ALASKA STATE LEGISLATURE
HOUSE HEALTH AND SOCIAL SERVICES STANDING COMMITTEE

February 28, 2017
3:04 p.m.

MEMBERS PRESENT

Representative Ivy Spohnholz, Chair
Representative Bryce Edgmon, Vice Chair
Representative Sam Kito
Representative Geran Tarr
Representative David Eastman
Representative Jennifer Johnston
Representative Colleen Sullivan-Leonard

MEMBERS ABSENT

Representative Matt Claman (alternate)
Representative Dan Saddler (alternate)

COMMITTEE CALENDAR

HOUSE BILL NO. 25
"An Act relating to insurance coverage for contraceptives and related services; relating to medical assistance coverage for contraceptives and related services; and providing for an effective date."

- HEARD & HELD

HOUSE BILL NO. 43
"An Act relating to prescribing, dispensing, and administering an investigational drug, biological product, or device by physicians for patients who are terminally ill; providing immunity related to manufacturing, distributing, or providing investigational drugs, biological products, or devices; and relating to licensed health care facility requirements."

- HEARD & HELD

PRESENTATION: REDUCING USE OF EMERGENCY DEPARTMENT SERVICES

- HEARD

PREVIOUS COMMITTEE ACTION

BILL: HB 25

SHORT TITLE: INSURANCE COVERAGE FOR CONTRACEPTIVES
SPONSOR(s): REPRESENTATIVE(s) CLAMAN

01/18/17	(H)	PREFILE RELEASED 1/9/17
01/18/17	(H)	READ THE FIRST TIME - REFERRALS
01/18/17	(H)	HSS, FIN
02/28/17	(H)	HSS AT 3:00 PM CAPITOL 106

BILL: HB 43
SHORT TITLE: NEW DRUGS FOR THE TERMINALLY ILL
SPONSOR(s): REPRESENTATIVE(s) GRENN

01/18/17	(H)	PREFILE RELEASED 1/13/17
01/18/17	(H)	READ THE FIRST TIME - REFERRALS
01/18/17	(H)	HSS, JUD
02/28/17	(H)	HSS AT 3:00 PM CAPITOL 106

WITNESS REGISTER

REPRESENTATIVE MATT CLAMAN
Alaska State Legislature
Juneau, Alaska
POSITION STATEMENT: Presented HB 25 as the sponsor of the bill.

LIZZIE KUBITZ, Staff
Representative Matt Claman
Alaska State Legislature
Juneau, Alaska
POSITION STATEMENT: Presented HB 25 on behalf of the bill sponsor, Representative Claman.

MARGARET BRODIE, Director
Director's Office
Division of Health Care Services
Department of Health and Social Services
Juneau, Alaska
POSITION STATEMENT: Answered questions during discussion of HB 25.

REPRESENTATIVE JASON GRENN
Alaska State Legislature
Juneau, Alaska
POSITION STATEMENT: Presented HB 43 as the sponsor of the bill.

BROOKE IVY, Staff
Representative Jason Grenn
Alaska State Legislature

Juneau, Alaska
POSITION STATEMENT: Presented HB 43 on behalf of the sponsor of the bill, Representative Grenn.

LINDA BRUCE, Attorney
Legislative Legal Counsel
Legislative Legal Services
Juneau, Alaska
POSITION STATEMENT: Answered questions during discussion of HB 43.

STARLEE COLEMAN, Vice President
Communications
Goldwater Institute
Phoenix, AZ
POSITION STATEMENT: Testified in support of HB 43.

CONNIE BEEMER, Director
Member Services and Operations
Alaska State Hospital and Nursing Home Association (ASHNHA)
Anchorage, Alaska
POSITION STATEMENT: Presented a PowerPoint presentation of the Alaska ED Coordination Project.

ANN ZINK, MD
President
Alaska (ACEP) American College of Emergency Physicians
Palmer, Alaska
POSITION STATEMENT: Testified during the presentation of the Alaska ED Coordination Project.

BEN ZANIELLO, MD
Vice President
Chief Medical Officer
Collective Medical Technologies (CMT)
Sandy, Utah
POSITION STATEMENT: Testified during the presentation of the Alaska ED Coordination Project.

ACTION NARRATIVE

3:04:05 PM

CHAIR IVY SPOHNHOLZ called the House Health and Social Services Standing Committee meeting to order at 3:04 p.m. Representatives Spohnholz, Kito, Johnston, and Eastman were present at the call to order. Representatives Edgmon, Tarr, and Sullivan-Leonard arrived as the meeting was in progress.

HB 25-INSURANCE COVERAGE FOR CONTRACEPTIVES

3:05:35

CHAIR SPOHNHOLZ announced that the first order of business would be HOUSE BILL NO. 25, "An Act relating to insurance coverage for contraceptives and related services; relating to medical assistance coverage for contraceptives and related services; and providing for an effective date."

3:05:44 PM

REPRESENTATIVE MATT CLAMAN, Alaska State Legislature, explained that Alaskan women living and working in rural areas, in the tourism industry, in the military, and on the North Slope did not always have ready access to women's health services, and faced additional barriers for obtaining access to family planning options. He stated that women who currently used hormonal contraceptives had to return to a pharmacy everyone to three months to refill their prescriptions. He reported that proposed HB 25 required health insurers to offer consumers the option to receive a 12-month supply of hormonal contraception. He declared that the women in his family supported the proposed bill as improved access to contraceptives meant huge reductions in unintended pregnancies. He added that unintended pregnancies had a profound effect on the overall well-being of Alaskan families, as it was associated with adverse maternal and child health outcomes. Along with health concerns, unintended pregnancy was a dramatic cost driver to public health programs. He pointed out that it was often time consuming and inconvenient to obtain a prescription for contraceptives every one to three months. He offered his belief that, with the financial challenges in the state, there should be discussion for ways to reduce costs in both the short and long term. He declared that proposed HB 25 offered these cost reductions, and that it made sense for Alaska women and families.

3:07:34 PM

LIZZIE KUBITZ, Staff, Representative Matt Claman, Alaska State Legislature, stated that proposed HB 25 mandated that health care insurers provide coverage for a 12-month supply of contraceptives. She pointed out that prescriptive contraceptives included self-administered hormonal contraceptives which did not require insertion or other administration by a medical professional, namely oral contraceptives, noting that this was discussed in Section 1 of the proposed bill. She moved on to discuss the Sectional Analysis of the bill [included in members' packets]. She said that Section 1 also included a religious exemption and defined a health care insurer as including a self-insured employer, such as the State of Alaska. She moved on to discuss Section 2 of the proposed bill, which directed the Department of Health and Social Services to pay for the 12-month supply of prescription contraceptives for eligible recipients of medical assistance. She relayed that Section 3 of the proposed bill required the Department of Health and Social Services to amend and submit for federal approval a state plan for medical assistance coverage consistent with Section 2. She explained that Section 4 provided a conditional effect of Section 2 and Sections 5 and 6 pertained to the effective dates.

MS. KUBITZ stated that one major premise behind the proposed bill was that when women had greater access and availability to contraceptives, there was a reduction of unintended pregnancies. This resulted in a direct cost savings to the state, which was reflected in the fiscal notes from Department of Health and Social Services [included in members' packets]. She relayed that one 2010 study in Alaska [included in members' packets] found that 48 percent of all pregnancies in Alaska were unintended. She added that an estimated 94.3 percent of these unintended pregnancies were publicly funded. She reported that Alaska spent $113.7 million on unintended pregnancies, of which $70.8 million was paid for by the federal government and $42.9 million was paid for by the state. She pointed to an additional study [included in members' packets] which studied 84,000 women in California given 1 month, 3 month, or 12 month supplies of oral contraceptives. The researchers of this study observed a 30 percent reduction in the odds of conceiving an unintended pregnancy for those women given the 12 month supply of oral contraceptives. This study also reported that the California family planning program paid $99 more annually for women who received three cycles and $44 more for women who received one cycle than for women who received a year-long supply all at once. She stated that this cost "was mostly due to the costs of associated visits and the higher use of pregnancy tests among women who received fewer cycles." She relayed that women who received three cycles were almost twice as likely as women who received the 12 month supply to visit a clinic to get a pregnancy test. She noted that the proposed bill did not change who was eligible for coverage, or the types of prescriptions covered. The bill merely allowed women already receiving coverage for prescription contraceptives to receive, if they so choose, a 12 month prescription. She addressed concerns brought forward by the Alaska National Federation of Independent Business (NFIB) and by America's Health Insurance Plan (AHIP) [included in members' packets]. As NFIB had concerns for whether the proposed bill would include the state employee health care plan, a definition of health care insurer which included self-insured employers, such as the State of Alaska, had been included in the proposed bill. She relayed that an additional concern voiced by NFIB was for the cost burden of supplying a 12 month supply of contraception at one time. She pointed to multiple studies which had found that contraceptive coverage did not raise insurance premiums, and that the employers providing coverage could save money by avoiding the costs associated with unintended pregnancy. She relayed that the average commercial insurer payment for all maternal and newborn care ranged from $18,000 to $28,000, whereas the average hormonal birth control cost ranged from $100 to $600 per year. She stated that prevention of one unintended pregnancy could save an insurer at least $17,000, enough savings to pay for 29 additional years of contraception. She moved on to discuss the concerns from AHIP [included in members' packets] which concluded that the 12-month supply of contraceptives could compromise patient safety as a result of decreased patient visits to the prescribing physician. She pointed to research which showed that birth control pills were safe and could be safely prescribed based on a careful review of the patient's medical history and blood pressure measurement. For most women, no further examinations were necessary after the initial prescription, unless the patient asked for a follow up during the recommended yearly examination. She stated that the Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO) had presented a study in 2013 which recommended dispensing a yearly supply of contraception with an advisement to return at any time for discussion of side effects or other problems, or to change the method. The study had declared that no routine follow-up was required. She added that, although AHIP had concerns for the efficacy of oral contraceptives due to improper storage for a 12 month supply, CDC had declared that oral contraceptives had a shelf life of three to five years, dependent on the manufacturer, although temperature and moisture could diminish this time frame. CDC stated that most women who opted for a 12-month supply, and were regular users of hormonal contraception, would know how to properly store the medication. She addressed concerns for waste, fraud, and abuse, and pointed out that research had found that the average waste of a 12-month supply was for one cycle of prescription contraceptives, and this was insignificant in comparison to the other cost savings for fewer clinician and pharmacy visits, and the associated costs for pregnancy. Regarding fraud and abuse, although there were existing criminal statutes for sale of hormonal contraceptives, this was not anticipated as women would have greater access to the contraceptives. She concluded by stating that proposed HB 25 would offer "huge advantages for Alaskan women, from eliminating the inconvenience of refilling the prescription every one to three months at a time, to the real inability of some Alaskan women to make it to the clinic, hospital, or pharmacy to refill that prescription at all." She pointed out that fisherwomen sometimes spend three to four months out on a boat, women attending college often have busy schedules balancing school and a job, and women in Rural Alaska often had trouble making it to a clinic or hospital due to a lack of transportation and limited operating hours. She declared the HB 25 ensured that all Alaskan women had the freedom to make decisions about their futures.

3:16:28 PM

REPRESENTATIVE JOHNSTON shared that a three month supply of birth control pills for her daughter was $800. She asked if there was a discount for a 12 month supply.

MS. KUBITZ replied that her research had shown a cost savings for buying in bulk.

REPRESENTATIVE JOHNSTON suggested more research for this.

3:17:40 PM

REPRESENTATIVE EDGMON pointed to the zero fiscal note.

MS. KUBITZ replied that there were two zero fiscal notes [included in members' packets] provided by the Department of Health and Social Services [OMB Component 242 and OMB Component 2007]. She relayed that one fiscal note projected anticipated costs due to implementation of the proposed bill and the second fiscal note detailed the cost savings.

3:18:35 PM

MARGARET BRODIE, Director, Director's Office, Division of Health Care Services, Department of Health and Social Services, addressed the Department of Health and Social Services (DHSS) fiscal note labeled OMB Component 2007, and explained that this fiscal note analyzed 7,940 female Medicaid recipients using oral contraceptives. She estimated that 10 percent, 794 women, would require duplication of services because the medication was not effective, it was lost or stolen, or was not stored properly and could lose its efficacy. She based the replacement value at $45 per month which was the national average drug acquisition cost and the cost that the state used for its determination. She shared that DHSS assumed that 75 percent of the women planned to use oral contraceptives longer than 12 months, and that, as the CDC cited a standard failure rate of 9 percent, this would result in 540 unintended pregnancies. She reported that the failure rate would decrease about 30 percent with a 12-month supply of contraceptives, thereby lowering the failure rate to 7 percent. She pointed out that about 120 unintended pregnancies could be avoided by using the 12-month contraception. She stated that the estimated savings was based on the Medicaid data, which reported that 5.28 births of the 120 avoided pregnancies would have been complicated births, with the remainder of births being non-complicated. She reported that the cost factor for a complicated birth was $110,000, whereas the cost factor for a non-complicated birth was $8,000. This would result in a benefit cost savings to the Medicaid program estimated to be $1,498,000, of which $562,000 would be attributed to the Medicaid expansion population. She reported an annual projected savings of $1,355,600. She added that this was a conservative estimate, as some complicated births could cost hundreds of thousands of dollars.

MS. BRODIE addressed the second fiscal note, OMB Component 242. She offered her belief that this fiscal note could be removed, as there was no state or federal statute that declared a need for the department to go back and collect from the recipients.

3:24:41 PM

CHAIR SPOHNHOLZ expressed her agreement with saving the "money in this particular area." She suggested that the savings would be $1.2 - $1.3 million annually in overall Medicaid costs related to contraception and unintended pregnancies.

MS. BRODIE expressed her agreement.

3:25:03 PM

REPRESENTATIVE SULLIVAN-LEONARD asked whether the proposed bill would allow the state workers' health insurance program to offer this benefit.

REPRESENTATIVE CLAMAN, in response, relayed that the intent of the proposed bill was for this benefit to be included in the state workers' health insurance plan.

REPRESENTATIVE SULLIVAN-LEONARD asked if there were other medications that could be prescribed on a yearly basis, or was this the first proposal for a year-long prescription.

MS. KUBITZ asked if Representative Sullivan-Leonard was asking specifically about contraceptives. She stated that she was not aware of any other medications that could have a year-long prescription, as often many of these medications were controlled substances.

REPRESENTATIVE SULLIVAN-LEONARD asked if any other prescription drugs could be included in this format, pointing out that a 90-day prescription was because a physician wanted to oversee the interaction of the drug for the patient.

REPRESENTATIVE CLAMAN said that his office had not researched this specific question. He recollected that certain mail-in drug programs allowed for longer prescriptions, although it depended on the medication.

CHAIR SPOHNHOLZ offered her belief that some other medications, including some hormonal medications, were available on a yearly prescription.

REPRESENTATIVE CLAMAN replied that he would look into this.

3:28:53 PM

CHAIR SPOHNHOLZ said that HB 25 would be held over.

3:29:18 PM

The committee took an at-ease from 3:29 p.m. to 3:32 p.m.

HB 43-NEW DRUGS FOR THE TERMINALLY ILL

3:32:40 PM

CHAIR SPOHNHOLZ announced that the next order of business would be HOUSE BILL NO. 43, "An Act relating to prescribing, dispensing, and administering an investigational drug, biological product, or device by physicians for patients who are terminally ill; providing immunity related to manufacturing, distributing, or providing investigational drugs, biological products, or devices; and relating to licensed health care facility requirements."

3:32:49 PM

REPRESENTATIVE JASON GRENN, Alaska State Legislature, shared that the proposed bill was often referenced nationally as "Right to Try" legislation. He stated that the goal of the proposed bill was:

> to create a legal climate in which terminally ill patients who have exhausted all FDA (U.S. Food and Drug Administration) approved treatment options may work with their doctors and drug manufacturers to access investigational and safe treatments that have passed Phase I of the FDA approval process but are not yet widely available.

REPRESENTATIVE GRENN reported that "Right to Try" laws had been passed in 33 states, with this legislation being considered in another 15 states, now including Alaska. Paraphrasing from the Sponsor Statement [included in members' packets], he stated that, each year, it was estimated that more than 1 million Americans died from terminal illness. "For those who have exhausted all FDA approved options, clinical trials become the next step. However, of those patients who attempt to gain entry into a clinical trial, it is found that fewer than 3 percent are accepted." He declared that, although the FDA did have a program in place for accessing investigational drugs outside of clinical trials, which was known as the "Compassionate Use Program," it was estimated that only about 1200 people made it through the long, arduous federal process annually. He declared that the goal of the proposed bill was to provide the same access as the existing program but on a shorter timeline. He said that by assuring that terminally ill patients had more timely access to safe, though experimental drugs, in consultation with their doctor, the proposed bill would offer new hope after all FDA approved options had been exhausted.

3:35:02 PM

BROOKE IVY, Staff, Representative Jason Grenn, Alaska State Legislature, presented a PowerPoint titled "House Bill 43: The Right to Try." She directed attention to the sectional analysis [included in members' packets] and to slide 2, "House Bill 43." She addressed Section 1 of the proposed bill, and stated that this section prohibited disciplinary action by the State Medical Board against physicians for prescribing or administering an investigational drug to a terminally ill patient who met certain criteria. She reported that patients had to be ineligible or unable to participate in an ongoing clinical trial, had considered all available treatment options in consultation with their doctor, and had provided written consent. She moved on to Section 2 of the proposed bill, which established that physicians, medical team members, manufacturers, importers, and distributors acting in good faith and with reasonable care would not be held liable in the case of injury or death of a terminally ill patient from the use of an investigational drug, provided that the informed consent was obtained from the patient and notice of immunity was also given to the patient in advance. She added that the section also established immunity for physicians and manufacturers who chose not to participate in the distribution of investigational drugs. She addressed Section 3 which amended AS 17.20.110, and would allow physicians to prescribe or administer investigational drugs under the conditions established in Section 1 of the proposed bill. She spoke about Section 4, which prevented the Department of Health and Social Services from requiring a licensed health care facility to increase its services, solely to accommodate physicians who were prescribing or administering investigational drugs to a patient.

3:37:37 PM

MS. IVY directed attention to slide 3, "FDA Drug Review Process," and explained this process. She reported that, prior to Phase 1, the sponsors of a drug were required to submit an "Investigation New Drug" (IND) application, and through this application, the FDA reviewed the applicant's pre-clinical testing results, and then determined whether the drug was reasonably safe for testing in humans.

MS. IVY spoke about slide 4, "FDA Drug Review Process (cont'd)," and explained that in Phase 1, the studies occurring after approval of the IND application, the studies could be conducted on healthy volunteers dependent on the purpose of the medication, or on individuals with specific diseases or terminal illness. She stated that safety to determine possible side effects and toxicity levels was the goal of Phase 1. She addressed slide 5, "FDA Drug Review Process (cont'd)," and spoke about the Phase 2 studies, which began when a drug was determined to be safe, and was focused on the effectiveness of the drug. She stated that, if there was evidence that a drug was effective, it moved on to Phase 3, slide 6, "FDA Drug Review Process (cont'd)." In Phase 3, more information was gained on safety and effectiveness, particularly in varying populations and in different dosages. After Phase 3, sponsors of the drug have a review meeting with the FDA, and submit a new drug application requesting approval to market the drug in the United States, slide 7, "FDA Drug Review Process (cont'd)." After this application, the FDA had 60 days to decide whether to file an application for review and then applications were generally processed within 10 months.

3:39:26 PM

MS. IVY reviewed slide 8, and explained that investigational drugs had passed the safety testing in Phase 1, and were currently in ongoing clinical trials in Phase 2 and Phase 3 of the FDA process.

3:39:43 PM

MS. IVY directed attention to slide 9, "FDA's Expanded Access Program," and spoke about the "Compassionate Use" program, which was designed for terminally ill patients without access to clinical trials so they could apply for these investigational treatments. She explained that the patient had to work with their doctor to apply directly to the FDA. She noted that, until recently, this application took more than 100 hours for a doctor to complete, but it had now been shortened. She acknowledged that this was still just the first step in the approval process. She added that manufacturers also had to submit lengthy documentation before the application went through the internal FDA approval process and on to a separate institutional review board, often a lengthy multi-month process. She reported that approximately 1200 applicants made it through the process annually. She addressed slide 10, "The Right to Try - A Nationwide Effort," and pointed out that this legislation had been passed or was under consideration in all but one state.

3:41:20 PM

REPRESENTATIVE SULLIVAN-LEONARD, referencing slide 9, asked how many applicants did not make it through the process.

MS. IVY said that she did not have that number.

REPRESENTATIVE SULLIVAN-LEONARD offered her belief that it was an important component to the proposed bill.

3:42:05 PM

MS. IVY pointed to the Clinical Trials document [included in members' packets] which included stories of Alaskans facing terminal illness and the benefit of having access to the drugs. She stated that, additionally, there was a Goldwater Institute policy report [included in members' packets] which delved into greater detail for the challenges of the Compassionate Use program.

REPRESENTATIVE TARR asked for an update to the policy signed by President Obama prior to leaving office, which had included some provisions to expand drug trials for non-approved drugs, and for its interaction to the proposed bill.

MS. IVY said that she would research the specifics.

3:44:18 PM

REPRESENTATIVE KITO asked why the legislation was vetoed in Hawaii.

MS. IVY replied that, although the legislation had passed unanimously from the legislature in Hawaii, the governor had vetoed it. She shared that Governor Brown in California had also vetoed the legislation, but had since changed his mind, purportedly because of instances of benefits to patients in Texas.

3:46:00 PM

REPRESENTATIVE KITO referenced the statement from the bill sponsor that this was an opportunity for individuals who have terminal illnesses to try something that was not a standard procedure. He offered his belief that there might be opportunities for treatment benefits prior to waiting until a diagnosis of terminal illness. He asked why it was necessary to wait to prescribe a potential remedy until a terminal diagnosis.

MS. IVY replied that the national advisors on this legislation had suggested to keep a narrow focus, as this was something already available through the FDA. She pointed out that taking on preventative care with all medications that go through the FDA approval process was a much larger federal policy discussion regarding the approval of drugs in the U.S.

3:47:59 PM

CHAIR SPOHNHOLZ added that, as medications had side effects, an important part of the FDA approval process was to ensure that the medication was safe, did what it claimed, and its benefits outweighed the costs. The FDA approval process was set up to protect consumers. She offered an example of aspirin being taken to prevent heart problems, whereas it actually increased gastric problems as a side effect. She pointed out that experimental drugs needed to be proven safe. She asked for the definition of terminally ill in the proposed bill.

MS. IVY directed attention to page 2, line 12 of the proposed bill, and she read:

> "terminal illness" means a disease that, without life-sustaining procedures, will result in death in the near future or a state of permanent unconsciousness from which recovery is unlikely.

3:50:43 PM

LINDA BRUCE, Attorney, Legislative Legal Counsel, Legislative Legal Services, stated that this was a new definition which had been drafted for this bill.

MS. IVY offered her belief that the definition came from model legislation in other states.

3:51:32 PM

REPRESENTATIVE SULLIVAN-LEONARD asked whether the information collected from terminally ill patients could be used for other patients.

MS. IVY replied that the data from investigational drugs, used outside a clinical trial, was being collected and that federal law dictated that manufacturers needed to provide this information to the FDA. She offered her belief that it was required that the data be collected.

3:53:16 PM

REPRESENTATIVE TARR commented that this was Rare Diseases Awareness Day. She shared that, as there was not a large enough population to have statistically relevant information for appropriate interventions, it was often a fight to get access to medication.

3:54:50 PM

STARLEE COLEMAN, Vice President, Communications, Goldwater Institute, reported that her organization had crafted the language on which proposed HB 43 was based, although, she acknowledged, there had been some Alaska specific adjustments. She relayed that diagnosis for a terminal illness currently offered three paths of approved options for the access to promising investigational treatments: the first path was for the clinical trials; the second path was for those who could afford to travel overseas to access drugs that were already available in countries other than the U.S; the third path was for the connected, the aforementioned FDA "Expanded Access" program. For the remainder of the public, there was no path to access investigational treatments, hence the "Right to Try" program. She stated that it was important to understand that this program was the opposite of the right to die movement, which was for people ready to end their own lives. The "Right to Try" program allows patients with terminal illnesses who had tried existing treatments with no success, and could not enroll with a clinical trial, to access promising treatments being safely used in government approved clinical trials. She pointed out that it was not a question for whether or not trying an investigational treatment was too risky, as the risk from these treatments was exactly the same as for those entered into government clinical trials. She emphasized that it was hard to be selected for a clinical trial. She offered an example of clinical trials for children diagnosed with spinal muscular atrophy (SMA). She reported that 97 percent of cancer patients had to rely on drugs already on the market, even if a drug in a clinical trial was being developed specifically for their type of cancer, and had already been approved in other countries. She reiterated that, although about 1200 people annually made it through the application process, it was not known how many people were declined as FDA did not keep records. She reported that, although the FDA declared that its approval rate was about 99 percent, she had questioned this rate. She offered an example of a cancer trial center in Houston, the largest in the world, which claimed that it had only been able to get one person through the FDA "Expanded Access" process annually. She surmised that many doctors spoke to the FDA in advance and would not apply if the FDA stated they would not accept the application. She pointed out the difficulty for doctors in Alaska who were not familiar with the FDA process or hierarchy. She compared the FDA program with a similar program in France which treated 25,000 people annually, and declared that there was a problem with the FDA program.

4:04:00 PM

MS. COLEMAN stated that, although no one expected a guarantee that an investigational drug would offer a cure, they just wanted an opportunity to try the medications already being used in clinical trials. She declared that dying people and their families were owed that opportunity. She stated that "Right to Try" was already working and saving lives. She offered an example of terminal pancreatic cancer patients. She emphasized that states were able to do this to complement the federal drug approval process, and not compete with it. She declared that the right to save your own life was a human right, and that it should not be necessary to also fight government red tape.

4:05:49 PM

REPRESENTATIVE JOHNSTON asked for clarification that the proposed bill was for the right to try drugs that had gone through the first, second, and third steps toward FDA approval.

MS. IVY replied that all of these drugs had passed Phase 1 for safety testing and were currently in Phase 2 or Phase 3.

REPRESENTATIVE JOHNSTON asked if drugs allowed in Europe had already passed Phase 1 by the FDA, and were also in Phase 2 or Phase 3.

MS. IVY replied that was correct. She stated that in some countries medications or treatments were in general use, and considered safe and effective, but had not yet gone through Phase 1 of the FDA process in order to be eligible under the "Right to Try" program. She pointed out that a person could travel to that country and utilize the medication, but that was outside this process.

MS. COLEMAN offered an example for five FDA investigational treatment drugs for breast cancer which had been approved in other countries. She stated that "Right to Try" would allow those treatments already in use to become available to American women.

4:07:59 PM

CHAIR SPOHNHOLZ asked how many people had taken advantage of the access to "Right to Try."

MS. COLEMAN replied that there was not a complete record for that information, as there was not a state specific reporting requirement for the use of drugs in a state with a "Right to Try" law. She noted that this would be duplicative of drug company reports to the FDA, adding that the FDA did not make this information available under public records laws.

4:09:27 PM

REPRESENTATIVE JOHNSTON asked if a drug would qualify if it was used for one treatment, even though its purpose was for something else. She pointed out that it had already gone through the Phase 1 safety test, but not through the next phases.

MS. COLEMAN said that she would need more specifics about the drug's placement in the trial process. She reiterated that the goal of "Right to Try" was to provide access for terminal patients to any drug which had passed the initial safety trial, and was in on-going trials and under active investigation. She said that it was legal for drugs to be used for another purpose, which she termed "off label use."

4:11:28 PM

REPRESENTATIVE TARR expressed concern for the provision of immunity, noting that medical malpractice provisions were still in place, and asked if this had been an issue in any other states. She asked if there was protection for an individual who felt pressured or coerced into taking a drug.

MS. COLEMAN shared this concern that patients were protected from any undue pressure to try something they were not fully comfortable with and to protect them from medical malpractice. She shared that the proposed bill had two patient protections: (1) that a patient must voluntarily sign a comprehensive, informed consent document, and (2) that this was totally voluntary with no incentive for the pharmaceutical company to participate. She said that medical malpractice laws were not impacted by the proposed bill, and these laws would remain in place. She declared that a point of the liability shield was to ensure that doctors, hospitals, and pharmaceutical companies understand that should a patient in a terminal situation die while taking an investigational treatment, that, in and of itself, was not a reason to be sued.

4:15:05 PM

MS. IVY added that there were other protections in the proposed bill, as it included investigational drugs in on-going trials. She offered her belief that, under federal law, manufacturers cannot engage in the marketing and sale of unapproved drugs, and were not legally permitted to sell investigational drugs for more than the production cost. She stated that this removed the cost benefit for manufacturers to participate.

CHAIR SPOHNHOLZ asked whether the informed consent described in the proposed bill included a verbal discussion for the risks and benefits.

MS. IVY, in response to Chair Spohnholz, expressed her agreement and added that discussion would include all available treatment options currently approved by the FDA.

CHAIR SPOHNHOLZ directed attention to page 2, lines 26 - 27, as the guarantee of a verbal conversation with the doctor regarding the risks and benefits of a potential treatment, and that writing was a codification of that consent.

MS. IVY expressed her agreement that this was the intent of the proposed bill, and expressed her support of any necessary amendment to clarify the requirement for a verbal conversation.

4:18:24 PM

CHAIR SPOHNHOLZ said that HB 43 would be held over and public testimony would be opened at that time.

4:18:51 PM

The committee took a brief at ease.

Presentation: Reducing Use of Emergency Department Services

4:20:00 PM

CHAIR SPOHNHOLZ announced that the final order of business would be a presentation titled "Reducing Use of Emergency Department Services."

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CONNIE BEEMER, Director, Member Services and Operations, Alaska State Hospital and Nursing Home Association (ASHNHA), directed attention to the PowerPoint titled "Alaska ED Coordination Project," and stated that the project was a result of the Medicaid Redesign efforts initially proposed in 2015. She noted that rising health care costs and the decline in the state budget had been a reason for this project in collaboration with the Alaska Chapter of the American College of Emergency Physicians. She stated that the project was not solely focused on Medicaid patients, but for all patients, as they wanted to do the right things for their patients. She acknowledged that emergency rooms were a great place if there was an emergency, but that it was not the best place to provide for re-occurring primary care and behavioral health issues. She reported that this project was based on the State of Washington seven best practices model, slide 3. She shared that Alaska saw these successes and "we wanted to steal them so that's what we're working on." She reported that Washington was also under financial pressures, similar to Alaska, and was faced with threats from the governor to limit emergency department (ED) visits for Medicaid patients. She addressed slide 4, "Learning from Others," which listed the reductions for ED use in the first year, and included a 10.7 percent reduction among frequent utilizers and a 24 percent reduction for narcotic prescriptions from the ED.

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ANN ZINK, MD, President, Alaska (ACEP) American College of Emergency Physicians, offered her belief that "what you do really matters." She said that a lot of great things can build off this project. She directed attention to slide 5, "Alaska's ED Coordination Project," and reported that this was actual language from Senate Bill 74, emphasizing that this was Alaska specific. She shared that ideas had been taken from the States of Washington and Oregon, as well as others, for what had been done well, what could have been done differently, what would be recommended, and what made sense for Alaska. She read from the list on slide 5, which included creating an interdisciplinary process for defining, identifying, and minimizing the number of frequent visitors of emergency department services, creating a real-time electronic information exchange mechanism which crossed all IT platforms for electronic medical records, educating patients, and providing primary care and behavioral health follow-up within 96 hours. They also reviewed ways to create statewide narcotics guidelines for the emergency departments, and ways to review the successes and challenges of this program when moving forward. She relayed that they had been receiving input from other hospitals, as well as working on the statewide opiate guidelines; however, the big project was research for an IT system that would cross the platforms, be easy to use, be interface friendly, and have the potential for future expansion. She lauded Collective Medical Technologies as an ideal partner.

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BEN ZANIELLO, MD, Vice President, Chief Medical Officer, Collective Medical Technologies (CMT), shared that he was also a practicing physician at Providence Hospital in the State of Washington. He shared some background about Collective Medical Technologies (CMT), slide 7, stating that it was a small, mission driven company started by an Emergency Room (ER) social worker in Idaho, and that CMT was focused on ER care coordination and the sharing of information between hospitals. He said that the focus of CMT was to create a national care coordination network around the concept of medical uncertainty versus medical necessity. He pointed out that there was a lot of information asymmetry in the emergency department (ED), as decisions had to be made quickly. He stated that the CMT software would provide the information to reduce the medical uncertainty, and they were now working with more than 1,000 hospitals. He directed attention to slide 8, "PreManage Platform," and said that the program was called EDIE, Emergency Department Information Exchange. He explained that, in order to focus on the emergency department, it was necessary to get information from outside the ER, from all aspects of the "care ecosystem." He pointed to slide 9, as an example of the type of data shared.

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DR. ZINK moved on to slide 10, "ED Narcotic Guidelines." She reported that there was a coordinated effort with the ED departments to implement statewide guidelines to reduce drug seeking and drug dispensing to frequent emergency room users. She shared that the State of Washington had reported "a huge difference in their overall narcotic dispensing out of the emergency department." She directed attention to slide 12, "Ultimate Goal," and stated that, since the IT platform had been determined, there was work to get the platform in place in hospitals. She shared that support was widespread. She pointed to slide 13, "Participating Organizations," which listed many of the collaborating organizations. She declared that this was an opportunity to put patients first, and reduce restrictions and decrease silos between different providers. She stated the need for tools to reduce costs and improve care.

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REPRESENTATIVE JOHNSTON asked if she would encourage her facility to use this platform for all patients.

DR. ZINK explained that this was emergency department specific, as it was different than for someone with chronic pain, and that it had 100 percent support from the emergency department physicians, as well as support from the urgent cares.

REPRESENTATIVE JOHNSTON asked it the IT platform could be used for all emergencies, and not just Medicaid.

DR. ZINK replied that this was correct. She said that it crossed all platforms and patients, and it could access data from the other states that had the CMT platform.

REPRESENTATIVE JOHNSTON asked whether any hospital or organization which used this IT platform could interchange throughout the system.

DR. ZINK said, "Correct."

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REPRESENTATIVE SULLIVAN-LEONARD asked if there were forms which were clearly highlighted for sharing this information with another facility for an emergency room patient. She questioned the Health Insurance Portability and Accountability Act (HIPAA) information.

DR. ZINK replied that different hospitals could set up individual criteria and this was on a tracking board. She reported that when a patient checked into an emergency room, they agreed to be treated via the Health Insurance Portability and Accountability Act, hence there was access to the information, and then their information could be accessed. She offered some examples for the information, including any recent violent actions by the patient, an important care plan, or a notice of frequent visitations to emergency departments.

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REPRESENTATIVE SULLIVAN-LEONARD reiterated her question that the patient would need to sign an agreement for the medical facilities to share their personal information.

DR. ZINK said that, when checking in to the emergency department, the patient basically agrees to allow access for anything to do with their medical emergency at that moment, which is in compliance with HIPAA. She added that any follow-up in an outpatient clinic does not automatically allow access to that patient information. She explained that all the patients in the mental health court signed a full information release for willingness to share their information.

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REPRESENTATIVE TARR asked if this was a tool which fed into each EMR system, and, as a result, there was not any unnecessary information, although this was governed by HIPAA.

DR. ZANIELLO explained that, when a patient registered in the ER, the IT system was fed a narrow slice of patient data which was matched against their larger data base. He reported that the CMT system would report on recent patient activities and actions. He stated that each emergency room maintained its "deep clinical repository on each patient."

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REPRESENTATIVE TARR asked about any issues of privacy, as each use of electronic records allowed an opportunity for a data breach.

DR. ZANIELLO replied that a lot of his work was with data privacy concerns. He reminded that committee that HIPAA referenced portability, not privacy. He reported that CMT had not had any data breach or HIPAA violation.

CHAIR SPOHNHOLZ asked about the projected time line for implementation of the CMT platform.

MS. BEEMER said that the bulk of the CMT implementation was for the legal review, projected to be a 3 - 4 month process. She allowed that the actual IT implementation was "a fairly light lift." She pointed out that the program had been implemented at Providence Hospital in Anchorage, as it had already been implemented in other Providence Hospitals in Oregon and Washington. She reported that her team was currently demonstrating the CMT program to the mid and large hospitals in Alaska.

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CHAIR SPOHNHOLZ offered her belief that it was important to have as many hospitals involved as possible. She mentioned an earlier reference to prescription drug monitoring programs, and asked about the timing for integrating that information.

MS. BEEMER offered her belief that the language in Senate Bill 74 regarding the prescription drug monitoring program allowed for some regulations which were due to go into effect in July. She expressed the desire to soon have discussions with that program.

CHAIR SPOHNHOLZ asked whether regulations were necessary to take effect prior to integration with the prescription drug database.

MS. BEEMER offered her understanding that this was already underway.

CHAIR SPOHNHOLZ asked for the end date goal to have a complete rollout of integration with EDIE.

MS. BEEMER opined that the hospitals needed six months to have a legal review before signing the contract. She reported that phase 2 would be access by the communities and primary care through the portal. She added that discussion was still necessary with the rural critical access hospitals. She allowed that there was still a lot of work, although there was hope to have this in all the large and mid-size emergency departments within six months.

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DR. ZINK pointed out that the IT was only one component, and the prescription drug database regulation component was now being finished. She stated that there was a lot of opportunity to build on care coordination, end of life care, and other cost savings issues for improvement for patient health.

REPRESENTATIVE TARR asked about participation with Indian Health Services or Tri Care.

DR. ZINK replied that there was extensive work with Indian Health Services. She reported that there was ongoing work with the leaders within the VA (Veterans Administration) system for changes to regulations, with a desire to bring this program to the federal level. She surmised that this was just a temporary barrier in the work toward integrating these systems.

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ADJOURNMENT

There being no further business before the committee, the House Health and Social Services Standing Committee meeting was adjourned at 4:47 p.m.