MINUTES

SENATE HEALTH & WELFARE COMMITTEE

DATE:	Thursday, March 03, 2016
TIME:	3:00 P.M.
PLACE:	Room WW54
MEMBERS PRESENT:	Chairman Heider, Vice Chairman Nuxoll, Senators Lodge, Hagedorn, Martin, Lee, Harris, Schmidt and Jordan
ABSENT/ EXCUSED:	None
NOTE:	The sign-in sheet, testimonies and other related materials will be retained with the minutes in the committee's office until the end of the session and will then be located on file with the minutes in the Legislative Services Library.
CONVENED:	**Chairman Heider** called the meeting of the Senate Health and Welfare Committee (Committee) to order at 3:15 p.m.
MINUTES APPROVAL:	**Senator Hagedorn** moved to approve the Minutes of January 19, 2016. **Vice Chairman Nuxoll** seconded the motion. The motion carried by **voice vote**.
	Senator Harris moved to approve the Minutes of January 20, 2016. **Vice Chairman Nuxoll** seconded the motion. The motion carried by **voice vote**.
H 481	**Relating to the Right To Try Act**. **Representative Melissa Wintrow** presented this bill.
	Representative Wintrow stated that this bill gives a terminally ill patient the right to try investigational medication that has successfully completed Phase 1 of the Food and Drug Administration (FDA) trial process. She read a statement from her constituent, John Knudsen, who suffers from ALS, or Lou Gehrig's Disease (see attachment 1). **Representative Wintrow** indicated that she collaborated with multiple groups, including physicians groups, insurers and regulatory boards and there has been no known opposition to this bill. She yielded her time to Kurt Altman.
	Kurt Altman, Of Counsel representing the Goldwater Institute, spoke in support of this bill. He stated that he drafted the model legislation for this and similar bills all around the nation. He explained that right-to-try laws give terminally ill patients who have exhausted all other FDA approved treatments an opportunity to access investigational new drugs, biologics or devices that have passed Phase 1 of the FDA approval process. Physician approval is required. He explained that the FDA has a three-phase approval process a drug must go through before it can be marketed to the general public. This process usually takes 8 to 15 years. The bill protects patients by requiring that the drug (i) successfully complete Phase 1 of the FDA approval process and (ii) continue processing through Phases 2 and 3. **Mr. Altman** stated that the FDA does have a compassionate use program, but this program is time consuming and bureaucratic (usually 2 months to 4 months) when an individual usually does not have this kind of time. This bill makes the review and approval process much shorter. He noted that this bill is not a guarantee for a cure.

Chairman Heider asked the Committee members if they had any questions.

Senator Schmidt asked if Mr. Altman or the drug companies were aware of other consequences for patients, such as possibly ending someone's life sooner than would have otherwise occurred. **Mr. Altman** answered affirmatively. He noted that the informed consent requirements in the bill make sure that the patient is aware of the risks involved. Restating his question, **Senator Schmidt** asked if Mr. Altman was aware of premature death actually occurring under the right-to-try laws. **Mr. Altman** replied that there has been no occurrence of premature death under right-to-try laws. He noted that 95 percent of these types of laws went into effect in late fall 2015 and early 2016.

Senator Hagedorn asked how this bill would affect medical malpractice for doctors prescribing this service and the drug companies providing it. **Mr. Altman** answered that this bill releases providers and pharmaceutical companies from liability solely for the adverse effects of the investigational drug. The bill does not release providers from general malpractice liability. The informed consents mirror the informed consent forms used in clinical trials. **Senator Hagedorn** asked if malpractice insurance costs have increased in the states that have passed similar right-to-try bills. **Mr. Altman** replied that he does not have that information. He stated that he has not found evidence that malpractice insurance has increased, but he does not know for sure.

Senator Martin asked how the physician obtains experimental drugs. **Mr. Altman** responded that a physician will get the drugs directly from the pharmaceutical company.

Senator Harris asked what role the federal government plays in regulating the right-to-try activity. **Mr. Altman** answered that the FDA is solely responsible for drug approval. The FDA sets the standards and monitors the clinical trials. Noting that Senator Harris may be asking about preemption, **Mr. Altman** commented that the U.S. Constitution sets the floor for rights, and states can recognize greater rights for their citizens. Therefore, a state's enactment of a right-to-try law would be the state simply recognizing the constitutional right of self-preservation. No federal government agency regulation can preempt a state constitutional right in this situation.

Noting that the bill requires an eligible patient to consider all other FDA-approved options before attempting to use experimental drugs, **Vice Chairman Nuxoll** asked how a patient would prove that they have satisfied this requirement. **Mr. Altman** answered that this occurs in conjunction with the physician. Physicians would attest that they have considered all other FDA approved options before attempting to use experimental drugs. **Vice Chairman Nuxoll** asked if this basically meant that this requirement is fulfilled by the physician. **Mr. Altman** responded that it is a medical decision and Vice Chairman Nuxoll's assessment of the physician's role is correct.

Senator Jordan asked if there are any established best practices or benchmarks for administering this program. **Mr. Altman** answered that the American Medical Association (AMA) and related organizations do not have benchmarks for this program. The benchmarks are based on the clinical trials and other studies for the medication. **Senator Jordan** asked if the bill provides for data collection regarding use and outcomes for right try patients. **Mr. Altman** responded that one of the typical conditions for a drug company to allow use of their drug in this situation is for the data to be relayed back to the sponsoring company. He reported that this bill does not mandate data be collected by the State, but some states have referred data collection to the regulatory boards and the rulemaking process.

TESTIMONY: **Chairman Heider** invited testimony.

Penny Caldwell, concerned citizen, spoke in support of this bill. She related the story of her husband and son being diagnosed with ALS at the same time. She explained that they did not have the chance to try experimental treatments, but would have wanted the right to do so.

Dr. James Quinn, physician, spoke in support of the bill. He discussed the importance of this bill because it would give terminally ill patients hope. **Senator Schmidt** asked Dr. Quinn if he practiced in Idaho. **Dr. Quinn** responded that he is associated with Advanced Clinical Research, which conducts Phase 2 and Phase 3 clinical trials. He has been a physician for 48 years. **Senator Schmidt** asked how Dr. Quinn or other proponents would reconcile this bill with current statute that dictates that a physician is subject to medical discipline if they represent that an incurable condition can be cured. **Dr. Quinn** replied that he is not privy to that information and he assumes that this would be addressed by the Legislature.

Matt Keenan, representing the Idaho Freedom Foundation, spoke in support of this bill. He spoke about a man's story regarding a cancer diagnosis. He stated that this man was able to receive experimental treatment under Oregon's right to try law. **Mr. Keenan** stated that Idahoans with terminal illnesses to have the hope provided by the right-to-try.

CLOSING REMARKS: **Representative Wintrow** stated that she appreciates Senator Schmidt's point about reconciliation. This bill is about the philosophy of life and death. She indicated that no doctor can guarantee anything. She related the story of her mother's desire to try experimental medication. **Representative Wintrow** reminded the Committee about the extensive informed consent requirements. This bill releases physicians from liability for both trying experimental medications or deciding not to pursue experimental medications for their patients. This bill releases barriers so that terminally ill patients have the choice to seek experimental treatments.

MOTION: There being no more questions, **Vice Chairman Nuxoll** moved to send **H 481** to the floor with a **do pass** recommendation. **Senator Hagedorn** seconded the motion. The motion carried by **voice vote**. Senator Buckner-Webb will carry the bill on the floor of the Senate.

H 500 **Relating to Medicare Provider Payment**. **Jeff Morrell**, Chief Executive Officer of Intermountain Hospital, presented this bill.

Mr. Morrell stated that this bill provides a technical correction to legislation signed into law during the 2015 Legislative Session. The reimbursement methodology for services provided to an adolescent by a private, freestanding mental health facility incorrectly stated the rate for payment. The statute is being amended to reflect the original intent of the legislation. The Department of Health and Welfare (Department) supports this change.

The Committee members together with Mr. Morrell and Sheila Pugatch, Bureau Chief of Bureau of Financial Operations in the Department, discussed the rate of reimbursement for services provided to an adolescent by a private, freestanding mental health facility and the fiscal note and fiscal impact of this legislation.

MOTION: There being no more questions, **Senator Schmidt** moved to send **H 500** to the floor with a **do pass** recommendation. **Senator Harris** seconded the motion. The motion carried by **voice vote**. Senator Schmidt will carry the bill on the floor of the Senate.

ADJOURNED: There being no further business, **Chairman Heider** adjourned the meeting at 4:15 p.m.

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Senator Heider
Chair

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Karen R. Westbrook
Secretary

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Michael Jeppson
Assistant