there may be a placebo effect and she asked whether there is any evidence that patients respond better to a brand name medication just because they believe it is a better medication. Dr. Hanel said Workforce Safety and Insurance has considered the placebo effect and if it is documented that a patient has a better response to a brand name medication, that would be adequate to authorize purchase of the brand name medication for that patient.

Representative Delmore requested a description of evidence that street drugs are sold by Workforce Safety and Insurance patients. Dr. Hanel said the Bureau of Criminal Investigation has informed Workforce Safety and Insurance staff that when they trace back to the source of illegal drugs found in street traffic, it is often found that the drugs originated with prescriptions written for Workforce Safety and Insurance patients.

Senator Lee asked whether there are studies showing more untoward effects for generic medications as compared to brand name medications. Dr. Hanel said the Food and Drug Administration has a rigid reporting mechanism for incidents of adverse reactions with brand name or generic drugs. He said if significant problems surface, generic medications are pulled from the market due to adverse reactions among users.

Representative Delmore asked whether there have been generic medications that caused adverse reactions and whether the state would be subject to liability if the state forces recipients to use generic medications and they suffer adverse reactions. Dr. Hanel said he is not familiar enough to describe specific instances in which generic medications have been pulled from the market because of adverse consequences.

Representative Galvin asked whether active ingredients in generic medications must always be the same as the active ingredients in brand name medications. Dr. Hanel said the active ingredients must be identical.

Chairman Devlin said 2005 legislation was extensively debated and finally approved by the Legislative Assembly to govern a prior authorization program for medication under the medical assistance program administered by the Department of Human Services. He said the program as finally approved involved a compromise of interests and assures input from physicians, pharmacists, and consumers. He said he believes there is a significant degree of interference with a physician's discretion in treating a patient in the rule as adopted by Workforce Safety and Insurance. He said it was his hope that Workforce Safety and Insurance would discuss the rule, as adopted, with representatives of the North Dakota Medical Association to reach a consensus recommendation. He said it appears the views of the North Dakota Medical Association have not been considered by Workforce Safety and Insurance. He asked what involvement of the medical profession has occurred in consideration of the rule as adopted. Dr. Hanel said Workforce Safety and Insurance presented the rule, as adopted, for consideration by the Workforce Safety and Insurance medical guidance council, composed of physicians treating injured workers. He said Workforce Safety and Insurance thought it had reached a consensus with the North Dakota Medical Association but it appears that consensus does not exist.

Chairman Devlin called on Mr. David Peske, Director of Governmental Relations, North Dakota Medical Association, for testimony relating to the Workforce Safety and Insurance rule limiting prescriptive authority of physicians. A copy of Mr. Peske's prepared testimony is attached as Appendix G.

Mr. Peske said North Dakota law includes a statutory provision allowing physician prescribers to require that a brand name medication may be

dispensed by handwriting the words "brand necessary" on the prescription form in compliance with North Dakota Century Code Section 19-02.1-14.1. He said Workforce Safety and Insurance has had an administrative rule in place allowing "dispense as written" prescriptions. He said the rule, as adopted, would eliminate the "dispense as written" provision and require generic brand dispensing unless documentation exists that the injured worker developed an adverse response to the generic medication.

Mr. Peske said that after the Administrative Rules Committee carried over consideration of the Workforce Safety and Insurance rule, the North Dakota Medical Association Board of Directors met on August 29, 2006, and after discussion of the issue affirmed its opposition to the elimination of the "dispense as written" option for physicians and their patients. He said Workforce Safety and Insurance argues that "dispense as written" prescriptions cost more but there has not been any offer of information showing that physicians and other prescribers inappropriately prescribed "dispense as written" prescriptions or that "dispense as written" prescriptions are not medically necessary.

Mr. Peske said the Medical Association also believes the process for formulary changes and updates, the structure and responsibilities of the Pharmacy and Therapeutics Committee, and the procedures for medication class review and utilization management should be set forth in administrative rules rather than subject to unilateral change at any time by Workforce Safety and Insurance.

Senator Klein asked whether the North Dakota Medical Association concern is that physicians could not provide adequate treatment under the rule as adopted. Mr. Peske said a state statutory provision was adopted to allow a prescriber to require brand-necessary prescriptions. He said the statute was adopted to recognize the discretion of a physician in prescriptive authority. He said the rule as adopted contravenes that statutory authority.

Representative Sitte asked whether doctors have adequate training and information on the problem of reselling drugs on the street. Mr. Peske said this has been an ongoing problem for many years. He said the North Dakota Medical Association has conducted seminars on this topic and he believes doctors are well aware of the problem. Mr. Peske said there is also a prescription drug monitoring program created by 2005 legislation that should help identify abuses.

Representative Delmore asked if the Medical Association has concerns about adverse reactions to generic drugs. Mr. Peske said that is an underlying medical concern of physicians in treating patients. In answer to a question whether the cost of treating an adverse reaction could negate cost-savings from generic drugs, Mr. Peske said that is a significant possibility.

Senator Brown said private insurance can impose an automatic requirement for prescription of generic

drugs unless a brand drug requirement is handwritten by a prescriber. He asked how that differs from the rule adopted by Workforce Safety and Insurance. Mr. Peske said it appears much of prescriptive practice is moving to a formulary process. He said the North Dakota Medical Association does not believe Workforce Safety and Insurance has adequately set up a mechanism to establish a formulary process. Senator Brown said he does not think the Public Employees Retirement System formulary process is set by law.

In response to a question from Senator Lee, Mr. Peske said the existing rule for the state health insurance plan allows a worker to pay for the difference in cost if the worker wants a brand name drug.

Senator Andrist said the rule adopted by Workforce Safety and Insurance seems a reasonable way to save money. Mr. Peske said the concern of the North Dakota Medical Association is that nothing is spelled out on the structure of the procedure to set standards for prescription drugs and the rule as adopted contravenes the statutory provision allowing "dispense as written" prescriptions.

Chairman Devlin said he wants to be sure committee members understand that the rule, as adopted, takes away the statutory authority for "dispense as written" prescriptive authority for physicians. He said the rule would require documentation of an adverse reaction to a generic medication before a brand name medication is allowed to be prescribed.

Representative Koppelman asked Mr. Peske how a physician makes the decision that a brand name drug is needed. He asked whether it is based on adverse reaction to generic drugs. Mr. Peske said that decision could be based on an adverse reaction but might also be initiated by a patient request because of the significant influence of advertising by drug companies. He said a physician may be prescribing a new brand name drug that is intended to reduce side effects experienced with other drugs.

Senator Andrist asked whether generic drugs have more adverse reactions than brand name drugs. Mr. Peske said he is not able to answer that question based on statistics he has seen.

Chairman Devlin said Workforce Safety and Insurance has not offered any suggestions for changes to the rule so the choices of the committee are to leave the rule in place, as adopted, or consider a motion to void the rule as adopted.

It was moved by Senator Triplett and seconded by Representative Sandvig that the Administrative Rules Committee void the rule adopted by Workforce Safety and Insurance relating to amendment of North Dakota Administrative Code Section 92-01-02-30(7) to require documentation of an adverse response to generic medication before brand name medication may be prescribed on the grounds that adoption of the rule was done with

an absence of statutory authority and is arbitrary and capricious.

In discussion of the motion, Senator Triplett said she believes Workforce Safety and Insurance is on the right track in trying to save money on prescription drugs but she believes the procedure is flawed and could be improved to involve more consideration by concerned parties.

Senator Klein said he does not believe the adverse response required by the rule as adopted is much different from requirements that apply to patients with private insurers.

Senator Triplett said she believes there is a difference between the rule, as adopted, and treatment under private insurance. She said for a private insurer, if a physician initials a prescription and writes "dispense as written," that is enough for a brand name drug prescription. She said under private insurance it is not necessary to document an adverse reaction to a generic drug.

Senator Andrist said he would oppose the motion. He said we hold physicians in high esteem and value their opinions on treatment but the rule does not unduly interfere with treatment decisions. He said there could be an additional benefit for physicians under the rule because, if a patient pushes for a brand name prescription and the physician does not see the need for it, the rule would allow the physician to tell the patient that the generic medication must be prescribed unless an adverse reaction has been demonstrated.

The question was called and the MOTION FAILED. Voting in favor of the motion were Representatives Devlin, Boehning, Koppelman, Sandvig, and Wrangham and Senators Fischer and Triplett. Voting in opposition to the motion were Representatives Bernstein, Galvin, Iverson, Sitte, and Thoreson and Senators Andrist, Brown, Klein, and Lee.

SECRETARY OF STATE

Representative Thoreson said the rules adopted by the Secretary of State for mixed fighting style competition provide a good framework for the sport. He said he still has one area of concern with the provision limiting ticket sales prices to not more than the face price of a ticket. **It was moved by Representative Thoreson, seconded by Representative Koppelman, and carried on a voice vote that the Administrative Rules Committee carry over consideration of North Dakota Administrative Code Section 72-02.2-02-11(1) relating to admission ticket prices for mixed fighting style competition.**

COMMITTEE REPORT

It was moved by Representative Koppelman, seconded by Senator Klein, and carried that the chairman and the staff of the Legislative Council be requested to prepare a report and present the report to the Legislative Council.

The meeting was adjourned at 11:30 a.m.

John Walstad
Code Revisor

[ATTACH:7](#)