[LB117 LB166 LB425]

The Committee on Health and Human Services met at 1:30 p.m. on Friday, January 27, 2017, in Room 1510 of the State Capitol, Lincoln, Nebraska, for the purpose of conducting a public hearing on LB425, LB166, and LB117. Senators present: Merv Riepe, Chairperson; Steve Erdman, Vice Chairperson; Sue Crawford; Sara Howard; Mark Kolterman; Lou Ann Linehan; and Matt Williams. Senators absent: None.

SENATOR RIEPE: Welcome, and thank you for being here. This is the Health and Human Services Committee. We apologize for being just a few minutes late, but we did have a vote, a call of the house, and we do extend the temporary rules that we function on in the Chamber. So with that accomplished, we are here and we're now free to go. I'm Merv Riepe; I serve as chairman of the Health and Human Services Committee. I'm from...I represent Legislative District 12, which is in Omaha with Millard and Ralston...are my territories, if you will. I'm going to go through some of the rules. I call them rules of engagement. But first I'm going to ask our committee members to introduce themselves. And then we will go through the rules, and then we'll get proceeding. So in today's interest, I'm going to start to the left here, to Senator...will open.

SENATOR LINEHAN: Hi. I'm Senator Lou Ann Linehan. I'm from District 39, which is everything in Douglas County west of 180th Street.

SENATOR WILLIAMS: Matt Williams, Legislative District 36: Dawson, Custer, and the north part of Buffalo Counties.

SENATOR CRAWFORD: Good afternoon. Senator Sue Crawford, District 45, which is eastern Sarpy County.

SENATOR HOWARD: Senator Sara Howard. I represent District 9 in midtown Omaha.

SENATOR RIEPE: We have two of our members we expect to be here, and that is Senator Kolterman and Senator Erdman. They just have not arrived and may have some other business they had to conduct prior to getting to here. You'll find that this is your opportunity to participate, and we encourage you to do that; that's part of our legislative process. And we will also...at times you'll see some committee members coming and going because they have other committees that they will either be opening bills on or testifying at. So don't take that as a personal affront, if you will. We also will have some that will be on computers and some of this information that we have is all electronics. Some of us are paper oriented and some of us are electronically oriented.

Health and Human Services Committee January 27, 2017

But we encourage the use of computers at this meeting. Today the process works as such that we will ask you to please silence or turn off your cell phones. If you're coming up to testify, we'd ask you to come up to the front row so that we can move the process along. When it gets close to when you will be testifying, the process will be: the introducer of the bill, the state senator; followed by any proponents and any opponents; and then we will have any that are testifying neutral; we will then ask Tyler, our committee clerk, to read any letters of support or opposition or neutral. If you're here and signing in, we have the orange sign-in sheets to be given to the committee clerk when you come up to testify. We would also ask you, when you get up to testify, that you please spell your name, give us your name and then spell your name out for the record, if you will. We'll also ask you to be concise. We operate on a five-minute clock. We have the...we'll have four minutes on the green, one minute on the amber, and then the red will come on and we'll ask you to conclude as quickly as you can, once the red light is on. I also...I want to read this one in, for the record. If you will not be testifying at the microphone but want to go on record as having a position on a bill being heard today, there are white sign-in sheets at each entrance where you may leave your name and other pertinent information. These sign-in sheets will become exhibits in the permanent record at the end of today's hearing. Written materials may be distributed to committee members as exhibits when you come up, only while testimony is being offered. And, if you would, hand them to a page for distribution to the committee, and the staff will then come up to testify. We need 10 copies, just as a matter of information. That said, we do now have two new senators who have joined us. Senator, would you introduce yourself and then...

SENATOR KOLTERMAN: Senator Mark Kolterman from Seward, York, and Polk Counties, District 24.

SENATOR RIEPE: And...Senator Erdman...no, Senator...

SENATOR ERDMAN: Oh.

SENATOR HOWARD: Oh, I (inaudible).

SENATOR RIEPE: Okay. This is Senator (inaudible).

SENATOR ERDMAN: Steve Erdman...Steve Erdman, District 47, which is about 80 percent of the Nebraska Panhandle.

SENATOR RIEPE: I also want to introduce Kristen Stiffler, to my right, who is our legal counsel for the Health and Human Services Committee. And to my extreme left is Tyler Mahood, who is

the committee clerk. We also have us...helping today is Brianne Hellstrom, who's from Simi Valley, California. And we also have Jordan Snader, who is from Oakland, Nebraska. And we're pleased to have them here with us, too. That said, we are going to get started with today's hearing. And the first one is LB425, and that is Senator Crawford. We appreciate you being here and it...the microphone is yours. [LB425]

SENATOR CRAWFORD: (Exhibit 1) Thank you. Good afternoon, Chairman Riepe and members of the Health and Human Services Committee. My name is Sue Crawford, S-u-e C-r-aw-f-o-r-d, and I represent the 45th Legislative District of Bellevue, Offutt, and eastern Sarpy County. I'm honored to be here today to introduce LB425 for your consideration. In 2015, with the support of some of you here in this room, LB107 was passed and signed into law by Governor Ricketts. The bill provided widely supported changes to the Nurse Practitioner Practice Act that allowed them to practice without an integrated practice agreement and put into place a transition to practice protocol. LB107 allowed full practice authority for nurse practitioners and did not change any of the collaboration, consultation, or referral provisions that remain in statute. I've asked the page to pass out a document that provides an overview of the goals of LB425 and, in particular, how they interplay with LB107. For those new members of the committee, it also provides a brief background on nurse practitioners, their role in the healthcare delivery system, where they...where in the state they practice, and the types of services that they offer. Simply, LB425 is regulatory cleanup language that is necessary to ensure the appropriate implementation of LB107 from 2015. Currently the APRN Board, which governs advanced practices nurses, including nurse practitioners, cannot proceed with the rules and regulations triggered by the passage of LB107 until the alignments are changed by the passage of the bill before you. Overall LB425 updates educational requirements for APRN-NPs, clarifies the transition to practice requirement of new graduates, and simplifies language requirements for experienced APRN-NPs moving to Nebraska from other states. To be clear, LB425 does not change scope of practice for nurse practitioners, nor does it change the requirements for licensure and practice that assure patient safety, quality, and outcomes. Furthermore, there is no fiscal note and, in my estimation, LB425 will actually allow the licensure unit dealing with nurse practitioners to work more effectively and efficiently. I want to thank the committee for their time this afternoon, and I ask for your support to advance LB425 to General File. Following me will be two testifiers who can answer any of the more technical questions that you have. With that, I'm happy to try to respond to questions at this time. [LB425]

SENATOR RIEPE: Thank you very much. Are there questions? Senator Howard and then Senator Erdman. [LB425]

SENATOR HOWARD: Thank you, Senator Riepe. Thank you, Senator Crawford. Could you...have you heard from the department about their thoughts on this bill? Have they weighed in <u>on these changes?</u> [LB425]

SENATOR CRAWFORD: I do not know if they're going to be testifying today. [LB425]

SENATOR HOWARD: Okay; that's fine. And then I wanted to...since we have some new people here, could you kind of tell the story of how you passed the bill originally and then we just missed the deadline, and tell that story so that they have a better view of the history of LB107? [LB425]

SENATOR CRAWFORD: Okay, sure. So in 2014 we had a bill that would have eliminated the integrated practice agreement and provided a transition to practice protocol for advanced practice nurses. And that bill was supported by the body; it passed, though, on the last day of session. And so it was vetoed and there was no opportunity to override the veto. So it passed by a large majority, but there was no time to override the veto because the session was over. So in 2015 we came back with that same bill and passed it earlier in the session, so it has a low number--107. And it was Governor Heineman who had vetoed it. In 2015 it was Governor Ricketts; he was supportive of the bill and signed it into law. And so there are changes that we've already been able to make, in terms of getting those nurse practitioners into practice without integrated practice agreements, but it is the case that, again, the APRN Board has indicated that these are changes that we need to make so that they can get the rules and regulations to support that policy change in place. [LB425]

SENATOR HOWARD: I always think of your bill when I look a the calendar and we have about a week before the last day of session... [LB425]

SENATOR CRAWFORD: Yes. [LB425]

SENATOR HOWARD: ...because that was the one year we didn't do that. [LB425]

SENATOR CRAWFORD: Yes. [LB425]

SENATOR HOWARD: And so we didn't have time to do any veto overrides or address any changes. Thank you. [LB425]

SENATOR CRAWFORD: Right, right. So when you look at the schedule, you'll see we have some recess days blocked in at the end, in case we need veto overrides, to prevent that from happening. Thank you. [LB425]

SENATOR HOWARD: Thank you. [LB425]

SENATOR RIEPE: Senator Erdman. [LB425]

SENATOR ERDMAN: Thank you, Chairman Riepe. Senator Crawford, so if this bill was adopted, or at one time introduced and adopted, and then last year it was approved again, are there any people practicing under the law that was adopted last year? [LB425]

SENATOR CRAWFORD: There are people behind me who can confirm. My understanding is yes. I mean there are people who clearly were already past their two years of practice. [LB425]

SENATOR ERDMAN: Okay. [LB425]

SENATOR CRAWFORD: And those individuals would be practicing without an integrated practice agreement. This clarifies those rules and regulations to make that very clear and to make sure people coming from other states...that path is clear, and those people who have that transition to practice, making sure those rules and regulations are all in place. [LB425]

SENATOR ERDMAN: So I see that, on the first page...second page there on line 20, "for 2,000 hours of initial practice." If those people are practicing now and they don't meet that requirement, will they be grandfathered in? Or will they have to go back and get the 2,000 hours? [LB425]

SENATOR CRAWFORD: Well, our original bill that we passed in...LB107...had that...had an expectation of this transition to practice. So it would be my understanding that, when they're showing this demonstration of 2,000 hours of practice, they could be banking...they could be earning those hours now. [LB425]

SENATOR ERDMAN: Okay. [LB425]

SENATOR CRAWFORD: That's my understanding; I will confirm that to make sure that's correct... [LB425]

SENATOR ERDMAN: Yeah, okay. [LB425]

SENATOR CRAWFORD: ...or perhaps someone behind me can confirm that; thank you. [LB425]

SENATOR ERDMAN: All right; thank you. [LB425]

SENATOR RIEPE: Are there other questions? I have one. Are we seeing any impact on rural health because of nurse practitioners? Or are they--most of them--on independent practice, concentrating in more urban areas? [LB425]

SENATOR CRAWFORD: When I have attended events, I meet nurse practitioners from all across the state, including some rural...including rural nurse practitioners, who are talking about the fact that they are now able to practice in their state. One of the great stories was one of our ranchers who was way out west, I think; and she had gone through some pretty great sacrifices to get her schooling to practice as a nurse practitioner, and was very excited. I had a chance to meet her. That was actually a story that I think was in the New York Times... [LB425]

SENATOR RIEPE: Oh. [LB425]

SENATOR CRAWFORD: ...about the bill... [LB425]

SENATOR RIEPE: Wow. [LB425]

SENATOR CRAWFORD: ...and about this rancher who was making a sacrifice to get this medical training because she wanted to serve her rural community. And so she's an example of someone who would be able to practice and serve that rural community because of this bill. [LB425]

SENATOR RIEPE: Sounds like a real success story with that one at least. Other questions? [LB425]

SENATOR ERDMAN: Maybe... [LB425]

SENATOR RIEPE: Senator Erdman. [LB425]

SENATOR ERDMAN: Thank you, Chairman Riepe. Maybe just a clarification. Can you tell me what way out west is (laughter)? [LB425]

SENATOR CRAWFORD: I mean way out west. [LB425]

SENATOR ERDMAN: Like by Kearney? [LB425]

SENATOR HOWARD: It's by your neighborhood. [LB425]

SENATOR CRAWFORD: No, no...further, further west, like... [LB425]

SENATOR ERDMAN: North Platte? [LB425]

SENATOR CRAWFORD: ...in Senator Brewer's district. [LB425]

SENATOR ERDMAN: Oh, wow. Thank you. [LB425]

SENATOR CRAWFORD: Yes. [LB425]

SENATOR RIEPE: For those in the audience that may not know, Senator Hughes, I think, lives a quarter of a mile from Colorado, so... [LB425]

SENATOR CRAWFORD: Right. [LB425]

SENATOR KOLTERMAN: That's not out west. [LB425]

SENATOR RIEPE: ...you don't win the prize, Senator (laughter). Thank you very much. [LB425]

SENATOR CRAWFORD: Thank you. [LB425]

SENATOR RIEPE: And we will hear proponents to follow. [LB425]

ALICE KINDSCHUH: (Exhibit 2) Good afternoon, Chairman Riepe, members of the committee. My name is Alice Kindschuh, A-l-i-c-e K-i-n-d-s-c-h-u-h, and I am speaking today on behalf of the Nebraska Board of Advanced Practice Registered Nurses, the APRN Board, in support of LB425, a bill designed to clarify provisions of the Nurse Practitioner Act (sic: Nurse Practitioner Practice Act). As an APRN Board member, I represent the nine-member board that governs advanced practice nurses: nurse practitioners, clinical nurse specialists, nurse midwives, and certified registered nurse anesthetists. Our goal, as a board, is to work towards common statutes and regulations that apply to all four APRN groups, to eliminate rework and expedite licensure. In order to do this, LB425 proposes to simplify antiquated requirements for coursework, as well as confounding language related to when malpractice insurance must be in place for clinical practice. It also adds a provision for grandfathering existing nurse practitioners into practice, which was inadvertently missing from the current law. I am the program director for the Nebraska Methodist doctor of nursing practice programs in Omaha. Methodist will graduate their first class of APRN-DNP students in 2017, and I feel it is important to minimize

the struggles they may encounter as they enter into practice as APRNs in this state. For these reasons, I support the changes proposed by this bill. I would like to be clear in that this bill proposes no new changes to the nurse practitioner's scope of practice, but merely a clarification of language that will better facilitate nurse practitioner licensure by DHHS. The APRN Board encourages the Health and Human Services Committee to advance LB425. The position, as stated in this letter, represents the position of the Board of Advanced Practice Registered Nurses and does not necessarily represent the position of the Department of Health and Human Services or the Division of Public Health. Thank you; I am happy to respond to any questions. [LB425]

SENATOR RIEPE: Okay; thank you very much. Are there questions? Senator Linehan and then Senator Williams. [LB425]

SENATOR LINEHAN: Thank you for being here today. Right at the very...at the top of page 2-it's line 4--explain, because I don't see how this exactly fits into what we're saying. This is a graduate-level program accredited by the national accrediting body recognized by the United States Department of Education. And then we strike minimum full-time academic year. So Methodist would, I assume, where you're at, qualifies under the U.S. Department of Education? [LB425]

ALICE KINDSCHUH: Correct. For an APRN to...who graduates from a program, they must be from an accredited program. And accreditation is very stringent, and it puts into practice our...into place...all these rules regarding to pharmacology, pathophysiology, all those sorts of things. So those requirements are met through accreditation and are not necessarily necessary to put into statute here. [LB425]

SENATOR LINEHAN: So they are accredited by the Department of Ed, United States Department of Ed. [LB425]

ALICE KINDSCHUH: Correct. [LB425]

SENATOR LINEHAN: And Methodist is accredited through that. [LB425]

ALICE KINDSCHUH: Yes. [LB425]

SENATOR LINEHAN: And UNMC has it. [LB425]

ALICE KINDSCHUH: Every college that graduates APRNs is. [LB425]

SENATOR LINEHAN: Okay. So if a student graduated from a school that's accredited in Kansas or California or Wyoming, they could work here without...that's all they need? [LB425]

ALICE KINDSCHUH: An accredited school is what you need for licensure, yes. [LB425]

SENATOR LINEHAN: Okay, okay; thank you. [LB425]

ALICE KINDSCHUH: Thank you. [LB425]

SENATOR RIEPE: Senator Williams. [LB425]

SENATOR WILLIAMS: Thank you, Chairman Riepe. I was just going to ask...your first graduating class is this year. Do you know how many will be graduating, roughly? [LB425]

ALICE KINDSCHUH: I do. There will be 11. [LB425]

SENATOR WILLIAMS: 11? Do you know how many graduate from all of the various schools, roughly? [LB425]

ALICE KINDSCHUH: Oh. I would say hundreds. [LB425]

SENATOR WILLIAMS: Approximately 100? Do you when they are seeking placement for jobs, where are most of them going? [LB425]

ALICE KINDSCHUH: That's very difficult to answer. It depends on where they're living. Most of our APRN programs are online, so many times we have students from all over the state and sometimes they choose to remain in their home communities. We certainly have a large number from the greater Omaha/Lincoln area. [LB425]

SENATOR WILLIAMS: Because this is a...it's a graduate-level program, so most of these students are working already, you know, to start with. [LB425]

ALICE KINDSCHUH: They're registered nurses, yes. [LB425]

SENATOR WILLIAMS: Okay; thank you. [LB425]

ALICE KINDSCHUH: Um-hum. [LB425]

SENATOR RIEPE: Are there added questions? [LB425]

SENATOR LINEHAN: I'm sorry. [LB425]

SENATOR RIEPE: Oh. Senator Linehan. [LB425]

SENATOR LINEHAN: Specialties...is there one that's for behavioral health? Is there any specialty? [LB425]

ALICE KINDSCHUH: You...you can get a mental health nurse practitioner, yes. [LB425]

SENATOR LINEHAN: Thank you. [LB425]

SENATOR RIEPE: Senator Kolterman. [LB425]

SENATOR KOLTERMAN: Thank you. And thank you for coming today. Would you talk a little bit about...you eluded to the professional liability insurance. If you're going to do a practice on your own, what kind of outlets are there for the professional liability insurance of the nurse practitioner? [LB425]

ALICE KINDSCHUH: There are certainly organizations that provide nurse practitioner liability insurance. Right now it...you are required to have it to apply for a license And it's difficult to get nurse practitioner insurance when you do not have...you have not secured a position. Also, many times through their employment, nurse practitioner insurance is provided. And so it might be an unnecessary cost to them because, once they secure that employment, they can get it through their workplace. [LB425]

SENATOR KOLTERMAN: Do you know if they're tied in, in any way, with medical...the medical liability that the doctors have available through the state? [LB425]

ALICE KINDSCHUH: I think the speaker that is going to follow me would be best prepared to answer that. She is a nurse practitioner; I am not. [LB425]

SENATOR KOLTERMAN: Okay. [LB425]

ALICE KINDSCHUH: And so she could answer that question much better than I. [LB425]

SENATOR KOLTERMAN: Thank you. [LB425]

SENATOR RIEPE: Are there other questions? A question I have: What is your demand, pent-up demand...students making application for the program? You said you had 11 in the program. [LB425]

ALICE KINDSCHUH: How many students apply each year? [LB425]

SENATOR RIEPE: Or on average. [LB425]

ALICE KINDSCHUH: Well, Nebraska Methodist just started their doctor of nursing practice program in 2014. And each subsequent fall we've been admitting more. So this fall we will--fall of 2017--we plan on admitting 20. And we usually will have 36-40 applicants. [LB425]

SENATOR RIEPE: How long is the program? [LB425]

ALICE KINDSCHUH: From bachelor's degree to DNP is three years. [LB425]

SENATOR RIEPE: Oh. [LB425]

ALICE KINDSCHUH: Full time, three full years. [LB425]

SENATOR RIEPE: Okay. Are there other questions? Hearing none, thank you very much. [LB425]

ALICE KINDSCHUH: Thank you. [LB425]

SENATOR RIEPE: We'll move on to our next proponent. [LB425]

TARA WHITMIRE: (Exhibit 3) Good afternoon, Chairman Riepe and members of the Health and Human Services Committee. My name is Tara Whitmire, T-a-r-a W-h-i-t-m-i-r-e. I am president-elect of Nebraska Nurse Practitioners and past legislative committee chair in 2015, when LB107 was passed. And I am here today in support of LB425. LB107 removed the integrated practice agreement requirement between nurse practitioners and physicians. Changes

Health and Human Services Committee January 27, 2017

in statutory provisions at that time inadvertently transposed requirements for practice to the time of licensure, including evidence of liability insurance. Many nurse practitioners do not acquire insurance until they are employed. It also became apparent, as Licensure Unit staff attempted to update the regulations for NP licensure to reflect statutory changes and conform to the Uniform Credentialing Act that descriptors for education hours and course requirements in the NP Practice Act were no longer relevant to current graduate education. Transition to practice requirements were not clearly identified. A grandfathering provision for existing licensees has been overlooked. The result has been rework and needless delays regarding licensure decisions for otherwise qualified applicants. These difficulties became even more apparent when the DHHS Licensure Unit was selected as one of the key focus areas for the process improvement initiative at DHHS. The proposed changes in language and descriptors in the NP Practice Act are summarized in the order that they appear in LB425, in the full written text of this testimony. In the interest of time. I will review one of these to illustrate the nature of the proposed revisions. Number 3: Section 38-2317(1)(c): evidence of having completed 30 contact hours of education in Pharmacotherapeutics is deleted. This language dates to the origin of the licensure requirements when prescriptive authority was new for nurse practitioners. The intent was to establish consistent baseline requirements for education and pharmacology to prepare nurse practitioners to prescribe medications. Pharmacotherapeutics are a standard inclusion in modern graduate curricula in compliance with national accreditation standards. As the requirement is currently written in statute, licensure staff must conduct a line-by-line review of transcripts for course content and hours that may be listed as individual courses or integrated in other courses. In the case of the latter, applicants are then required to submit additional proof, which they may or may not be able to retrieve from their program subsequent to the passage of time and inevitable changes in faculty and revisions in curriculum. There is no fiscal note associated with LB425. There are no changes to NP scope of practice, entry into practice, or licensure requirements. The proposed changes in language and descriptors eliminate rework and expedite licensure decisions for qualified applicants. Licensure staff will be able to proceed with much needed revisions, and licensure regulations within the department. I am pleased to be here today to testify on behalf Nebraska Nurse Practitioners. I wish to acknowledge Senator Crawford's sponsorship of LB107 that made Nebraska the 20th state with full practice authority for nurse practitioners. We are grateful to her and Senator Watermeier for their ongoing support of our profession, as cosponsors for the proposal before you today. Senators, thank you for your dedication and service to the citizens of our state. I am able to respond to any questions at this time. [LB425]

SENATOR RIEPE: Thank you very much. Are there questions? Any questions? Senator Kolterman. [LB425]

SENATOR KOLTERMAN: Are you the one I'm supposed to ask about professional liability (laughter)? [LB425]

TARA WHITMIRE: Yes. [LB425]

SENATOR KOLTERMAN: Would you tell me a little bit about that, please? [LB425]

TARA WHITMIRE: So, as I said, most...and as Alice had said, most nurse practitioners obtain malpractice insurance once they've been employed by their employers. And they are not a part of the malpractice...the malpractice of the state. They have their own insurance; they're not necessarily carried under the physician's malpractice insurance. [LB425]

SENATOR RIEPE: So you then benefit from the cap? [LB425]

TARA WHITMIRE: No. [LB425]

SENATOR KOLTERMAN: No. That's where I'm getting... [LB425]

TARA WHITMIRE: No, no we don't. [LB425]

SENATOR KOLTERMAN: So can I continue? [LB425]

SENATOR RIEPE: Please do. [LB425]

SENATOR KOLTERMAN: So my question is...walk me through this. You want to be a nurse practitioner, not in private practice, but with this credential. Do you then have to go out and apply for professional liability insurance and have that granted before you can open up your practice? [LB425]

TARA WHITMIRE: If you wanted to have your own practice, yes; I believe that's how it would be. But if you... [LB425]

SENATOR KOLTERMAN: And it doesn't dovetail off of the doctor or the other parties that you're coordinating with. [LB425]

TARA WHITMIRE: No. [LB425]

SENATOR KOLTERMAN: Okay; thank you. [LB425]

TARA WHITMIRE: Um-hum. [LB425]

SENATOR RIEPE: Okay. Other questions? Seeing none, thank you very much. [LB425]

TARA WHITMIRE: Thank you. [LB425]

SENATOR RIEPE: And will we move on to the next proponent. Are there other proponents? Are there any opponents, any in opposition? Seeing none, are there any testifying in a neutral capacity? Seeing none, Senator Crawford, would you like to close? [LB425]

SENATOR CRAWFORD: Yes, thank you. Well, I thank you very much for your attention to this bill, and it's an exciting change in healthcare. And I appreciate the efforts of the stakeholders, the nurse practitioners, to make sure we get all the changes made to make licensure as efficient and clear as possible, and also to make it easier for people to move into Nebraska and start practicing right away, if they've already met those requirements. That's a part of what...the bill really cleans that up, as well. I wanted to come back to a couple of questions that were answered. I don't have in front of me the change in rural practice but in your fact sheet you'll see that in Nebraska 44 percent of primary care NPs practice in rural areas; so you have a large percent of these folks, the primary care nurse practitioners, practicing in rural areas. And actually, in response to Senator Linehan's question, really, one of the areas that we expect growth and one of the areas where we see nurse practitioners stepping into a critical need in the state is the psychiatric nurse practitioner. They are an important mid-level prescriber in our behavioral mental health system. And so to be able to...part of one of the needs that we saw, as we were working on the bill, was that we were having some trouble recruiting and retaining those trained folks and, also, a lot of different ways in which someone with the...who is a psychiatric nurse practitioner could fit into lots of different institutions and really help bolster mental health care and be every healthcare that could be offered. And so that's really an important piece of improving and strengthening our behavioral mental healthcare system in the state. [LB425]

SENATOR LINEHAN: Excellent, that'll be good; thank you. [LB425]

SENATOR CRAWFORD: Thank you. [LB425]

SENATOR RIEPE: Very good. Senator Howard. [LB425]

SENATOR HOWARD: Thank you, Senator Riepe. Does this have an E clause on it? [LB425]

SENATOR CRAWFORD: I do not think it does. [LB425]

SENATOR HOWARD: Does it need one? [LB425]

SENATOR CRAWFORD: That's a good point. That'd be a good point. I think it would be supported enough that we could easily do that. So good suggestion. [LB425]

SENATOR HOWARD: Wonderful; thank you. [LB425]

SENATOR RIEPE: Good point. [LB425]

SENATOR CRAWFORD: Thank you. [LB425]

SENATOR RIEPE: Other questions or comments? Hearing none, thank you very much. [LB425]

SENATOR CRAWFORD: Thank you. [LB425]

SENATOR RIEPE: And with that, we conclude the hearing on LB...well, do we have read-ins? [LB425]

TYLER MAHOOD: I do not have any letters for the record for LB425. [LB425]

SENATOR RIEPE: Okay. So now we conclude the hearing on LB425. Thank you very much. [LB425]

SENATOR KOLTERMAN: There go all my friends (laughter). [LB425]

SENATOR RIEPE: Nothing personal, but... [LB425]

SENATOR KOLTERMAN: I can clear a room. [LB425]

SENATOR WILLIAMS: You're good at it. [LB425]

SENATOR RIEPE: We will now open the hearing for LB166, which is Senator Kolterman. The microphone is yours, sir. [LB166]

SENATOR KOLTERMAN: Good afternoon, Chairman Riepe and fellow members of the Health and Human Services Committee. I am Senator Mark Kolterman, M-a-r-k K-o-l-t-e-r-m-a-n, and I

Health and Human Services Committee January 27, 2017

represent the 24th District of the Nebraska Legislature. LB166 was introduced at the request of the Nebraska Pharmacists Association. The NPA has had several bills before this committee in the past few years to update pharmacy practice laws. While the statutes have evolved and been updated over the years as pharmacy practice has evolved, the regulations that govern pharmacy have not been updated since 2005 and 2007, but were recently set for a hearing this past December. In review of those regulations, the NPA found several references that needed to be put into statute for consistency and harmonization. LB166 updates a provision in the Controlled Substances Act to mirror federal law with regard to partial fills for controlled substances, which was passed in July 2016. Finally, LB166 adds provisions to the Health Care Facility Licensure Act to add provisions to statute to clarify the process for hospitals, particularly those in rural and underserved communities, to be able to provide medications to patients who are discharged who need medication when a local pharmacy is not open. This is particularly important for patients who visit emergency rooms in the critical-access hospitals. As I've said in the past, the professionals are behind me. This is a very technical bill in nature. I'm not a pharmacist; I'm the messenger. And so I would like to have you ask any questions after the testifier. I will be here to close. I will...if I can help with... [LB166]

SENATOR RIEPE: Okay. [LB166]

SENATOR KOLTERMAN: ...questions, I'd take them now. [LB166]

SENATOR RIEPE: Thank you; we'll take that into consideration. Is there anyone that has a question for Senator Kolterman? If not, we will... [LB166]

SENATOR KOLTERMAN: Thank you. [LB166]

SENATOR RIEPE: Thank you very much. Proponents? [LB166]

JONI COVER: Good afternoon, Senator Riepe and members of the Health and Human Services Committee. My name is Joni Cover; it's J-o-n-i C-o-v-e-r, and I'm the CEO of the Nebraska Pharmacist Association. And I'm here today in support of LB166, and I just want to say thank you to Senator Kolterman for carrying this bill for us. As he pointed out, there are some technical things and there are some clean-up things in the bill. I want to talk about the technical things first because then, if I run out of time, the clean-up things aren't as...not that they're not important, but anyway. I want to talk about...one of the things that he brought up was the change, pursuant to federal law, partial fills of controlled substances. The Care Act was passed and signed by President Obama in July 2016, which allows for partial fills of controlled substances for Schedule 2 to be filled within 30 days instead of 72 hours; that's an important provision for us so we want to harmonize that section so we added that to state law. That way we don't...it's

Health and Human Services Committee January 27, 2017

particularly important for our chain stores that are operated in more than one state, so that there's some consistency, because many states don't have that requirement like 72 hours, like we do, so consistency for them. But it's a good provision. We added a provision that says if you change your pharmacist in charge in your pharmacy, you need to have a controlled substances inventory audit. We do that so that we can make sure that there's no diversion when somebody leaves. We want to make sure...with all the things going on with controlled substances these days, we want to make sure that we keep pretty...pretty close tabs on that. There's a provision in our state statutes now that allows a pharmacist to sell hypodermic needles for the prevention of the spread of infectious disease. It happens a lot in HIV clinics or HIV patients, or drug abuse patients will come in and buy syringes in pharmacies, which is legal and it isn't considered drug paraphernalia. But the practicality of that is that it's not always the pharmacist that is selling the hypodermic needles; it's the technician or the student or the clerk. So we just expanded that language. We worked with the Attorney General's office so that they were okay with that. So we just made that slight tweak. We added a definition of repackaging. There's a definition currently in the Wholesale Drug Act (sic: Wholesale Drug Distributor Licensing Act) that talks about repackaging, but that's not the same activity as what is done in pharmacies. So we wanted to make sure that we had separate provisions. We changed, or me moved a provision dealing with pharmaceutical care agreements, which is currently in regulation; we put that into state statute. We've actually had a discussion with DHHS regarding there's a word in there that we need to change. And so we will be bringing an amendment forward, working with legal counsel and with Senator Kolterman's office. And the hospitals have brought up a few issues that we need to address. And we agree with that, so we'll be bringing an amendment; that's one thing we need to fix. We eliminated a provision that requires written training for pharmacy technicians. We eliminated the technician manual, which was something that we started when...before my time. When pharmacy technicians were first allowed in pharmacies we had a manual that pharmacists had to fill out to say we trained them on these things. Well, that ship has, sort of, sailed; we don't have to do that anymore. But pharmacists are still being told that they have to have written policies in place to prove that you trained your staff. I would...we would argue that, if we didn't train our staff, they probably wouldn't still be working there. So considering pharmacy technicians are under the guise of what a pharmacist does, and it's pharmacists that's ultimately responsible for what they do. They do need to be trained, but we don't need to have written policies to prove that they have been trained, so we struck that provision. A big section in this bill is Section 20, which talks about hospital continuation of care, and that's where we'll be working with some of our hospitals to tweak some of the language, two provisions in there that are important. So if I take my child in, who is an asthmatic and he gets an inhaler, two or three puffs of the inhaler while he's in the hospital, we don't want hospitals to have to throw that away or the patients did not get to take it home, because it's a waste of money. So we want to put some specific provisions in statute that says you can do that. The other provision, as Senator Kolterman said, is if you come in to the hospital at Bridgeport on a Saturday evening because you're out riding your horse and you hurt your leg--you fell off your horse and you hurt your

Health and Human Services Committee January 27, 2017

leg--there's probably not a pharmacy open within 100 miles that's open 24/7. So we want to have some continuation of care provisions so that you can take medication home to take care of you-patient care--until the pharmacy is open on Monday. So we added that. We wanted some consistency, but yet we still wanted it to be broad enough that the hospital in Bridgeport and Alliance and Gothenburg can have a little bit of flexibility in what they do because they don't do the same things as Methodist and CHI and Bryan Health. So again, it's really about the people that work there and the policies that they set. We included a provision to eliminate multi-dose vials in emergency boxes which are in long-term care facilities. I realize this is really technical; I'm sorry. But I just want you to know what we're doing so that we're not trying to hide anything. We're doing that so that if a resident in a long-term care facility needs insulin...right now they can't have insulin unless it's prescribed to them. So this would be in an E-box, so if somebody needed insulin they can access to that. So that's a good thing, and that's something that our longterm care pharmacists have said they've needed for a while, because we're getting more acute patients into long-term care facilities, particularly on a Friday night, Saturday dismissal from the hospital. And then this is kind of an interesting provision along the same lines as E-boxes. Right now if a pharmacy takes an emergency box to the long-term care facility, the director of nursing has to sign that they received that, which is great if the director of nursing is there. But if the director of nursing is not there, then they can't leave the E-box. So we added "or designee" language to the bill so that you can have...the director of nursing can have a designee for somebody to sign that you got the E-box. So those are the real technical sort of meaty provisions of the bill. There's a lot of other things in there and, if you'd like me to go through them, I'd be happy to. But a lot of the things I didn't talk about...Senator Kolterman had mentioned that we are in the process of updating. We've...DHHS is in the process of updating the pharmacy regulations, which haven't been updated for many, many years. And as they were going through-we were going through to make sure that we had the right words--we realized that there's some things that we left out when we moved things into statute that really need to all be put into statute so they're all in the same place. So for example, physicians or prescribers will often write a prescription and they'll write PRN, so as needed, and that was...we forgot to put that into statute. So I'm going to stop talking. [LB166]

SENATOR RIEPE: Okay. Hopefully we'll...some questions may come that will allow you to explain further... [LB166]

JONI COVER: Okay. [LB166]

SENATOR RIEPE: ...some of the details. We'll see how that goes. Any questions? Senator Howard, we'll let you go. [LB166]

SENATOR HOWARD: Thank you, Senator Riepe. I actually have a language question. Do you have a copy of your bill? [LB166]

JONI COVER: I do; I do. Can I use the same phrase, "I'm not a pharmacist?" So if you have anything technical, I'll have to get the smart people to talk to you. [LB166]

SENATOR HOWARD: No, this is more some of...some...a reasoning question. [LB166]

JONI COVER: Okay. [LB166]

SENATOR HOWARD: So on page 5, in line 22, you got rid of the emergency situation's definition in rules and regs, and then did you lift the exact same reg and put it down on line 28? Is it just the reg and putting it into statute? [LB166]

JONI COVER: Yes, I believe we did. I believe that's mirrored language. There were...there was one that we lifted from regulations and put into statute that we tweaked because the regulations language was old language. [LB166]

SENATOR HOWARD: Okay. [LB166]

JONI COVER: I can't remember if it was this one or if it was another one. But yes, the language that we took from regs and put into statute is pretty much, in every place, word for word, so... [LB166]

SENATOR HOWARD: Okay. And so for this one, can you help me understand what an emergency situation is? [LB166]

JONI COVER: Well, I will try. Again, not the...not the person who is a pharmacist, so. In a situation like this I believe that controlled substances...for a Schedule II drug to be dispensed in Nebraska, you have to have a written prescription or it has to be electronically prescribed. [LB166]

SENATOR HOWARD: Right. But this one uses the language of administration. [LB166]

JONI COVER: And maybe we need to tweak that. Let me...I'm going to have to go back and look at it really quick. [LB166]

SENATOR CRAWFORD: Administration. [LB166]

JONI COVER: Hmm. I'll have to go back and check that. I believe...I believe that came from regulations which those regulations are for pharmacy practice, not... [LB166]

SENATOR HOWARD: Right. [LB166]

JONI COVER: ...hospital practice. [LB166]

SENATOR HOWARD: Right. [LB166]

JONI COVER: So let me check on that; I'll get back to you. [LB166]

SENATOR HOWARD: Thank you. [LB166]

JONI COVER: That's a great catch, and I don't know. Again, it came from regs, so I want to make sure that we're consistent. [LB166]

SENATOR HOWARD: Right. [LB166]

JONI COVER: So I will make a big, purple circle here and make sure that I get back to you on that. [LB166]

SENATOR HOWARD: And then the other question I had was on page 21, on line 26. [LB166]

JONI COVER: Okay. Hold on; I've got to get there. Line 21...or page 21, line 26. Okay. [LB166]

SENATOR HOWARD: And this is, I think, going to the dispensing upon discharge. [LB166]

JONI COVER: Um-hum. [LB166]

SENATOR HOWARD: And this one talks about the judgment of the practitioner, and they're able to dispense a sufficient quantity. But we don't have...do we have guardrails and regs around what a sufficient quantity and what that might look like? [LB166]

JONI COVER: No. That is where, you know, we've talked about, with controlled substances, putting in best practice guidelines... [LB166]

SENATOR HOWARD: Right. [LB166]

JONI COVER: ...because there's no quantity limits on controlled substances. [LB166]

SENATOR HOWARD: Right. [LB166]

JONI COVER: So we've talked about putting in hour limits, like you can have a 72-hour supply, or something like that. But we haven't done that. [LB166]

SENATOR HOWARD: Okay. [LB166]

JONI COVER: So I kind of, I kind of assume that what will happen down the road...maybe the next clean-up bill we do... [LB166]

SENATOR HOWARD: Okay. [LB166]

JONI COVER: ...is maybe we'll have to then go in and say only this much. So again, it's the...it's the "do I live in Bridgeport or do I live in Omaha" situation... [LB166]

SENATOR HOWARD: Um-hum. Um-hum. [LB166]

JONI COVER: ...because if I live out in the middle of Timbuktu, maybe I'm going to need more...I say Timbuktu because I grew up in Timbuktu, so... [LB166]

SENATOR RIEPE: Oh sure. [LB166]

JONI COVER: Timbuktu...I may not be able to get to the pharmacy on Monday. So we want to be able to have more quantity available if I can't get there. [LB166]

SENATOR HOWARD: Right. [LB166]

JONI COVER: So some flexibility for the healthcare providers and, you know, with the PDMP reporting, hopefully we'll be able to see that, so... [LB166]

SENATOR HOWARD: Right. Thank you. [LB166]

JONI COVER: You're welcome. Good questions. [LB166]

SENATOR RIEPE: Additional questions from the committee? Senator Williams. [LB166]

SENATOR WILLIAMS: Thank you, Chairman Riepe. And thank you, Joni. My question surrounds the fact that you suggested fairly early in your testimony that there would need to be an amendment that you would be bringing. [LB166]

JONI COVER: Yes. [LB166]

SENATOR WILLIAMS: And then, later in your testimony, it seemed to be indicated that there were some other things you were still looking at needing to do in this. My question then is for all of us to consider the process that we're in. We're having a hearing today on the bill, and then you're talking about immediate changes. In any of those changes there would not be a hearing on those. [LB166]

JONI COVER: Correct. [LB166]

SENATOR WILLIAMS: So would...who would you...are there people that are going to be opposed to what we're talking about in this legislation? [LB166]

JONI COVER: Well, you know, like I told Senator Kolterman today when I was speaking with him about the bill, there's maybe people that are opposed that I don't know about, so I can't say a definitive no. But the people that I've heard from on the bill are the ones that I have said: I will work with you on an amendment. I can give you a couple of examples of amendments that we're going to bring forward. [LB166]

SENATOR WILLIAMS: Okay; please do. [LB166]

JONI COVER: If you look at Section 20, here's a great example: Section 20, which is... [LB166]

SENATOR RIEPE: Is there a page on that? [LB166]

JONI COVER: ...starts on page 21...page 21. [LB166]

SENATOR RIEPE: Okay. [LB166]

JONI COVER: On page...actually on page 22, on line 10, where it says, "Prior to providing the drug to the patient, a written order shall be in the patient's record." We need to add the word "or electronic" because many of our hospitals have electronic records. And we have that you can only put it in the paper record. So I will tell you that we won't bring anything forward in an amendment that hasn't been agreed to, so I don't know if that makes you feel better or worse. [LB166]

SENATOR WILLIAMS: My concern is always, always that process... [LB166]

JONI COVER: Right. [LB166]

SENATOR WILLIAMS: ...where we're going through where, if... [LB166]

JONI COVER: Right. [LB166]

SENATOR WILLIAMS: ...if you don't have a hearing, people don't have... [LB166]

JONI COVER: Right. [LB166]

SENATOR WILLIAMS: ...the opportunity to voice their concerns about those things. [LB166]

JONI COVER: Right, right. There...I will say that, when I've done this in the past, I won't bring anything substantive that I would feel like, okay, we need to have another hearing about this. We've have people approach us to make changes to the bill. [LB166]

SENATOR WILLIAMS: Other people don't make that promise. [LB166]

JONI COVER: Well, I'm going to. We've had people suggest that we tweak some things and I've said no, that's outside of the scope of what this bill...you know, we're happy to talk about it over the interim if we need to bring something back next year. [LB166]

SENATOR WILLIAMS: Right. [LB166]

JONI COVER: But we really want to maintain what this...what's in here. So... [LB166]

SENATOR WILLIAMS: Thank you. [LB166]

JONI COVER: You're welcome. [LB166]

SENATOR RIEPE: It's a very good point that Senator Williams makes; it's so that it doesn't circumvent the hearing process. [LB166]

JONI COVER: Right. [LB166]

SENATOR RIEPE: How many of those amendments do you anticipate? And will you have those to us posthaste so that, as we Exec, we will have an opportunity to look at those? [LB166]

JONI COVER: Yeah, I hope to have it to you early next week--Monday, Tuesday. I...really, what I think will happen is it will be mostly this hospital section in Section 20, because we don't want to put things in place that shouldn't be there. I will check on your administration language to make sure that that's correct. Let me think of what other section that I had somebody ask me a question about. In the Pharmaceutical Care Agreement, the department had asked us if we, because in the regulation here--section--there's a definition of practice agreement. In pharmacy, people say pharmaceutical care agreement or practice agreement or collaborative practice agreement, but there's no definition of practice agreement. So we may just add that word into the definition. So it will be things like that. There won't be anything that's substantive. [LB166]

SENATOR RIEPE: We're very accommodating here; we only ask for perfection. [LB166]

JONI COVER: Well, sorry (laughter). So yeah, I will work with legal to get that all taken care of, early as I can. [LB166]

SENATOR RIEPE: Okay, okay. Senator Erdman. [LB166]

SENATOR ERDMAN: Thank you, Chairman Riepe. Just for clarification, Bridgeport Hospital is in my district and so is Timbuktu (laughter). [LB166]

JONI COVER: I would agree with that. [LB166]

SENATOR RIEPE: Okay; thank you. [LB166]

SENATOR WILLIAMS: I thought that was in Brewer's district. [LB166]

SENATOR ERDMAN: No. [LB166]

SENATOR RIEPE: Other questions or comments, anything? Thank you for being here, and we will ask for any additional proponents. [LB166]

JONI COVER: Okay; thank you. [LB166]

SENATOR RIEPE: Any others speaking on behalf of LB166? Here we go. [LB166]

ELISABETH HURST: Good afternoon. [LB166]

SENATOR RIEPE: Hello again. [LB166]

ELISABETH HURST: Chairman Riepe, members of the HHS Committee, my name is Elisabeth Hurst, E-l-i-s-a-b-e-t-h H-u-r-s-t, and I'm director of advocacy with the Nebraska Hospital Association. I'm here today on behalf of Nebraska hospitals and the over 40,000 individuals they employ, in support of LB166. We thank the Nebraska Pharmacists Association and Senator Kolterman for putting together this language, which we think will help clarify some of the processes that Ms. Cover discussed. We did have several concerns with the language; and we are confident that those will be addressed in the forthcoming amendment, and are working very closely with Ms. Cover on those. I will point out specifically in Section 20(3)(j), the frequency of the physical inventory of the drugs is the main concern, which I think we'll be seeing, hopefully, in that amendment. I'm also not an expert in this area, but I am happy to answer any questions that I can or seek out an answer in lieu of one. [LB166]

SENATOR RIEPE: Are there questions from the members of the committee? Hearing none, thank you for being with us. [LB166]

ELISABETH HURST: All right; thank you. [LB166]

SENATOR RIEPE: Additional proponents? Seeing no additional proponents, any opponents? Seeing none, any in the neutral capacity? Seeing none, Tyler, do we have any letters? [LB166]

TYLER MAHOOD: Yes. I have two letters: One was signed by Kathy Siefken of the Nebraska Grocers Association (sic: Nebraska Grocery Industry Association), in support: and a letter signed by Michael Powell and Allison Dering-Anderson, who represented themselves with a letter of support. [LB166]

SENATOR RIEPE: No letters in opposition; okay. Thank you very much. With that, Senator Kolterman, we're here for your closing, please. [LB166]

SENATOR KOLTERMAN: Thank you, Senator Riepe. I really appreciate the fact that this is a very important piece of legislation. In the past six months, as many of you know, I've had an opportunity to frequent hospitals--emergency rooms. And I can tell you some of the practices that have been put into place from our legislation with prescription drug monitoring are working. And when they limit the amount of drugs you can take home and the amount of drugs that can be prescribed and things of that nature, it's of utmost importance. I was very supportive of Senator Howard's bill last year. So we need to get this right. I will work with Joni and the Hospital Association and those involved to get the right language. I will probably ask that we hold this in committee until we get that language, and can thoroughly explain it to everybody, before we move it to the floor. So thank you for the hearing today, and I would try to answer any questions you might have. [LB166]

SENATOR RIEPE: Are there any questions of Senator Kolterman? And Senator Kolterman, I think you're going to have an opportunity to support Senator Howard in her legislation that we shared last year. It's coming back around with some clean-up (inaudible). [LB166]

SENATOR KOLTERMAN: Clean ups. I understand that. [LB166]

SENATOR RIEPE: Thank you very much for being here. With that, that concludes the hearing on LB166. Our next hearing will be on LB117. Senator Hilkemann. [LB117]

SENATOR HILKEMANN: (Exhibits 1-3) Good afternoon, Senator Riepe and members of the Health and Human Services Committee. My name is Robert Hilkemann; that's R-o-b-e-r-t H-i-l-k-e-m-a-n-n, and I am proud to represent the 4th Legislative District. I'm here today to introduce LB117 for your consideration. LB117 is a reintroduction of LB804, which I carried last session. LB117 creates the Investigational Drug Use Act, or as better known as Right to Try. This bill allows patients with terminal illnesses to access potentially life-saving medications that have not yet been fully approved by the FDA. In order for a patient to gain access to one of these investigational medications or therapies under this legislation, first the medication or therapy must have passed Phase 1 of the FDA approval process, meaning that it must have completed basic safety testing and is part of an ongoing FDA approval process. Additionally, the patient must have a recommendation from their treating physician and they must give written informed consent. Furthermore, the patient must have tried all other conventional treatments. This truly is a last resort for those facing the unthinkable. The FDA does have a process in place for patients to access these investigational medications through its compassionate use application. However, this process is cumbersome and time-consuming; and if you or your child has a terminal illness,

Health and Human Services Committee January 27, 2017

you don't have time to waste. Right to Try removes the needless bureaucracy so that those facing unimaginable suffering can have timely access to medication or therapies that could potentially alter their fate. This bill also includes important protections. Under LB117, health insurers are not obligated to pay for this treatment. The patient is responsible for all related expenses. Manufacturers and doctors are not liable if the investigational medication does not work. And a healthcare provider cannot lose their license or certification for treating a patient with an investigational drug. Additionally, the Department of Health and Human Services suggested a technical amendment to the bill to ensure that Section 8, lines 23 and 25 on page 4, accurately describes Medicaid's relationship with providers. It changes the word "certification" to "enrollment," and you should have a copy of that that we passed out. Because Medicaid pays enrolled providers does not certify providers, as the original suggests. This is reflected in AM46, which the page has distributed. Last year, my Right to Try bill advanced from this committee on a 7-0 vote; it was named a Speaker priority but, as you well know, we had some issues that didn't get advanced last year due to time constraints near the end of the session and some things called filibusters. You know that very well, Senator Kolterman. 33 states have now adopted similar legislation with bipartisan support. And I believe that it is time for Nebraska to join this growing list of states that help terminally ill patients access to medication or therapies that may help them save their own lives. We don't know what type of therapies are on the horizon for Alzheimer's, for MS, for ALS, but we can offer patients the right to try potentially groundbreaking medications and therapies, to offer them hope when conventional therapy has not. Thank you for your consideration, and I will answer any questions you may have. And I ask that you advance LB117 to General File. [LB117]

SENATOR RIEPE: Thank you, Senator Hilkemann. Are there questions? Sara...Senator Howard. [LB117]

SENATOR HOWARD: Thank you, Senator Riepe. Thank you, Senator Hilkemann. Just a few clarifying points. This is the same bill as last year? [LB117]

SENATOR HILKEMANN: It's the same bill, Senator. [LB117]

SENATOR HOWARD: Okay. And then the amendment that we had worked on is integrated into this version. [LB117]

SENATOR HILKEMANN: It is integrated into this version. [LB117]

SENATOR HOWARD: Awesome; okay. Yesterday we heard from a young doctor who said that written informed consent slowed down his practice. Can you tell us why written informed <u>consent</u> is so important in this bill? [LB117]

SENATOR HILKEMANN: Well, I think that it's important because patients have to understand that there is a risk for this medication or any of these therapies. And the other thing, Senators, is that people...sometimes they get a false sense of hope that this is absolutely going to cure them, and that's not the case; it may not. And so we need...a patient needs to fully understand that, and going through that process of informed consent is very important for that. And it also provides protection for the doctor and for whatever institution is providing this therapy as well, that they have explained to that patient that this is experimental. It's better to have all this agreed to before you begin than after you begin. [LB117]

SENATOR HOWARD: Right. Perfect. And then one other question. There's no immunity provision for the treating physician. Is that correct? [LB117]

SENATOR HILKEMANN: No immunity? Yeah, that's...they're not held liable. [LB117]

SENATOR HOWARD: Okay. [LB117]

SENATOR HILKEMANN: Right. [LB117]

SENATOR HOWARD: They are held...they can be held? [LB117]

SENATOR HILKEMANN: They're not held liable. [LB117]

SENATOR HOWARD: They're not held liable. So there is an immunity provision. Okay; just checking. [LB117]

SENATOR HILKEMANN: Okay. [LB117]

SENATOR HOWARD: Thank you. [LB117]

SENATOR HILKEMANN: You're speaking legalese to me, Senator (laughter). [LB117]

SENATOR HOWARD: Senator Williams, I'll have you take them all from there. [LB117]

SENATOR WILLIAMS: You started me. [LB117]

SENATOR HOWARD: I'm sorry. [LB117]

SENATOR RIEPE: Are there additional questions? Senator Crawford. [LB117]

SENATOR CRAWFORD: Yes. So we might come back to that in a minute. I wanted to just clarify the portion that talks about having considered...oh, here we go, page 2, line 26, "Have considered all other treatment options approved by the United States Food and Drug Administration at the time." I guess I'm assuming that it is the physician that the documentation on the beginning of the next page, I suppose, that documents that that has been...that has happened. The treating physician documents that they have considered all other treatment options provided by the FDA at that time. [LB117]

SENATOR HILKEMANN: That's correct. [LB117]

SENATOR CRAWFORD: Considered doesn't mean the same thing as tried. So they have...so it could...perhaps there was a discussion about an option, but it wasn't appropriate in their case or not a worthwhile risk in their case. I just want to kind of clarify that because... [LB117]

SENATOR HILKEMANN: You're...you're exactly right. [LB117]

SENATOR CRAWFORD: ...one thing is to require that you try them all... [LB117]

SENATOR HILKEMANN: Right, right. [LB117]

SENATOR CRAWFORD: ...or be treated in all by all of them. This considered... [LB117]

SENATOR HILKEMANN: Yeah. [LB117]

SENATOR CRAWFORD: ...the physician documents they've considered them all. [LB117]

SENATOR HILKEMANN: That's correct. And if you...you know, as a physician you know what has a potential to help out for someone and even...and if you know it's not going to help out, you certainly considered it, but you're not going to do it if you don't think it's going to help them out. [LB117]

SENATOR CRAWFORD: Thank you. [LB117]

SENATOR RIEPE: Other questions? Senator, I have a question and that is that I've read some that there are some concerns, by the people conducting research, that this may impact...and I

don't know what the experience has been in the other states...impact their control variables as they're looking at...there's research studies to try to determine the, you know, the effectiveness of this particular drug or any drug. [LB117]

SENATOR HILKEMANN: The fact of the matter, Senator, is that a lot of...most of the time, when people go this route, the drug company will come along and put them into their study as well, so that... [LB117]

SENATOR RIEPE: Okay. [LB117]

SENATOR HILKEMANN: ...they like to take advantage of that as well. [LB117]

SENATOR RIEPE: Okay. It... [LB117]

SENATOR HILKEMANN: But if they don't, and the patient wants that therapy, this at least gives them the right to try it. [LB117]

SENATOR RIEPE: Okay. I also heard you say, on a different subject here, that the phraseology that was changed was so that it would be reimbursable under Medicare. Is that correct? [LB117]

SENATOR HILKEMANN: No, not reimbursable. That would...we had used the term "certified" and Medicaid does not certify; they just pay enrollees. That's what this is...that's what that amendment is on page 4. [LB117]

SENATOR RIEPE: Okay. So they would still be personally (inaudible). [LB117]

SENATOR HILKEMANN: It was a technical thing brought to me on that bill. [LB117]

SENATOR RIEPE: Because I was kind of trying to chase that down from Medicare on down to Medicaid, to see if there was a state liability potentially, but it sounds like no. [LB117]

SENATOR HILKEMANN: That's right; okay. [LB117]

SENATOR RIEPE: Other questions? Senator Linehan. [LB117]

SENATOR LINEHAN: I just have a question. If this would pass and then there was a patient and they wanted to try a drug that had been through the first trial, would the company that's developing the drug have ability to say: no, we don't want you to try it? How would that work? And it doesn't mean we shouldn't do this; I'm just kind of thinking in the future. We pass this and then somebody wants a drug and then the company says: well no, you can't. It's not...doesn't affect this legislation, but... [LB117]

SENATOR HILKEMANN: Yeah I...that's an interesting question. I haven't...if they say: no, you can't have our drug. [LB117]

SENATOR LINEHAN: And then I just think it's something we might... [LB117]

SENATOR HILKEMANN: I'll get you the answer to that one. [LB117]

SENATOR LINEHAN: Okay; thank you. [LB117]

SENATOR HILKEMANN: I'm not sure I have the answer to that one. [LB117]

SENATOR LINEHAN: Thank you. [LB117]

SENATOR RIEPE: Senator Williams. [LB117]

SENATOR WILLIAMS: Thank you, Senator Riepe. And thank you, Senator Hilkemann. Is this bill patterned off the bills that are...have been adopted in other states? [LB117]

SENATOR HILKEMANN: Yes, it is. [LB117]

SENATOR WILLIAMS: Okay. My concern, when you use the term "immunity," I think...our thought is that the doctor that's involved would be held harmless for handing this medication out or whatever it is. This is the stuff lawyers are made of. When it's, you know, on page 4, line 28, when it...the "treating physician while acting in good faith"--define that for me--"in the course of his or her professional practice as authorized by the Investigational Drug Use Act may not be subject to arrest, prosecution, penalty, or denial of any right or privilege granted otherwise." I'm not convinced you're protected from civil liability with that definition, and I think part of what...well, if you were the physician here, you would want to be protected from civil liability, meaning the patient themselves sues you for damages, not...you're not being arrested; you

haven't broken a law. But what you dispensed, that you arguably did in good faith, could have damaged the patient. [LB117]

SENATOR HILKEMANN: Senator, so what you're saying is that you're not talking about in the sense of malpractice; you're saying that on a civil basis. [LB117]

SENATOR WILLIAMS: Yeah. [LB117]

SENATOR HILKEMANN: Okay. [LB117]

SENATOR WILLIAMS: I think that needs to be looked into...lawyer for the committee. [LB117]

SENATOR HILKEMANN: Senator, also (inaudible). [LB117]

SENATOR WILLIAMS: Because I think the idea... [LB117]

SENATOR HILKEMANN: Um-hum. [LB117]

SENATOR WILLIAMS: ...and I'm not disagreeing with the idea...but I think the idea here is that the doctor that is acting in good faith... [LB117]

SENATOR HILKEMANN: Right. [LB117]

SENATOR WILLIAMS: ...will be held harmless. And I...if that's what we're doing, we need to be sure that this does it. [LB117]

SENATOR HILKEMANN: That's exactly what this...but that is the intent... [LB117]

SENATOR WILLIAMS: Intent. [LB117]

SENATOR HILKEMANN: My intent is that they be held harmless. [LB117]

SENATOR RIEPE: Okay. Are there...thank you very much, Senator Williams. Are there additional questions from the committee, of Senator Hilkemann? You've been very forthright; we appreciate it very much. And we assume you'll be staying around for closing. [LB117]

SENATOR HILKEMANN: I'll be here. [LB117]

SENATOR RIEPE: And we will now hear any other proponents of LB117. [LB117]

MATT SCHAEFER: Good afternoon, Chairman Riepe, members of the committee. My name is Matt Schaefer, M-a-t-t S-c-h-a-e-f-e-r, appearing today on behalf of the Nebraska Medical Association, in support of the bill. While we didn't request the senator to introduce this bill on our behalf, we did want to go on record again this year in support of this version of the bill. I think we supported it last year, as well. Anything that we can do to support well-crafted, expanded access to potentially life-saving medication to folks who don't have any other options is a good thing. I think I can try to answer a few questions that I heard. Senator Linehan, I read the bill on page 4, line 5, to say that nothing in the bill requires a drug company to make available an investigational drug. So this is one of the hurdles a patient would have to go through to use this bill, is to convince the drug company to let them use the drug. Senator Williams, I think the section you're looking for is Section 11 that, I think, provides...it says there's no cause of action is created against the manufacturer or any other person or entity involved in the care of an eligible patient when they complied, in good faith, with the terms of this act. We've discussed this as an association. We've run the language by at least one medical malpractice insurer, and they were comfortable with that language. And I think the senator has worked with us on that, as well. That's all I have prepared. I'd try to answer other questions. [LB117]

SENATOR WILLIAMS: Thank you, Lawyer Schaefer (laughter). [LB117]

SENATOR RIEPE: Thank you very much. Are there questions? The advantage of being a young law graduate...so you're still all fresh. Any other questions? Hearing none, thank you very much for being here. [LB117]

MATT SCHAEFER: Thank you. [LB117]

SENATOR RIEPE: Any other proponents? Any opponents? Any in a neutral capacity? [LB117]

JOHN LINDSAY: Senator Riepe and members of the committee, for the record my name is John Lindsay, L-i-n-d-s-a-y, appearing in a neutral capacity on behalf of the Nebraska Association of Trial Attorneys. Don Wesely, from my firm, had a discussion with Senator Hilkemann and, after reviewing the language, we agreed to appear in a neutral capacity because, hopefully, this will clarify at least how we read some of...some of the language. We do not believe that it creates an immunity from liability. We believe that the operative section is Section 11. And what Section 11 says is that this act does not create a new cause of action and that, under this act, there is no new

liability. However, when read with the common law, and I think this may be where Senator Williams was getting, when read with the common law, any duty, when one has a duty, you have a duty to further that in the manner that a reasonable and prudent person would do. You have a...you basically have the obligation to use due care in any duty that you undertake. So in accomplishing their duties, whether under this act or whether under any other act, unless there's a specific relief thrown, the obligation to be careful, then you would be governed by general negligence law, so. And that's why we're appearing in a neutral capacity, is because...because we don't believe this does this. We believe it just simply says that this act does not create a new cause of action. With that, I'd be happy to answer any questions. [LB117]

SENATOR RIEPE: I'll go to Senator Williams first. [LB117]

SENATOR WILLIAMS: Thank you, Chairman Riepe. And Mr. Lindsay, I'm assuming that, if this did what you just said--removed that completely--trial lawyers would not be neutral. You would be here opposing the legislation. [LB117]

JOHN LINDSAY: That would be correct. [LB117]

SENATOR WILLIAMS: Thank you. [LB117]

SENATOR RIEPE: Okay. Senator Kolterman. [LB117]

SENATOR KOLTERMAN: He just asked my question (laughter). [LB117]

JOHN LINDSAY: Well then, that would be correct. [LB117]

SENATOR WILLIAMS: So we don't want to fix that. [LB117]

SENATOR RIEPE: Is it a correct legal assumption that you cannot protect against negligence? [LB117]

JOHN LINDSAY: You can protect against negligence. [LB117]

SENATOR RIEPE: You can. [LB117]

JOHN LINDSAY: But this language does not do that. [LB117]

SENATOR RIEPE: Okay. [LB117]

JOHN LINDSAY: And that's why you will occasionally see the...whatever...manufacturer shall not be civilly liable for any error or omission that it does. That would be specifically addressing the negligence aspect. [LB117]

SENATOR RIEPE: Well, this is not in your particular domain necessarily. Do you...are you aware that this particular legislation has been tested in the courts of any other states? [LB117]

JOHN LINDSAY: I'm not aware of that, and it...I don't know. [LB117]

SENATOR RIEPE: Okay; thank you. Senator Kolterman. [LB117]

SENATOR KOLTERMAN: So if a doctor...thank you. You've helped me so far (laughter). So if a doctor decides that they want to continue down this road and hang their hat on this particular legislation, and we advance it and it goes through, their medical liability protection would still give them the protections they need, wouldn't it? [LB117]

JOHN LINDSAY: Absolutely. [LB117]

SENATOR KOLTERMAN: Okay. [LB117]

JOHN LINDSAY: Yes, they would still be covered by the medical liability, which gives them all... [LB117]

SENATOR KOLTERMAN: They just don't have immunity under this. [LB117]

JOHN LINDSAY: Right, right. [LB117]

SENATOR KOLTERMAN: So it's not like, if they're part of the medical liability Nebraska state... [LB117]

JOHN LINDSAY: Right, it does not remove those protections in any way whatsoever. Any protections, like the cap on damages... [LB117]

SENATOR KOLTERMAN: Right. [LB117]

JOHN LINDSAY: ...and some of those types of things, remain in place. This would not take them outside of that. [LB117]

SENATOR KOLTERMAN: Okay. [LB117]

SENATOR RIEPE: If they didn't charge for this particular visit, would they qualify under the Good Samaritan clause? [LB117]

JOHN LINDSAY: That's a great question. I think the Good Samaritan Act, you have to...is a exigent circumstances sort of characterization. But I will have to go back and, for the next time I appear here and you ask me a question... [LB117]

SENATOR RIEPE: Curious George. Other questions? Senator Crawford. [LB117]

SENATOR CRAWFORD: Thank you, Senator Riepe. So just so we understand what new cause means, can you help us understand that? Because that means...well, I'm not going to try (laughter). Just help us understand... [LB117]

JOHN LINDSAY: I think an example... [LB117]

SENATOR CRAWFORD: ...what the new cause means. [LB117]

JOHN LINDSAY: I think an example may be: You have an investigational drug not approved by FDA for use to treat whatever medical condition. Pursuant to this act, it does not...it would not create use of that investigational drug rather than an FDA-approved drug... [LB117]

SENATOR CRAWFORD: Okay. [LB117]

JOHN LINDSAY: ...would not, in and of itself, be a cause of action or give rise to liability. However, doing that, what would happen if they--trying to think of an example. But you have investigational drug A and a pharmacist gets a prescription, is going to dispense that prescription but, instead, does investigational drug B, that is absolutely the wrong drug. [LB117]

SENATOR CRAWFORD: Um-hum. [LB117]

JOHN LINDSAY: That's not a matter of operating under the act; that's doing it carelessly. [LB117]

SENATOR CRAWFORD: Okay. [LB117]

JOHN LINDSAY: And so that's where the difference would be. [LB117]

SENATOR CRAWFORD: Thank you. [LB117]

SENATOR RIEPE: Okay. Additional questions? Thank you very much; it's been very helpful. [LB117]

JOHN LINDSAY: Thank you. [LB117]

SENATOR RIEPE: Any others in a...testifying in a neutral capacity? Seeing none, Tyler, do we have any letters? [LB117]

TYLER MAHOOD: (Exhibit 4) Yes. I have a letter signed by Dr. Richard Azizkhan, who is representing Children's Hospital, with a neutral position on the legislation. [LB117]

SENATOR RIEPE: Okay. And that's it? Okay. That concludes our hearing on...what? What? [LB117]

SENATOR WILLIAMS: Oops. [LB117]

SENATOR CRAWFORD: Oops. [LB117]

SENATOR RIEPE: Oops, oops, oops? [LB117]

SENATOR WILLIAMS: Closing. [LB117]

SENATOR ERDMAN: Closing. [LB117]

SENATOR CRAWFORD: Closing. [LB117]

SENATOR ERDMAN: Closing. [LB117]

SENATOR RIEPE: Oh. Oh, I'm sorry. [LB117]

SENATOR HILKEMANN: You sure? [LB117]

SENATOR RIEPE: Well, you did such a good job the first go, I thought... [LB117]

SENATOR HILKEMANN: Well, it's always good to have attorneys follow you up when it comes through it, because they've answered several of your questions because it was, as...Senator Linehan, it's already in there; I just didn't... [LB117]

SENATOR LINEHAN: It's okay; (inaudible). [LB117]

SENATOR HILKEMANN: ...hadn't picked that one up there on that one. And I was just handed that, as far that you may want to reference the FDA guidance as demonstration or a measurement of what's called good faith for physicians pursuing extending access for patient care. Thank you very much for hearing this. You know, this...you've all heard stories of, and probably had friends who have had serious illnesses like ALS and so forth. We had a...recently had a doctor, Tom Tonniges in Omaha, who just has now expired. He went to Israel to try to get therapy for these things. And I've known people who go to Mexico and to different countries. And this is just an opportunity to bring this opportunity for people here. It...these are folks that are in a desperate situation in their life. And yes, you've all heard them; they'll try anything. And life is precious, and this gives them one more opportunity. And I thank you very much. [LB117]

SENATOR RIEPE: Are there final questions? Okay. Thank you, Senator Hilkemann. [LB117]

SENATOR HILKEMANN: Thank you. [LB117]

SENATOR RIEPE: This now concludes the hearing on LB117. Thank you very much. [LB117]