MINUTES OF THE MEETING
OF THE
COMMITTEE ON HEALTH AND HUMAN SERVICES

Seventy-Eighth Session
March 6, 2015

The Committee on Health and Human Services was called to order by Chair James Oscarson at 12:13 p.m. on Friday, March 6, 2015, in Room 3138 of the Legislative Building, 401 South Carson Street, Carson City, Nevada. The meeting was videoconferenced to Room 4406 of the Grant Sawyer State Office Building, 555 East Washington Avenue, Las Vegas, Nevada. Copies of the minutes, including the Agenda (Exhibit A), the Attendance Roster (Exhibit B), and other substantive exhibits, are available and on file in the Research Library of the Legislative Counsel Bureau and on the Nevada Legislature's website at www.leg.state.nv.us/App/NELIS/REL/78th2015. In addition, copies of the audio or video of the meeting may be purchased, for personal use only, through the Legislative Counsel Bureau's Publications Office. (email: publications@lcb.state.nv.us; telephone: 775-684-6835).

COMMITTEE MEMBERS PRESENT:

Assemblyman James Oscarson, Chair
Assemblywoman Robin L. Titus, Vice Chair
Assemblyman Nelson Araujo
Assemblywoman Teresa Benitez-Thompson
Assemblywoman Jill Dickman
Assemblyman David M. Gardner
Assemblyman John Hambrick
Assemblywoman Amber Joiner
Assemblyman Brent A. Jones
Assemblyman John Moore
Assemblywoman Ellen B. Spiegel
Assemblyman Michael C. Sprinkle
Assemblyman Tyrone Thompson
Assemblyman Glenn E. Trowbridge

COMMITTEE MEMBERS ABSENT:

None

GUEST LEGISLATORS PRESENT:

Assemblyman James Ohrenschall, Assembly District No.12

STAFF MEMBERS PRESENT:

Kirsten Coulombe, Committee Policy Analyst
Karen Buck, Committee Secretary
Jamie Tierney, Committee Assistant

OTHERS PRESENT:

Craig Handzlik, State Policy Coordinator, Goldwater Institute, Phoenix, Arizona
Elayna J. Youchah, Private Citizen, Las Vegas, Nevada
Janette Dean, Private Citizen, Reno, Nevada
Stacy M. Woodbury, MPA, Executive Director, Nevada State Medical Association
Denise Selleck, Executive Director, Nevada Osteopathic Medical Association

Chair Oscarson:
[Roll was taken. Committee rules and protocol were explained.] We are going to start with a Committee bill draft request (BDR) introduction. Bill Draft Request 40-417 was requested by the Legislative Committee on Senior Citizens, Veterans and Adults with Special Needs. This measure prescribes requirements concerning the care of patients in facilities for skilled nursing. I will entertain a motion to introduce BDR 40-417.

BDR 40-417—Prescribes requirements concerning the care of patients in facilities for skilled nursing. (Later introduced as Assembly Bill 242.)

ASSEMBLYWOMAN SPIEGEL MOVED TO INTRODUCE BDR 40-417.

ASSEMBLYWOMAN TITUS SECONDED THE MOTION.

THE MOTION PASSED. (ASSEMBLYWOMAN BENITEZ-THOMPSON WAS ABSENT FOR THE VOTE.)

Chair Oscarson:
Now we will have our work session. For those in the audience and watching online, Assembly Bill 52 is going to be moved to next week. We will start with Assembly Bill 28.

Assembly Bill 28: Revises the duties of the State Long-Term Care Ombudsman. (BDR 38-415)

Kirsten Coulombe, Committee Policy Analyst:
Assembly Bill 28 was brought forward by the Nevada Silver Haired Legislative Forum, and the hearing was on February 9. Assembly Bill 28 requires the State Long Term Care Ombudsman to develop a training course that encourages long-term care facilities to allow residents to follow their own routine and make their own decisions concerning the daily activities in which they participate. The training course is to be made available to officers, directors, and employees of long-term care facilities. There are no proposed amendments to this bill (Exhibit C).

ASSEMBLYWOMAN TITUS MOVED TO DO PASS ASSEMBLY BILL 28.

ASSEMBLYMAN THOMPSON SECONDED THE MOTION.

THE MOTION PASSED UNANIMOUSLY.

Chair Oscarson:
Next is Assembly Bill 39.

Assembly Bill 39: Removes the cap on the application fee for the Physician Visa Waiver Program. (BDR 40-328)

Kirsten Coulombe:
This bill was brought forth by the Division of Public and Behavioral Health, Department of Health and Human Services. It was heard on February 23. Assembly Bill 39 removes the cap on the amount the State Board of Health may establish for the application fee for the Physician Visa Waiver Program, also known as the J-1 Visa Program. In response to members' questions following the hearing, the sponsor did propose to limit the application fee to not exceed $2,000 or administrative costs, whichever is the lesser amount (Exhibit D).

Chair Oscarson:
Is there a motion?

ASSEMBLYWOMAN TITUS MOVED TO AMEND AND DO PASS ASSEMBLY BILL 39.

ASSEMBLYWOMAN DICKMAN SECONDED THE MOTION.

Assemblywoman Joiner:
I plan to vote for it today, but I would like to reserve my right to change my vote on the floor.

Assemblywoman Benitez-Thompson:
I would also like to reserve the right to vote no on the floor because it is a two-thirds bill. I want to make sure we are okay on the fees.

Assemblywoman Spiegel:
I would also like to reserve my right to vote no on the floor.

Assemblyman Thompson:
I would also like to reserve the right to change my vote on the floor.

Assemblyman Araujo:
I would also like to reserve the right to change my vote on the floor.

Assemblyman Sprinkle:
There are still questions I have with this bill that have not been answered, so I will be voting no.

THE MOTION PASSED. (ASSEMBLYMAN SPRINKLE VOTED NO.)

Chair Oscarson:
Next is Assembly Bill 41.

Assembly Bill 41: Revises provisions relating to funding for indigent care. (BDR 38-327)

Kirsten Coulombe:
The last bill in work session is brought forth by the Division of Health Care Financing and Policy, Department of Health and Human Services (Exhibit E). It was heard on February 20. Assembly Bill 41 provides that any money remaining in the Fund for Hospital Care to Indigent Persons at the end of each fiscal year does not revert to the State General Fund and must be carried over

to the next fiscal year. The bill removes certain limitations on agreements entered into by the Board of Trustees of the Fund for Hospital Care to Indigent Persons. The Supplemental Account for Medical Assistance to Indigent Persons is replaced with the Fund for Hospital Care to Indigent Persons allowing each board of county commissioners to remit the amount previously reverted to the Supplemental Account directly to the Fund. Assembly Bill 41 also repeals provisions authorizing the Board to require certain hospitals to pay an assessment in order to prevent a reduction in federal participation for Nevada Medicaid. Lastly, the bill repeals the inactive Fund for the Institutional Care of the Medically Indigent. There are no proposed amendments for this bill.

Chair Oscarson:
Is there a motion?

> ASSEMBLYMAN TROWBRIDGE MOVED TO DO PASS ASSEMBLY BILL 41.
>
> ASSEMBLYWOMAN TITUS SECONDED THE MOTION.

Assemblywoman Benitez-Thompson:
I will be voting no, not because of the premise of the bill, but because section 1, subsection 5 does not allow dollars to revert to the General Fund. With a $250 million budget deficit presently and not a great prospect on the horizon for revenue, I want to make sure we are not fencing off dollars so we can meet our constitutional mandate for a balanced budget. We never sweep them when we want to, we sweep them because we have to.

Assemblyman Sprinkle:
For the exact same reasons that my colleague just stated, I will be voting no on this bill.

Chair Oscarson:
We will take a vote.

> THE MOTION PASSED. (ASSEMBLYMEN ARAUJO, BENITEZ-THOMPSON, AND SPRINKLE VOTED NO.)

Chair Oscarson:
I will assign the floor statements now. ASSEMBLY BILL 28 is assigned to Assemblywoman Titus. ASSEMBLY BILL 39 is assigned to Assemblyman Trowbridge. ASSEMBLY BILL 41 is assigned to Assemblyman Moore.

We will now hold the hearing on Assembly Bill 164. Assemblyman Ohrenschall is going to talk to us about revising the provisions relating to access by patients to certain investigational drugs, biological products, and devices.

Assembly Bill 164: Revises provisions relating to access by patients to certain investigational drugs, biological products and devices. (BDR 40-125)

Assemblyman James Ohrenschall, Assembly District No.12:
With me today, I have Craig Handzlik who flew in from Phoenix, Arizona. He is the State Policy Coordinator for the Goldwater Institute. I also have Janette Dean who has been researching and helping me with this legislation. About a year ago, I was approached by a good family friend who read about the model legislation that is being sponsored by the Goldwater Institute. So far, this legislation has become law in five jurisdictions: Louisiana, Missouri, Michigan, Colorado, and most recently in Arizona by initiative petition. This friend of mine had lost his father through a terminal illness and had cared for him for quite a while. An idea like "Right to Try" was not available for him back then. However, he approached me and asked if I would consider introducing it. I read about it, put in the bill draft request, and once I did that, I learned that it is an idea that a lot of people are interested in. Senator Woodhouse is my chief cosponsor in the Senate. Assemblyman Wheeler gave me a call and said I had beat him to the punch. He was going to put in this bill, and he thinks it is great idea. I am proud to have them on the bill with me. We all thought it was good legislation.

What "Right to Try" is attempting to do is help terminally ill patients who want the chance to try a medication, a therapy, a drug that has made it through Phase 1 of the U.S. Food and Drug Administration (FDA) trials but has not made it through the entire FDA process. The research I have done shows the timeline to get any drug through the FDA process is 10 to 15 years. Around the country, we have patients who are told by their doctor, I am very sorry. I have run out of therapies, and I have run out of treatments. There are medications that have been studied. Trials are available at major medical centers but, unfortunately, we do not live in Chicago, New York, or San Francisco. We do not live near one of those major medical centers. Some of the doctors will talk to the patients about an exception the FDA has called the compassionate use exception. That is a wonderful thing that came about in the 1980s during the acquired immunodeficiency syndrome crisis. It does help many patients; unfortunately, it has drawbacks. Last year, statistics show that 600,000 Americans were diagnosed with a terminal form of cancer. Unfortunately, a thousand people, from the data I have, were granted the compassionate use exception to try these medications and therapies that have not made it through the entire FDA process. To me, that is unacceptable. That

number is way too low, and I think we need to do something. I think the Goldwater Institute has hit it right on the head in terms of sponsoring this legislation and shepherding it through the jurisdictions that it has passed in, and I believe the compassionate use exception is pending in 20 more.

The way the bill is crafted, medication and therapy would have to make it through Phase 1, which ensures that there is no toxicity and that the medication is not going to kill the patient make the patient any worse than the underlying condition would. When I have talked to constituents, other people, and people who have or have had relatives that are going through a terminal illness, I have not met anyone who would not want the opportunity to try this.

I think the bill is constructed conservatively, in that the patient must work with their doctor of medicine (M.D.) or doctor of osteopathic medicine (D.O.). We have tried to make sure that we are not opening the door to snake oil salesmen or charlatans who might try to prey on someone's desperation. I hope that the Committee will be open to this idea. I am happy to answer any questions.

Assemblyman Gardner:
I want to thank you very much for bringing this bill. I think it is very important, and I, too, have had situations where this would have been very helpful to relatives of mine. I think it is a very important bill and suggest we all support it.

Assemblywoman Dickman:
I want to echo what Assemblyman Gardner said. My mother would have benefitted greatly from this.

Craig Handzlik, State Policy Coordinator, Goldwater Institute, Phoenix, Arizona:
We crafted the original language of "Right to Try," and we have helped to have it pass in the five states where we do have it. In the four states where it has passed legislatively, we only received two dissenting votes, and that was in the Michigan Senate. In Arizona where it passed as a ballot referendum, it passed with a vote of 78.5 percent. Assemblyman Ohrenschall was pretty spot-on. It is running through an additional 29 state legislatures this session. Currently, it is sitting on the governor's desk in four states.

I wanted to thank you all for having me here, and I wanted to share one additional patient's story, which drove the effort in Arizona with the ballot initiative. That was the story of Diego Morris. He was our honorary spokesperson for Proposition 303 in Arizona. When he was 11 or 12 years old, he was diagnosed with osteosarcoma, which is bone cancer. In his case, it was in his leg. His parents and physicians wanted to do everything they could to

save Diego's life, but they ran out of options. They could not get him any additional treatments, and he was essentially told that he would have to go home and enjoy the time he had left with his family. There was nothing else they could do for him, but his parents were industrious, smart, and resourceful people. They continued looking for options, just as you would for your child, mother, or brother, and they found a medication that had been approved in the United Kingdom (UK) for use on osteosarcoma patients. After a long and careful deliberation, they decided they would go to the UK, move their family there, and give it a shot. They did so. Diego's dad had to commute back and forth between Arizona and the UK for about a year until Diego responded positively to the treatment. His cancer went into remission, and he returned home to Arizona to face a few more struggles with repairing the damage that the disease had done to his leg, but Diego is alive today. I saw him two weeks ago. He is a regular kid, and he is actually traveling the country now, speaking about "Right to Try" and the need for this law in all the different states.

The interesting thing in this story is that the medication that Diego used in the UK still is not approved for use in the United States. For me, it seems as though with the advanced cutting-edge medical environment we have in this country, being a patient that has to travel around the world to get a medication that has been approved for use would be hard to swallow.

Assemblywoman Titus:
I definitely support the concept. I have had patients that have sought care in other countries because our FDA is sometimes less than stellar in their timing and their requirements of getting things brought forward. My patients had to sneak off to Canada to get Tagamet years ago because it took so long to get it here. Now it is over the counter. However, having said that, when patients have been diagnosed with a terminal illness, they will do just about anything, as any of us in this room would do to keep our family members alive.

I appreciate that you commented that they have to complete a Phase 1 trial, so at least you are giving some protection to the consumers. But I have a concern on section 1, subsection 2, paragraph (a) and paragraph (b), that they "Provide the investigational drug, biological product or device to the patient without charge; or charge the patient only for the costs associated with the manufacture of the investigational drug." Potentially this could be thousands and thousands of dollars to bring one drug forward. I am a little anxious about that component of this bill and who is going to pay for it. Unfortunately, this means that sometimes only the people who have lots of money can do this.

Craig Handzlik:
I understand you are a physician. It is a great question and one that I receive often as I travel the country. The simple answer is that you are right. Manufacturers are able to give the medication away for free. The intent of the legislation and the language is to allow the manufacturers to recoup the costs that it would cost them to produce the dose for that patient, not the billion or billion-and-a-half dollars that go into the research development, marketing, and that type of thing.

That being said, the point that you make about folks with resources is a good one. I will answer that in two ways. The first way is in the current language of "Right to Try." The situation exists where patients can receive the medication for free and be treated by their physicians free of charge. The biggest advantage is that it is unlike clinical trials, which are currently structured for folks with resources. Secondly, as many rural Nevadans will tell you, if they are allowed into a clinical trial, the chances of them being able to travel to a metro hospital or to another state are very slim. The current situation is set up to benefit those folks. Under "Right to Try," it would allow the medication to be brought to a facility closer to the patient.

An anecdotal story is about a patient we talked to in Tucson, Arizona, who actually was admitted to a clinical trial in northern California. After many weeks of having to travel with her family and expending resources, she had to give up because her family could not expend any more time or money to travel there. Frankly, she could not handle it physically. I would just say that there is a situation in "Right to Try" that benefits folks with fewer resources. As a side note, I would also mention that Jonathan Johnson, who is the Chairman of the Board of Overstock.com and a supporter of "Right to Try" in Utah, has just announced that he is starting a "Right to Try" foundation to raise funds for patients who are trying to utilize the law.

Elayna J. Youchah, Private Citizen, Las Vegas, Nevada:
I am a more than 20-year Las Vegas resident. I am a daughter, and I am here today to speak not only for myself but also for my father. This is what my father has to say:

> My name is Michael Youchah. I am not able to be here today because illness prevents my appearance. I am the child of immigrant parents who came to the United States in the early 1900s. I put myself through school, joined the Reserve Officers' Training Corps, received a bachelor of science degree in what was then aeronautical engineering, served in the Air Force in Korea,

> came home in one piece, earned my master's degree, and am happy to say that I have fulfilled the "American dream."
>
> I have been suffering from multiple myeloma for four years. This is an incurable blood cancer. I am near the end of all drugs that are FDA approved for treatment of this disease. There is, however, a very promising drug in Phase 3 trials that could not merely prolong my life but would prolong the quality of my life. I deserve the right to try this drug. I deserve the right to make the decision with my doctor. I have lived a long and wonderful life. Please help me by giving me the right to choose to continue that life through passing this bill.

I would like to add to my father's statements. I love my dad, but I am not here just as someone who loves him but also as someone who believes in this bill. He has fought this disease honorably and with grace. He has been an inspiration to me and to my family throughout this process. For anybody who knows anything about multiple myeloma, it is a painful form of cancer. It affects your bones. It deteriorates the interior of your bones and can be quite painful. He never complains. He is 86 years old, but he is a great guy, and he has a tremendous will to live. In this country, we have so many rights, and as a lawyer, I understand them, and I understand the implications of this bill. We have the right, for example, to refuse treatment: medical treatment, devices, or therapies that might prolong our lives and therefore allow us to choose to die. It seems odd, given that we have that right, that we would not have the equal right to choose, with proper medical supervision, to take advantage of drugs that are in clinical trials.

Adding to what the witness said earlier, my father was considered for a clinical trial in Phoenix, Arizona. Unfortunately, the timing of his application was such that he was not accepted. Now, of course, he is too ill to travel back and forth to Arizona, which would be required fairly consistently for quite a number of months and possibly years to take advantage of that clinical trial. He has a wonderful, exceptionally well-trained doctor who is more than capable of supervising the administration of this drug were it available to him at the cancer centers that are available in Las Vegas. Unfortunately, it is not. This bill would give him the opportunity to take advantage of that drug, remove a hurdle to the advantage of that drug. I urge you to pass this bill, and I thank you for your time. I am happy to answer any questions that you have.

Assemblywoman Benitez-Thompson:
In section 1 when we talk about who could be considered in this pool of folks to access drugs in Phase 2, we have the language, someone who "has been

diagnosed with a terminal condition." The way I read that is it would be anyone who has a diagnosis that could potentially be terminal but not that they are indeed a terminal person. Could you clarify that?

Craig Handzlik:
It is important to mention that this definition here is the *Nevada Revised Statutes* (NRS) definition of the term "terminal condition."

Assemblywoman Benitez-Thompson:
Working in hospice, I know that for someone to be certified terminally ill requires two physicians' statements. What I am trying to understand is the pool of people who are eligible. Is it anyone who has any kind of a cancer diagnosis or someone with cancer who has been certified terminally ill?

Assemblyman Ohrenschall:
The definition that we are using is defined under NRS 449.590, which states that the patient has an "incurable and irreversible condition that, without the administration of life-sustaining treatment, will, in the opinion of the attending physician, result in death within a relatively short time." That time is not defined. It is in stark contrast to another citation in NRS 449.0195, which states that "a person has an anticipated life expectancy of not more than 12 months." We chose with the drafters and Mr. Handzlik not to limit it to the group of patients that have been told that they only have less than 12 months, but to someone who has that broader definition under NRS 449.590.

Assemblywoman Benitez-Thompson:
This might just be semantics to figure it out, but it is interesting because with the Medicare benefit, when you are diagnosed terminally ill, that medical certification is 6 months of life. We need a clear understanding of what group of people we are talking about. The pool of people who are diagnosed with cancer is very large. This legislation would touch a lot of different people. However, if you are looking at the NRS definition of 12 months, I am not sure and maybe we can get clarification if there is a medical certificate of being terminally ill with 12 months. I know of the 6-months standard mark. The question we have is your intent of this legislation in the specific world of terminal illness.

[Assemblywoman Titus assumed the Chair.]

Assemblyman Ohrenschall:
My intent with the drafters was to keep it as broad as possible for the patients who had been given that diagnosis and who, with their doctor, believe there is a medication out there that might help them. In terms of 6 months or 12 months,

I was not looking to put any limitation in terms of time. However, if the Committee thinks that is appropriate, I am certainly open to having more conversations on that.

Vice Chair Titus:
For me personally, I had some concern about the definition of terminal illness, and if you want to restrict it to that. We are all basically terminally ill from the time we are born. It is one of those broad definitions. Do we want to put it in a smaller box or broaden it? What is the intent? There are lots of diseases, perhaps they are all terminal, with potential trials out there to improve the quality of life. A little more clarification will make me feel better.

Craig Handzlik:
I want to add to the definition of terminal illness and the intent of the legislation. As you know as a physician, Vice Chair Titus, amyotrophic lateral sclerosis (ALS) is a terminal illness that could take 20 years or more to be fatal. Duchenne muscular dystrophy is a very brutal form of muscular dystrophy that children experience, and that can take 10 years to be fatal, and I would argue that it is just as fatal as terminal cancer. I wanted to make that point.

Vice Chair Titus:
That is exactly what I was getting at. Some illnesses are definitely terminal, but it may take a long time. If you can get into some of these trials, your quality of life could be dramatically improved.

Assemblyman Sprinkle:
It would be helpful if you could describe the different levels of trials with the FDA and what is accomplished at each level, so we know exactly what we are talking about here.

Assemblyman Ohrenschall:
I have done a lot of research on this bill and can probably do a pretty good job of answering that, but I believe Mr. Handzlik can do an even better job.

Craig Handzlik:
Phase 1 of the FDA clinical trials is to establish basic safety levels of toxicity. In layman's terms, it means that in the terminal illness context, this medication is not going to be toxic to you and kill you any faster, sooner, or easier than the underlying illness would kill you. It is a human trial and is typically administered to between 20 and 80 healthy patients. Phase 2 starts testing on the efficacy. This is where dosages are starting to be worked out. Phase 3 fine-tunes the efficacy process and dosage process as well. After the third phase, it is subject to approval by the FDA. These are the three phases. What "Right to Try"

seeks to do is to get terminally ill patients access to medications that the federal government has said are not toxic and would be less of a risk than their very certain outcome, which would be death.

Assemblyman Sprinkle:
That is helpful. I absolutely understand now what you are trying to accomplish with this bill, and I am supportive of that. I want to talk a little about the doctors who are prescribing. In the language in the bill, it talks about disciplinary action. Purely from a liability standpoint, is that in reference to discipline from the Board of Medical Examiners? Is that in reference to protection from civil or criminal charges? What if something happens because these drugs have not been fully vetted in the United States through an FDA approval? Where is this going to leave the physician who is prescribing if something goes wrong? What I just heard was in the second stage, you are trying to work out dosages. If we do not know exactly the efficacy of a certain dosage, if they give too much, that could have very detrimental ramifications. Then is the doctor that prescribes it going to be liable?

Assemblyman Ohrenschall:
What we have in the bill is Board discipline. The way the bill envisions this happening is informed consent from the patient working with the doctor. We are not addressing civil liability, so we are not actually touching on that area.

Craig Handzlik:
I echo Assemblyman Sprinkle's sentiment, and this was a big concern of ours from the inception of "Right to Try" at Goldwater Institute. The intent of the bill is to encourage physicians to participate in "Right to Try" through giving them liability protections only as it relates to the investigational medication. There is no bill or law in the country that is going to protect a bad actor or a physician that is performing malpractice or is negligent. What we want to do is allow physicians who want to try to help their patients obtain an investigational medication that has gone through Phase 1, to do so without risk of losing their license, losing their ability to prescribe other medications, or doing jail time. This is only as it relates to the investigational medication.

Assemblyman Sprinkle:
I appreciate that, but my concern lies in when you start usurping the federal regulations that we already have and the reasons why we have the FDA to begin with. We are not doing anything to address the physician who is not a bad actor. He is maybe not fully educated in what the investigational medication is and, for example, has simply read the literature. I have real

concern about what we may be doing to the patients that they are prescribing for.

Assemblyman Moore:
When you say that you "provide the investigational drug, biological product or device to a patient without charge; or charge the patient only for the costs associated with the manufacture of the investigational drug" [section 1, subsection 2, paragraph (a) and paragraph (b)], how are they going to pay? Are they going to pay the manufacturer themselves because the manufacture of drugs seems to be a closely held industry secret? How do we know the true costs and that they are not just getting conned? They could say, We are used to charging you $1,000 a month for this prescription. We are not going to take the hit. We will just charge you $800, and then say that is what it costs.

Craig Handzlik:
That is a great concern. It is mostly addressed during the informed consent process that a patient, his physician, and the manufacturer would all enter into together. Each of those processes, each of those agreements, and each of those informed consent clauses are going to be wholly different based on the different circumstances, including the doctor's scope of practice, the patient's condition, the manufacturer, or the biological device that is being requested. It is important to note that "Right to Try" does not mandate that anybody do anything. It does not mandate that a physician participates, that a manufacturer must provide the medication, or that insurance companies have to cover the medication. It is important to remember that, additionally, it does not mandate that a patient has to go through this process either. During that informed consent process, the majority of those concerns would be not only explained but also agreed to or not agreed to.

Assemblywoman Dickman:
This question goes with Assemblyman Sprinkle's concerns. Do you have any information on how this affects a physician's malpractice insurance who participates?

[Assemblyman Oscarson reassumed the Chair.]

Assemblyman Ohrenschall:
"Right to Try" has recently passed in four jurisdictions and now Arizona for five. Therefore, it has really only been in effect the last year, so we do not have enough of a track record to tell us that. I am hopeful that it will not adversely affect the physician's malpractice insurance, but that is an answer we do not have the data for. The way we have written the bill, in terms of trying to shield

the physician, at least at the Board level, we hope to protect them. I expect to protect them, but I do not have that information.

Assemblywoman Dickman:
I was wondering if doctors might be afraid to participate if it was going to send their malpractice insurance through the roof.

Craig Handzlik:
To Assemblyman Sprinkle's point earlier about federal jurisdiction, in the five states where "Right to Try" has passed, no federal agency has challenged it. The FDA has come out as neutral on "Right to Try" publicly in the press. We are starting to see that the FDA is also beginning to change its process in which patients would utilize their compassionate use or expanded access programs. We are seeing, contrary to affecting a physician's malpractice insurance, the opposite reaction where, at the federal level, change is being made. They are starting to understand the movement in which 5 states have passed it and 29 states are running it now, and this is something they need to pay attention to. I would also add that in speaking with the Board of Medical Examiners this morning, they wholeheartedly supported the bill in its current form and asked that I tell you that today.

Assemblywoman Benitez-Thompson:
Are the folks who would opt into this at Phase 2 part of a study group that is happening at Phase 2?

Assemblyman Ohrenschall:
The way we have written the bill, medications would be available to those patients after Phase 1. That is the safety phase. Phase 2 is the efficacy phase. Would they be part of the trial? That would depend on the luck of the draw. If they lived in a rural community, they would more likely not be. If they lived near a medical center that had the medication, then it is possible.

Assemblywoman Benitez-Thompson:
What kind of data collection is there for the person who would opt into Phase 2?

Craig Handzlik:
I understand the nuance of your question. The answer is, to Assemblyman Ohrenschall's point, Phase 1 is the minimum hurdle. It does not necessarily have to be in Phase 2, but it cannot have been kicked out of the FDA's clinical trial process. I think what you are asking me is when patients opt in or utilize the "Right to Try" law, are they part of some bigger group that is working together and what happens to the data that is collected from that

group of patients during that time. The answer is there is no group of patients that a physician is treating all together. This is an individual choice that a patient works with his physician and directly with a manufacturer to fill out his informed consent and obtain the medication to be administered by the physician to the patient. The data would not go towards or against a manufacturer's clinical trials process with other patients. It is an important statistic to understand that only 3 percent of the 600,000 cancer diagnoses each year alone are admitted into clinical trials while 97 percent of terminally ill patients are not admitted. Those are two very different patient sets. One argument which I think you are grazing here is that somehow the data collected from a "Right to Try" case might affect an FDA clinical trial process situation when, in fact, the patients would never have had access to that clinical trial process anyway. Of those 3 percent that do gain access to FDA clinical trials, half of them are given a double-blind placebo, shrinking the numbers even further. Another function of "Right to Try" would be a patient, physician, and manufacturer all working together to make sure that the patient gets the medication instead of a placebo.

Assemblywoman Benitez-Thompson:
It is interesting, and Alzheimer's disease comes to mind. You get the diagnosis, there is not a cure, and it is going to be fatal. It could be 10 or 15 years. It might take five, but if you opted into a Phase 2 drug right after you are diagnosed and if it is still very early in the disease process, then I think it would be worthwhile and actually quite fascinating to collect that data to see what does happen. I do not know if that is something that manufacturers would be amenable to, but that is the perfect example of when you do not have a cure. Once you get a diagnosis and you could opt into something, why not track it and see how that does whether it comes out good, bad, or ugly?

Another question I have is on marketing. Are drugs in the Phase 2 process allowed to be marketed to patients?

Craig Handzlik:
The quick answer is "Right to Try" does not address marketing. That is a different issue. I know that some folks would be in favor of investigational medications being marketed to patients that have terminal illness, but this bill and the language within does not deal with that.

Assemblywoman Benitez-Thompson:
However, the status quo right now is they are or are not allowed to engage in marketing at Phase 2?

Craig Handzlik:
The status quo is no. Nobody can market a drug that is not approved by the FDA.

Assemblywoman Titus:
I have a few concerns along the same lines as Assemblywoman Benitez-Thompson's questions. On a Phase 2 trial, they really are working out the doses. If you allow providers and physicians, doctors of medicine and osteopathic physicians, to have access to these medications, they can be at will as to what the doses are going to be. There is really no feedback in this bill to the pharmaceutical companies or the folks who are doing a true clinical trial. They have a very controlled group on whether or not these medicines work, which is part of why you have these trials and the double-blind trials because of the placebo effect all across the board. I am a little anxious that you would not mandate that some of the data is at least collected so that you can know that the person who died a month after they took this medication had been given 20 milligrams instead of 10 milligrams, which everybody else was doing, because their doctor thought that would be correct.

Secondly, having been a member of the Board of Medical Examiners, I would have anxiety about practicing medicine, the doses, patient complaints, and those kinds of things on a lawsuit level.

Thirdly, just because the state says I can do it does not mean my Drug Enforcement Administration (DEA) registration says I can do it. My drug registration comes from the federal government, which is why we are all uncomfortable about legalized marijuana. Even though the federal government says they are turning their heads, I am not permitted to prescribe marijuana on my DEA registration. It also says I cannot prescribe these investigational drugs, so I am a little anxious because the state says I can. What if the federal government is okay now, but what if they suddenly are not? I am worried about protection in this bill.

Craig Handzlik:
Assemblywoman Titus, these are all great concerns. The first thing I would mention is "Right to Try" does not mandate that a physician participate. It does not mandate that a patient participate or a manufacturer participate. If that is a concern, then I would say you do not have to do it. Additionally, I want to be careful here with the marijuana argument. There are parallels, but there are no connections. Let me explain that a little further. For instance, the FDA and the Department of Justice (DOJ), they have publicly decided that they are not going to expend resources or prosecute certain marijuana crimes. I would argue that it is difficult for the FDA or the DOJ to say something like that and then go after

folks who are trying to save patients' lives or patients trying to save their own lives. That being said and I am not a lawyer, the federal government and the *United States Constitution* grant the states extra latitude in terms of personal freedom. You see that in speech and other issues. Currently an issue that I know you are aware of, which is right to die or the end stage ability of patients to end their own lives, was argued nine years ago in court in Oregon. The case is called *Gonzales v. Oregon* 546 U.S. 243 (2006). They have decided that they are going to uphold that state law to allow patients and physicians to work together to prescribe dosages that would assist a patient in ending his own life. I think that you will see the "Right to Try" with parallels, and not connections, could be argued in the same way.

Assemblyman Ohrenschall:
I would like to respond to the question as to why the bill does not mandate data collection. There is a concern about skewing the data since the folks who are working with their M.D. and D.O. are not part of those trials and the dosage issues that you brought up, Assemblywoman Titus. That is the concern in terms of not trying to mandate. There is nothing preventing a pharmaceutical company or the doctor from trying to collect the data and sending it to the company or sending it to the FDA if they want. That was a concern I had with trying to mandate it with talking to Goldwater Institute and the other folks that I have spoken with.

Assemblywoman Joiner:
I can see how this bill would benefit a lot of people. I definitely support the concept of it. In the states where it has passed, it is not clear to me how long it has been implemented, so maybe there is not an answer. How does word get out to folks about which drugs are available and whom it might have helped in the past? Is there some sort of group or social media? Is there research or data accumulating on that? Are you finding that folks are using it? Sometimes we have cancer drug donation programs that nobody ends up using. Are you seeing volumes of folks who are actually benefitting from this? This information would be very helpful.

Craig Handzlik:
It has passed in five states, the first state was Colorado and that was just in May of 2014, so it is very new. Secondly, I have patients that call me all the time asking me the same exact question that you just asked, which is I have a terminal illness. What do I do next? Again, the answer is, Talk to your physician. Work with him or her on trying to obtain the medication. We as an organization do not recommend medications or anything like that. The answer to your third question is, Goldwater Institute is in the process of working on social media, op eds, and Facebook to provide patients information and so are

independent folks all around the country. If you go on Facebook now, you can search for national "Right to Try" and find 5, 10, or 15 other organizations doing the same thing on their own. I would answer your other question by saying that I do know of patients who are working with their physicians and manufacturers to try to get the bill through the process. Again, Arizona passed it in November and was the latest state. Colorado was the first state and that was just in May.

Assemblyman Ohrenschall:
Assemblywoman Joiner, the way I met Ms. Youchah, the witness from Las Vegas, was that she had heard about it through a kind of groundswell with this issue, and she contacted Senator Tick Segerblom, who is a longtime friend of hers, and asked if he would introduce it. Senator Segerblom checked and saw that I had submitted the bill, and he is one of my cosponsors. There are a lot of people who are facing these issues who do know about this and are talking to their doctors. I hope with what I am hearing about the foundation that is being set up and the laws pending around the country that more people will find out about it.

Assemblyman Sprinkle:
I am still on the liability aspect. These drugs have not been released and are still in clinical trial. How is it possible for them to even be releasing these drugs outside of a clinical trial and what kind of liability are they assuming when, or if, something were to go wrong, when the efficacy of dosages has not even been established yet?

Craig Handzlik:
The answer is in the bill's language; there are protections for manufacturers that have medications that have passed Phase 1 of the FDA's clinical trials in their use for the "Right to Try" context. There is language in the bill that allows them to do this at the state level.

Assemblyman Sprinkle:
In the other states that are doing this now, have you found that the pharmaceutical representatives have generally been onboard with this and are okay with going outside the trial study with drugs that may not be fully ready to be released yet?

Craig Handzlik:
Yes, Assemblyman Sprinkle, medical systems, pharmaceutical companies, manufacturers, physicians, and patients are all currently adjusting to their states' new laws. They are trying to wade into the waters of how this is going to work and find out about it.

Chair Oscarson:
I am reading in the first section of this bill that this is for patients in the state that have been diagnosed with a terminal condition according to NRS 449.590. This is, as I understand it, a last effort to try and prolong the life of someone who has exhausted all the other treatment options that there might be to do something. This is a hope that might take away some of their suffering or prolong their life. I think that is where the bill gets me right in the first part of the language. I understand the liabilities, the advertising, and all those things because those are all very important questions. However, that is what I keep going back to.

Assemblyman Ohrenschall:
There was discussion earlier about why we are using NRS 449.590 versus NRS 449.0195, which defines a terminally ill patient as having less than 12 months to live. We did not use that more limited definition, and Assemblywoman Benitez-Thompson mentioned the Medicare definition of someone only having 6 months. There are many conditions. Mr. Handzlik brought up patients with ALS, which does not confine them to that subset of people who have been given that most grim diagnosis. We wanted to have a broader set of people who have been told that they have a terminal condition so they can get the benefits of this legislation.

Craig Handzlik:
Chair Oscarson, I would also add that you are exactly right. These are patients who have exhausted all other available treatments, and essentially, "Right to Try" is an additional arrow in their quiver in the fight against their end-stage illness.

Assemblywoman Titus:
Conceptually, I am good with this. However, all these questions have to be asked because a patient or somebody administrating the drug could be harmed by these medications. Let us say a nurse is going to give this medication that just has made it through Phase 1. Many drugs come to market through all phases, only to be released to the general population five years later. We decide they work, but we really do not know. For example, there were many cardiac drugs that worked well on stopping a dysrhythmia, but everybody died of a heart attack afterwards, so we took them off the market after five years. It is only after huge exposure that we sometimes recognize how bad some drugs are.

I understand that it is not a perfect science, but what happens to the nurse or doctor who is administering the drug and he pokes himself with a needle? Now he goes to the emergency room. Then the insurance company says, We are not

going to cover this. You are doing experimental treatments there. There are all these things that we cannot even predict may happen. I am asking these questions to try and address them now before we pass this bill. I would love to have patients have access to these drugs, if possible. However, what happens when someone with ALS, who might have a 20-year diagnosis, decides to do this experimental program and has a stroke because of it? Now the insurance company says, Well, you were on this experimental program, and we are not going to cover you for this. I want to make sure that we are looking at all angles of what the possible implications are.

Chair Oscarson:
I am in complete agreement that we need to vet out the questions to the experts while they sit here and are available to us.

Assemblywoman Spiegel:
I do not see in the bill where there is a requirement that the patient try FDA-approved medications, devices, et cetera before trying something that is not yet FDA approved.

Assemblyman Ohrenschall:
It is not in there and is not part of the "Right to Try" legislation. However, the way we have crafted the legislation, the patient cannot try the avenue of the experimental investigational medication unless they are working with their M.D. or D.O. who is licensed here in the state. In my opinion, they would have tried those beforehand because they would have to. I am certainly not opposed to language like that, but I do not think it is necessary.

Craig Handzlik:
In other states where it has passed and is effective, there is language that essentially says that a patient has reasonably exhausted all other medical options or has applied to FDA clinical trials. I echo Assemblyman Ohrenschall's sentiment about how that would also be part of the informed consent process where a physician explains all treatment options, all good and bad possible outcomes that are known to a patient, and they both sign on to it and also get a manufacturer or device producer to agree to it as well.

Assemblywoman Spiegel:
Would you be willing to entertain an amendment to include the language that talks about having exhausted all other approved remedies or approaches, language you mentioned that they have in other states?

Craig Handzlik:
Assemblywoman Spiegel, I would be okay with including an amendment that says that a patient has exhausted all options because that is really what the intent of the bill is.

Assemblywoman Titus:
Under section 3, subsection 1, paragraph (a), "Diagnosed the patient with a terminal condition" and paragraph (b) "Discussed with the patient all available methods of treating the terminal condition that have been approved. . . and the patient and the physician have determined that no such method of treatment is adequate to treat the terminal condition of the patient" is the current language already in this proposed bill. They have at least discussed the methods of treatment but not necessarily tried them. I am not sure if there is a need or desire to change that language, but the language exists that they have at least had the discussion about availability of other treatments.

Assemblyman Ohrenschall:
Assemblywoman Titus and Assemblywoman Spiegel, in my mind the discussion would be enough, especially if the current available treatments that are FDA approved are not considered to be effective by the doctor. I might be worried about adding language. I would have to see what the language looks like in terms of actually exhausting the treatments.

Chair Oscarson:
That door was opened when you said other states have that type of language, so perhaps you could provide the language that is in other states to Assemblywoman Spiegel and see if that meets her intent. It sounds like it says the same thing.

Craig Handzlik:
I agree completely, and I will send all the pieces of language from the five states that have it. I would also say that I agree with Assemblyman Ohrenschall that it is very difficult to tell patients that they have to try every possible thing that could possibly help them before they can utilize a medication that may help them.

Chair Oscarson:
That point is well taken.

Assemblywoman Titus:
You are right. Some of the approved treatments can actually kill them prior to death from the disease, and they may choose to not go that route with say a

70 percent success rate or risk of dying. They may choose not to go down that avenue.

Assemblywoman Joiner:
As a follow-up to my previous question about participation, more and more as we talk, it seems like the manufacturers hold a lot of cards, right? It depends on how many doses they want to release for free and whether or not they want to do it at cost. Have you had support from the manufacturers of drug and devices nationally or not? Are they really holding a supply? In other words, are they participating?

Craig Handzlik:
We have five states now that have passed the laws very recently, and there are 29 states that are currently considering it in their legislatures. As states begin adopting and enacting "Right to Try" laws, I think you are going to see a whole wave of different approaches to this situation with terminal illness and patients. At least that is our hope. As we start collectively as a country saying that this is what we want for this very small segment of terminally ill patients, folks at all levels of government and the private industry will be encouraged to help other people out.

Assemblyman Jones:
I also appreciate this bill and want to thank you, Assemblyman Ohrenschall, because you brought in an expert who has been working with the model legislation, so he comes across all these issues throughout all the different jurisdictions. That means that we have a level of expertise here that has already vetted, if not everything we asked, almost everything and anything that we are not even thinking about. That is very well done on your part. I will give you my support.

Assemblywoman Dickman:
This statement is to the idea of exhausting all other approved treatments. When I was growing up, my mom's best friend was a regular patient of the Mayo Clinic and was diagnosed with pancreatic cancer. They recommended trying a megadose of chemotherapy. She died within two weeks from that chemotherapy, and that was an approved treatment. I do not think we should insist that people exhaust all the conventional treatments.

Chair Oscarson:
Are there any other questions or people in support?

Janette Dean, Private Citizen, Reno, Nevada:
I wanted to address where in the bill we answer some of the questions that were asked. As far as malpractice insurance, in section 1 and section 2, we do protect the physician and any person that is also helping provide the treatment. Section 2, subsection 2, paragraph (c) is where we are protecting nurses as well as anyone that is involved in furnishing or providing the drug once the physician, the manufacturer, and the individual have given informed consent. Malpractice insurance should see that those individuals are protected.

Another issue I would like to address is about the definition of the terminally ill and the terminal condition. As Mr. Handzlik pointed out, these trials can often take 10 to 15 years, and if we limit terminal patients to 6 or even 12 months, that is often not enough time for the treatment to begin to work. Some of these treatments need more than a year or two or even three to start showing their effects. Also, NRS does say the terminal condition must be an incurable and irreversible condition that, without the administration of life-sustaining treatment, will, in the opinion of the attending physician, result in death within a relatively short time. The chance is slim that they would think of this as a 20- or 30-year terminal illness. I think the physicians are going to abide by this description of being a relatively short time. That might be three years or five years, or it might only be eight months. However, at least that gives the patient time for the treatment to work.

I wanted to touch upon the phases of the trial as well. By the time the drugs reach Phase 2, 60 percent are deemed safe enough to continue. By the end of Phase 1, 40 percent of the drugs have been rejected for Phase 2. In my opinion the reason why we should let patients in at Phase 2 is that there will be different dosages. Phase 3 is trying to fine-tune the dosage to a very sharp level, as well as avoiding most common side effects. However, what we are trying to do with the intent of this bill is to help the families and patients who are thinking, What if this drug could have helped me at Phase 2 even if I would have had a smaller common side effect or the dosage could have been fine-tuned a little bit? I am willing to take that risk because my life is at risk, and my family is concerned. Phase 3, in my opinion, is just too late. That could be another four or five years of trials where they are really fine-tuning the drug for the whole general populace.

At this point, we are trying to help those who are terminal and are willing to take the extra risk because their lives are on the line. I know that the public has signed so many petitions to try to help people get over these hurdles, and, as Assemblywoman Joiner said, the clinical trials of manufacturers often do not include terminally ill patients. They do not want these people in their studies because it will affect their results. Therefore, if we require them to track the

data, they are more likely to reject the request. However, if the data is supplementary, outside of the trial, they are more likely to let them in the trial. We do want to protect the general populace, but we also want to help individuals who have no other option.

Chair Oscarson:
I appreciate that clarification. Is there any testimony in opposition to A.B. 164 in Las Vegas or in Carson City? [There was none.] Is there any neutral testimony?

Stacy M. Woodbury, MPA, Executive Director, Nevada State Medical Association:
The Nevada State Medical Association is generally in favor of A.B. 164, and we recognize the value of assisting terminally ill patients with access to drugs and devices that may be helpful. [Continued to read from written testimony (Exhibit F).]

It is very common if you are in an institutional setting and you are making decisions relating to terminally ill patients, that there is an ethics review committee or some kind of panel of your peers that you consult with prior to proceeding with treatment. We would recommend that as one option to improve the bill. [Continued to read from written testimony (Exhibit F).] We appreciate the discussion and the concerns of the Committee on liability of physicians and others who present. We have very similar concerns about that as well. I would be happy to answer any questions.

Denise Selleck, Executive Director, Nevada Osteopathic Medical Association:
My comment is ditto to what Ms. Woodbury said.

Chair Oscarson:
Is there any other neutral testimony? [There was none.]

Assemblyman Ohrenschall:
There were a lot of good points made today. It is a complicated issue. I think we know with all of our legislation that we have to be careful about unintended consequences. That is why this bill has to be carefully crafted. I would be happy to meet and work with Ms. Woodbury, Ms. Selleck, and Ms. Partida. I know they have some concerns. Other than that, I have talked to most of the stakeholders. For the most part, people do like this bill. I believe that, not only in Nevada but also as this sweeps the nation, we are going to see, as Assemblywoman Joiner said, more people knowing about this, more companies participating, and more people who need it, having this discussion with their doctors. I do appreciate the Committee's time, and I thank you all.

Chair Oscarson:
One of the things that I really appreciate from the Committee is the questions because they are ones that I had not even thought of. The broad base of knowledge on this Committee serves the state well when it comes to health issues. I wanted to state that publicly. Is there any public comment? [There was none.] Meeting is adjourned [at 1:33 p.m.].

RESPECTFULLY SUBMITTED:

_____
Karen Buck
Committee Secretary

APPROVED BY:

_____
Assemblyman James Oscarson, Chair

DATE: _____

EXHIBITS

Committee Name: Committee on Health and Human Services

Date: March 6, 2015 **Time of Meeting: 12:13 p.m.**

Bill	Exhibit	Witness/Agency	Description
	A		Agenda
	B		Attendance Roster
A.B. 28	C	Kirsten Coulombe, Committee Policy Analyst	Work Session Document
A.B. 39	D	Kirsten Coulombe, Committee Policy Analyst	Work Session Document
A.B. 41	E	Kirsten Coulombe, Committee Policy Analyst	Work Session Document
A.B. 164	F	Stacy Woodbury, Nevada State Medical Association	Written Testimony