NORTH DAKOTA LEGISLATIVE MANAGEMENT

Minutes of the

# HEALTH CARE COMMITTEE

Wednesday, September 11, 2019
Roughrider Room, State Capitol
Bismarck, North Dakota

Representative George Keiser, Chairman, called the meeting to order at 9:00 a.m.

**Members present:** Representatives George Keiser, Dick Anderson, Gretchen Dobervich, Clayton Fegley, Jim Kasper, Mike Lefor, Lisa Meier, Marvin E. Nelson, Bob Paulson, Robin Weisz; Senators Dick Dever, Kathy Hogan, Judy Lee, Tim Mathern, Dave Oehlke, Kristin Roers, Shawn Vedaa

**Members absent:** None

**Others present:** See Appendix A

**It was moved by Senator Dever, seconded by Representative Meier, and carried on a voice vote that the minutes of the June 30, 2019, meeting be approved as distributed.**

## HEALTH FACILITY CONSTRUCTION AND RENOVATION STUDY

Chairman Keiser called on Mr. Monte Engel, Director, Life Safety and Construction, State Department of Health, for a presentation (Appendix B) regarding the health facility construction and renovation study, including an overview of the department's plan review process and a report on the status of implementation of Senate Bill No. 2317 (2019).

In response to a question from Representative Kasper, Mr. Engel said he will provide the committee with detailed information regarding the 40 construction projects the department has reviewed in calendar year 2019.

In response to a question from Senator Lee, Mr. Engel said as a result of Senate Bill No. 2317, small projects have been prioritized for review. Due to the limited staff, he said, this prioritization means the smaller projects are being reviewed before the larger projects.

In response to a question from Representative Weisz, Mr. Engel said the department adopted agency policies because the department viewed Senate Bill No. 2317 as providing clear direction. He said it is unusual to use administrative rules to regulate an agency.

In response to a question from Representative Keiser, Mr. Engel said department implementation of the new waiver through agency policies is quicker than through administrative rules. He said the waiver is intended to streamline the process and make it easier to receive plan approval.

In response to a question from Senator Roers, Mr. Engel said although the department is preparing a request for proposal for contracting with a vendor to provide assistance with plan reviews, the department has not been in contact with possible vendors.

In response to a question from Senator Mathern, Mr. Engel said if the department's open temporary position was changed to a permanent full-time position, it likely would be easier for the department to fill the position. Additionally, he said the plan review standards are national standards and are made public so all parties are aware of the standards.

Senator Mathern said he has the expectation that designers and builders be aware of and follow the national standards.

In response to a question from Representative Weisz, Mr. Engel said in performing plan reviews, there may be differences of opinion on the implementation of the standards. He said the department staff is competent and experienced as is a majority of designers.

In response to a question from Senator Dever, Mr. Engel said the Centers for Medicare and Medicaid Services standards are not at issue.

Chairman Keiser said members of the Legislative Assembly are not happy with the department's strategy of addressing the waivers through agency policy, especially as it appears the policy sets up more hurdles not fewer. He said during the next legislative session it is possible legislation will be drafted to expressly prohibit agencies from implementing legislation though agency policies.

Senator Oehlke said some of the problems identified during the plan review process may be the result of differences between the design and actual construction. He said he supports the concept of plan review and site review to identify possible problems early in the process.

In response to a question from Representative Kasper, Mr. Engel said the agency staff includes two employees who are licensed architects and two who are educated as architects but not licensed.

In response to a question from Chairman Keiser, Mr. Engel said although state law provides facility construction may not begin without plan approval by the department, the department has implemented the practice of breaking plans for large projects into smaller packets to allow for packet approval and construction to begin.

Mr. Engel said the department performs an initial plan review, monitors construction, and signs off before final occupancy. He said a different division of the department addresses program review.

Chairman Keiser requested the State Department of Health to report to the committee in 6 months with data comparing the length of time for plan approval before and after the change in the law.

In response to a question from Senator Lee, Mr. Engel said the request for proposal is being written and if it is posted, it will be posted within the month.

Chairman Keiser called on Ms. Shelly Peterson, President, North Dakota Long Term Care Association, for comments (Appendix C) regarding the implementation of Senate Bill No. 2317.

In response to a question from Senator Mathern, Ms. Peterson said facilities typically use competent architects, contractors, and engineers. She said often the issues that arise are due to a difference of opinion regarding interpretation of the standards.

In response to a question from Senator Lee, Ms. Peterson said the standards for basic care facilities vary slightly from the federal standards; however, the waiver process should help with any issues that may arise due to these differences.

In response to a question from Representative Dobervich, Ms. Peterson said the old waiver includes an appeal process.

Representative Dobervich said she is concerned the new waiver does not allow for an appeal process.

In response to a question from Chairman Keiser, Ms. Peterson said the new waiver process is more difficult than the old waiver process.

Senator Hogan said it may be a good time to review the basic care rules. She said basic care is unique to North Dakota and ripe for review, and as a result of current *Olmstead* litigation relating to long-term care, it may be timely to review how basic care fits into the continuum of care in the state.

Ms. Peterson said there may be benefits to revisiting the basic care program to determine whether it is meeting the intended goals.

Senator Hogan said at a future meeting she would like to receive information regarding the history of basic care in North Dakota.

Senator Lee said she questions why the standards for a basic care facility's physical structure should differ from those for other health facilities. She said the new waiver process was intended to make it easier for facilities to be granted a waiver.

Senator Mathern said at a future meeting he would like to receive a status report on the hiring or contracting for additional agency staff for these plan reviews.

Chairman Keiser said he encourages the State Department of Health to reconsider the actions by which it adopted agency policies instead of administrative rules for the new waiver process.

Chairman Keiser called for a moment of silence in recognition of the anniversary of the September 11, 2001, attacks.

## HEALTH CARE DELIVERY STUDY AND INSURANCE PREMIUM TREND STUDY

The committee watched the Wall Street Journal video "How Drug Prices Work" (https://www.wsj.com/video/how-drug-prices-work/C9D3F950-DFE3-4E37-9120-836D411A9A66.html)

The committee reviewed a bill draft [21.0006.02000] to provide for prescription drug cost transparency.

Senator Roers said stakeholders should consider whether the bill draft provisions for quarterly versus annual reports are appropriate as well as whether the reporting deadlines provide adequate time to collect data.

In response to a question from Senator Roers, the Legislative Council staff said, regarding the criminal penalty for business entities, a prosecutor can charge a business entity with a crime.

Senator Roers said it may be valuable to add a criminal or civil fine provision.

In response to a question from Senator Mathern, Chairman Keiser said this bill draft may help consumers by taking a first step in pricing transparency in the marketplace. He said ultimately he seeks information on why drug prices are increasing and seeks lower drug prices for consumers.

Senator Mathern said he is concerned transparency is not adequate to help the consumer with the rising cost of prescription drugs.

Representative Kasper said he is concerned pharmacy benefits managers (PBMs) and rebates are not making drugs less expensive. He said the Legislative Council staff should work with stakeholders to make certain the definition of "rebate" does not allow wiggle room to avoid being considered a rebate.

Representative Nelson said in revising the bill draft, the Legislative Council staff should clarify the reporting is limited to prescription drugs and does not include over the counter drugs.

Senator Lee said an all-claims database also may assist with health care transparency.

Senator Dever said since North Dakota is a small state, he questions whether a transparency requirement, such as the requirement in the bill draft, may have the effect of losing some players. He said it would be helpful to compare this bill draft to what other states have done, to provide for a civil penalty, and to consider whether the State Board of Pharmacy is the correct state agency to run this program.

Representative Kasper said transparent PBMs are becoming more common, and he is fine if North Dakota loses some nontransparent PBMs.

Senator Roers said similar legislation has passed in Texas, but has not yet been implemented. She said perhaps the bill draft could be amended to give the Insurance Department more duties.

Chairman Keiser called on stakeholders to comment regarding the drug cost transparency bill draft. As the committee moves forward in considering this bill draft, he said, the committee will receive information on the fiscal impact of the bill draft.

Mr. Jon Godfread, Insurance Commissioner, testified (Appendix D) regarding the bill draft. He said he supports the concept of drug pricing transparency and the Insurance Department can help administer some of the data collection. He said there has been a nationwide push to have insurance departments regulate PBMs; however, the Insurance Department does not have pharmacists on staff and therefore lacks the necessary expertise to regulate PBMs.

In response to a question from Senator Dever, Mr. Godfread said if North Dakota relied on drug cost transparency data from another state, such as from Texas, the committee would be looking at Texas claims and not North Dakota claims, which would be less helpful to North Dakota. He said if other states are requiring drug cost transparency, North Dakota does not need to recreate the wheel but can base its reporting requirements on what other states are doing.

Mr. Mark J. Hardy, Executive Director, State Board of Pharmacy, said the board would be happy to work with the Insurance Department in implementing the drug price transparency bill draft. He said although the board regulates the drug supply chain, it does not regulate PBMs or health insurers.

Ms. Sara Orrange, Regional Director, State Affairs, America's Health Insurance Plans, provided testimony (Appendix E) on the drug cost transparency bill draft and how other states are attempting to address drug cost transparency. She said regarding the language of the bill draft, clarification of the term "manufacturer-packaged drug container" would be helpful, it would be preferred to have health insurers submit reports to the Insurance Department instead of the State Board of Pharmacy, and consideration should be given to including confidentiality language similar to the language used by Texas.

In response to a question from Representative Kasper, Ms. Orrange said although she does not have express examples of what types of information should be kept confidential, language similar to the Federal Trade Commission's language may be considered.

Representative Kasper said it seems the information she seeks to keep confidential is exactly the information the consumer needs to receive.

Representative Lefor requested additional information regarding the confidentiality language used in Texas and why this language was perceived as being necessary.

Ms. Megan Smith Houn, Director of Government Relations, Blue Cross Blue Shield of North Dakota, said Blue Cross plans in Texas and California will be complying with drug cost transparency legislation; however, these states are on the front end of implementation. She said the Texas law differs in that it includes confidentiality provisions. She said Blue Cross Blue Shield is comfortable with reporting to the Insurance Department and relies on the department's cybersecurity protections. She said for insurance carrier reporting, the February date may be early and a delay of a couple months would be beneficial.

Mr. Zach Poss, Senior Manager, State Advocacy, Pharmaceutical Research and Manufacturers of America said drug cost transparency bill drafts like this do not decrease what consumers are paying for drugs. He said there is concern rebates are not making their way to the consumers.

In response to a question from Senator Mathern, Mr. Poss said New Hampshire introduced legislation to require PBMs pass through a portion of rebates to consumers.

Representative Kasper said of the $344 billion total cost of drugs in 2018, the total cost of drugs in 2018, approximately one-half the cost of drugs, $166 billion, was rebated. He said if rebates were not paid, the price paid by the consumer would decrease.

In response to a question from Representative Dobervich, Mr. Poss said the health plans determine what drugs will be placed on plans formularies.

In response to a question from Senator Oehlke, Mr. Poss said brand manufacturers spend more on research and development than on advertising.

In response to a question from Representative Nelson, Mr. Poss said he can provide the committee with information regarding the availability of coupons and copay assistance programs. He said some states have laws providing the amount of the prescription drug copay may not exceed the cost of the drug.

Mr. Josh Askvig, North Dakota State Director, AARP, presented testimony (Appendix F) regarding the prescription drug cost transparency bill draft. He said he encourages the committee to work on a definition for the term "manufacturer-packaged drug container" and to consider which state agency should be responsible for implementation.

Dr. Bradley King, Bismarck, said as a dentist and employer, he has experience with insurance plans. He said an employer does not have a choice over which PBM a health carrier uses and he supports legislation that mandates employers have a choice in selecting a PBM.

Mr. Matthew Schafer, Director, Government Relations, Medica, said cost transparency is helpful as it allows for more information on which to establish public policy. He said Minnesota has health care cost transparency, which enables heath carriers to make policy interventions.

Mr. Danny Weiss, Senior Director of Pharmacy Benefits, Sanford Health Plan, said he supports transparency, but as the bill draft is written, it is missing inclusion of drug wholesalers. He said drug wholesalers are part of the drug distribution chain and are reimbursed on a percentage of the margin, thus resulting in increasing profits as drugs cost more money.

In response to a question from Representative Kasper, Mr. Weiss said rebates are paid from the drug manufacturer through a PBM to the employer or the insurer. He said rebates also are paid from drug wholesalers to pharmacies.

Mr. Weiss said there was a recent situation in which the Medicaid Expansion program was overcharged for a prescription drug. He said the overcharge was the result of a setup error by the PBM and the brand name price was charged instead of the generic. He said errors like this are caught during the regular audit process and the overcharges are corrected at that time.

The committee watched the United States Food and Drug Administration (FDA) video "The Basics of Biosimilars" (https://www.youtube.com/watch?v=1s7W1EKUekk)

Chairman Keiser called on Mr. Hardy to make a presentation (Appendix G) regarding biosimilars.

In response to a question from Senator Oehlke, Mr. Hardy said a biologic patent offers enhanced protection and and a patent for an orphan drug offers extra enhanced protection of the patent.

In response to a question from Representative Kasper, Mr. Hardy said biologics are to biosimilars as brand names are to generics.

In response to a question from Senator Roers, Mr. Hardy said although the FDA has not designated any biosimilars as interchangable, he expects eventually some of these biosimilars currently on the market will be recognized as interchangable.

Senator Dever said he supports open communication between doctors and patients and doctors should be told if an interchangable is dispensed.

The committee watched the FDA video "The Concept of Interchangeability" (https://www.youtube.com/watch?v=ooP7djSgtBE)

The committee reviewed a bill draft [21.0011.01000] regarding dispensing of biologics.

In response to a question from Representative Kasper, the Legislative Council staff said under the existing law and the bill draft, the prescriber of a biologic retains the ability to specify "brand medically necessary" in much the same way a prescriber of a drug retains the ability to prohibit dispensing of a generic instead of a brand name drug.

Ms. Angela Gochenaur, Director, State Government Affairs - Eastern Region, Biotechnology Innovation Organization, said she supports open communication between the parties. She said if an interchangable is dispensed instead of the prescribed biologic, there is the risk of an adverse reaction. She said she supports open communication between the parties if this occurs.

Ms. Gochenaur said the Biotechnology Innovation Organization has worked for less onerous notice requirements if a pharmacist dispenses an interchangable drug. She said the law provides for notice within 24 hours, a time period that may be too short. She said a 72-hour window to give notice may be more appropriate.

In response to a question from Chairman Keiser, Ms. Gochenaur said of the states that address biologics, two states do not allow for substitution; however, 72 hours is a common notice range for those states that allow for substitution.

In response to a question from Senator Mathern, Mr. Brendan Joyce, Medical Assistance, Department of Human Services, said the biologics law in North Dakota was enacted before a biologic was FDA approved and that has worked fine. He said he does not anticipate any problems with implementing law regarding interchanables before the FDA has approved any interchangables. He said as interchangables become FDA approved and confidence and experience grow within the prescriber community, he expects the prescribers may not want the extra notice requirement. He said any time there are extra steps in a process, it makes it less likely the process will be implemented.

Chairman Keiser said the bill draft keeps the prescriber in the driver's seat by allowing the prescriber to specify brand specific. He said interchangables may save money.

Senator Roers said she likes the suggested notice change made by BIO. She said the comfort level with interchangables may be similar to the experience prescribers faced when generics became available. She said it may be a matter of time before prescribers are comfortable with the concept of interchangables.

Chairman Keiser requested the Legislative Council staff to revise the biologics bill draft to provide a 72-hour window for notice.

Senator Hogan requested the North Dakota Medical Association to provide testimony regarding the revised bill draft at a future meeting.

Chairman Keiser called on Mr. Christopher D. Jones, Executive Director, Department of Human Services, for an introduction (Appendix H) to the state's role in addressing social determinants of health.

Chairman Keiser called on Ms. Janell Regimbal, Vice President of Children's Services, Lutheran Social Services of North Dakota, for a presentation (Appendix I) regarding community-based services.

In response to a question from Senator Mathern, Ms. Regimbal said although the services offered in North Dakota are on a small scale, data collected at the national level support the effectiveness of the services.

Senator Hogan requested data regarding the effectiveness of the program at a national level.

Ms. Regimbal said Lutheran Social Services of North Dakota networks with a statewide coalition of support providers.

Mr. Jones said longitudinal studies on such programs date back to the 1960s. He said the data exists. He said it is best to focus on how to use the data to face issues such as intergenerational poverty.

In response to a question from Representative Dobervich, Mr. Jones said the department is mapping where services are being provided and where there are service gaps.

Chairman Keiser called on Mr. Godfread for a presentation (Appendix J) on the status of the Section 1332 Waiver application and the insurance premium trend study activities.

## HEALTH INSURANCE GUARANTEED ISSUE STUDY

The committee reviewed a bill draft [21.0013.01000] to provide for guaranteed issue for health insurance.

Ms. Orrange provided testimony (Appendix K) regarding the guaranteed issue bill draft.

Senator Oehlke said under the bill draft, if the federal Affordable Care Act (ACA) goes away, there may be adverse selection unless there is an open enrollment period. He asked how the Comprehensive Health Association of North Dakota relates to guaranteed issue.

Senator Mathern said he would like to expand the bill draft to include guaranteed issue for group plans as well as for individual plans.

Senator Hogan requested additional information regarding state guaranteed issue laws in effect before the ACA.

Mr. Godfread said before the ACA, several states experimented with guaranteed issue. He said he will provide additional information at a future meeting.

In response to a question from Senator Mathern, Mr. Godfread said if the goal is to address both individual and group markets, the bill draft could be amended to address that goal. He said traditionally, the individual market has served as a safety net.

Mr. Godfread said he would like committee guidance regarding open enrollment versus continuous enrollment.

Senator Hogan requested the Insurance Department work with the Legislative Council staff to revise the bill draft for a future meeting.

Ms. Mylynn K. Tufte, State Health Officer, State Department of Health, said on Wednesday, October 30, 2019, the Main Street Initiative Summit will have the United States Surgeon General as a guest of honor.

Chairman Keiser said Wednesday, November 20, 2019, is the tentative date for the next meeting of the committee.

No further business appearing, Chairman Keiser adjourned the meeting at 3:07 p.m.

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Jennifer S. N. Clark
Counsel

ATTACH:11