SENATE FINANCE COMMITTEE
March 29, 2017
9:04 a.m.

9:04:12 AM

CALL TO ORDER

Co-Chair MacKinnon called the Senate Finance Committee meeting to order at 9:04 a.m.

MEMBERS PRESENT

Senator Lyman Hoffman, Co-Chair
Senator Anna MacKinnon, Co-Chair
Senator Click Bishop, Vice-Chair
Senator Mike Dunleavy
Senator Peter Micciche
Senator Donny Olson
Senator Natasha von Imhof

MEMBERS ABSENT

None

ALSO PRESENT

Senator Shelley Hughes, Sponsor; Aimee Bushnell, Staff, Senator Shelley Hughes; Jeannie Monk, Alaska State Hospitals and Nursing Homes, Juneau.

PRESENT VIA TELECONFERENCE

Rylan Hanks, Amgen, Los Angeles; Mark Guimond, The Arthritis Foundation, Washington D.C.; Ashlyn Antonelli, Self, Anchorage; Robert Thoms, Self, MatSu; Cindy Caserta, US Pain Foundation, MatSu; Kerry McClelland, Colon Cancer Alliance, Anchorage.

SUMMARY

HB 57 APPROP: OPERATING BUDGET/LOANS/FUNDS

HB 57 was SCHEDULED but not HEARD.

SB 32 PRESCRIPTIONS FOR BIOLOGICAL PRODUCTS

SB 32 was HEARD and HELD in committee for further consideration.

#sb32
SENATE BILL NO. 32

"An Act relating to biological products; relating to the practice of pharmacy; relating to the Board of Pharmacy; and providing for an effective date."

9:04:38 AM

Co-Chair MacKinnon invited the sponsor and staff to present the bill.

SENATOR SHELLEY HUGHES, SPONSOR, discussed the bill. She relayed that the bill provided safe access to a new, affordable, Federal Drug Administration (FDA) approved treatment option called “interchangeable biologic products.” She asserted that the State Medical Association and Alaska State Hospital and Nursing Home Association (ASHNHA) supported the bill.

Senator Hughes discussed generic medical products and how they differ from biologic products. She stated that generic prescription drugs were 100 percent identical to the corresponding medical product. She conveyed that bio-similar products were made from living cells and could not be replicated identically. Biologic products include insulin and Humira. She detailed that the FDA was on the verge of creating a new category of drugs called “interchangeable biologic products.”

9:07:49 AM

Senator Hughes continued discussing bio-similar drugs, indicating that there would be a very specific category of biologics that were not a 100 percent copy, and that there could be a very slight variance from the original. The bill would require a pharmacist to notify the physician of the substitution with the interchangeable biologic product. The new category of "interchangeables" would be so similar to the original drug that there would be no discernable

clinical difference. She emphasized the importance of allowing pharmacists to substitute them, as they carried a far lesser cost. She highlighted that this category had not passed the FDA, but was in the pipeline, and legislation needed to be put in place. She thought the issue needed to be addressed to ensure Alaskans who were suffering from serious conditions could access the drugs as soon as they passed the FDA.

9:10:52 AM

Senator Olson asked if a patient would have to request a biologic in lieu of the prescribed product.

Senator Hughes stated that a doctor may prescribe a biologic, and the pharmacist would be able to substitute an "interchangeable" and then notify the physician. She relayed that the terms "dispense as written" and "call if substitution" would mean the pharmacist could not make that determination. The bill would not change the prescribing doctor's authority over the prescription. No prior authorization would be needed, but notification would be required.

Senator Olson asked if a pharmacist could make the substitution if the patient did not request it specifically.

Senator Hughes answered that a patient retained control and could request the original product that had been subscribed.

9:13:16 AM

Senator von Imhof relayed that she had heard the bill in the Senate Health and Social Services Committee, where there had been a rich and robust discussion. She underlined that the product would be FDA-approved. She thought the bill provided the flexibility for the doctor or patient to stipulate that the prescribed product not be substituted. She thought it was important to note that under the bill, a pharmacist would have a three-day window in which to notify the prescribing doctor. The patient would have to be informed at the time of filling the prescription, and would have a variety of options, including requesting the original product. She asked the sponsor for confirmation.

Senator Hughes answered affirmatively, and stated that the patient would be informed and could refuse the interchangeable product.

Senator Hughes pointed out that some history would be helpful in understanding the bill. She recounted that there had been a robust discussion between physicians, nurse practitioners and other prescribers. Originally physicians had wanted to require prior authorizations. Pharmacists had countered that they were qualified to fill prescriptions without waiting for authorization. The notification was consensus language that had been worked out between physician and pharmacist groups. She continued that younger doctors were happy to proceed without the notification period, however it had been left in as the product was not identical to the originally prescribed product.

9:16:40 AM

Senator von Imhof added that legislation similar to the bill had already passed in 26 states, and the proposed process had been occurring successfully in Europe for many years.

Senator Hughes concurred.

9:17:04 AM

Senator Olson asked about a letter of opposition from representatives of the pharmacist community and wondered what had been the objection.

Senator Hughes thought there had been concern about the notification requirement. She reiterated that the notification provision had been worked out and was streamlined.

Senator Olson identified that there were three boards in the state that oversaw prescriptive authority. He asked whether the sponsor had heard from nurse practitioners.

Senator Hughes was not sure whether they had and would check with her staff.

AIMEE BUSHNELL, STAFF, SENATOR SHELLEY HUGHES, stated that she had been approached by nurse practitioners asking whether other groups had supported the legislation.

Senator Olson asked whether the state medical board had supported it.

Ms. Bushnell relayed that the Alaska State Medical Board had submitted a letter of neutrality.

9:19:22 AM

Ms. Bushnell reviewed the document "SB 32 Interchangeable Biological Products - Sectional Analysis":

Sec. 1 – AS 08.80.030
Adds a new subsection requiring the Board of Pharmacy to have a link on the board's website to the United States Food and Drug Administration's (FDA) list of approved interchangeable biological products.

Sec. 2 – AS 08.80.294
Amends this section by requiring a pharmacist to include on the label of a biological product container the proprietary or proper name of the biological product. This section also includes language to differentiate between drugs that are and are not biological products to ensure that statutes regarding equivalent generic drugs are not substantively changed.

Sec. 3 – AS 08.80.294
Adds a new subsection to define the term "proper name" being the name that reflects scientific characteristics of a biological product. This new subsection also defines "proprietary name" which is the trademarked and registered name of the product.

Sec. 4 – AS 08.80.295
Adds language to differentiate between equivalent drug products and interchangeable biological products.

Sec. 5 – AS 08.80.295
Adds new subsections to provide guidelines as to how pharmacists or their designee will need to communicate with a prescribing doctor when dispensing a biological or interchangeable biological product if an interchangeable product is available.

Under subsection (c), a pharmacist must communicate to the prescribing doctor the name and manufacturer of the biological product provided to the patient. This communication must happen within three days after dispensing the product by an entry through an interoperable electronic medical records system, an electronic prescribing technology, a pharmacy benefit management system, or a pharmacy record. If an entry under this subsection is not possible, the pharmacist may communicate by e-mail, telephone, fax, or by any other prevailing means.

Under subsection (d) provides an exception to the communication requirement under (c) if the dispensed biological product is a refill of the prescription and is the same biological product. Subsection (e) provides that communication provided under (c)(1) of this section is providing notice to the prescribing doctor. Under subsection (f), a pharmacist is required to maintain a record for two years after a biological product is dispensed. Finally subsection (g) defines "designee" as an agent or employee of a pharmacist who has been authorized to communicate information under subsection (c).

Sec. 6 – AS 08.80.480(34)
Changes language, and gives option to change the term "drug" and "equivalent drug" to "biological product" and "interchangeable biological product".

Sec. 7 AS 08.80.480
Adds new subsection (37) to define term "biological product".

Adds new subsection (36) to define term "interchangeable biological product" as a biological product as determined by the United States Food and Drug Administration.

Under subsection (A) provides that it meets the standard for interchangeability under US code (Regulation of biological products, Safety standards for determining interchangeability).

Under subsection (B) provides that it is therapeutically equivalent in the most recent edition

of the United States Food and Drug Administration evaluations.

Sec. 8 AS 08.80.480
Amends this section by adding transition regulations if necessary to implement changes made by this Act. Having changes take place in accordance with AS 44.62 (Administrative Procedure Act) but not before the effective date of this Act.

Sec. 9 AS 08.80.480
Adds language that section 8 of this Act takes effect July 1, 2017.

Sec. 10 AS 08.80.480
Adds language that this Act will take effect January 1, 2018, except for a provided in section 9.

9:21:13 AM

Senator Hughes added that she had received a letter of neutrality from the Alaska State Medical Association initially, and later the board had submitted a letter of support.

Ms. Bushnell informed that currently there were 29 states and Puerto Rico that had passed similar legislation and two states in the process of doing the same.

9:22:03 AM

Co-Chair MacKinnon OPENED public testimony.

9:22:10 AM
AT EASE

9:22:46 AM
RECONVENED

Co-Chair MacKinnon informed the committee that she had received a list of testifiers from the sponsor.

9:23:05 AM

RYLAN HANKS, AMGEN, LOS ANGELES (via teleconference), testified in support of the bill. He relayed that he was Director of Regulatory Policy for biotechnology company

Amgen, which made biosimilars. He was also a practicing pharmacist. He was formerly with the FDA in the Office of Generic Drugs. He noted that biosimilars were in the process of coming to market. The FDA was in the process of outlining guidelines for these products. He wanted to ensure that good communication happened between patients, pharmacists and physicians.

9:24:37 AM

JEANNIE MONK, ALASKA STATE HOSPITALS AND NURSING HOMES, JUNEAU, spoke in support of the bill. She was the Vice-President of Policy and Programs for ASHNHA. When the legislation first came forward the organization had consulted with hospital-based pharmacists and physicians to ensure the bill would provide guidance needed to give safe and effective treatments to patients while providing potential to lower pharmaceutical costs. Based on the positive views held, ASHNA had made the decision to support the bill. She specified that the communication and timeline required were critical elements to ASHNA's support. The legislation included a three-day notification period for pharmacists to contact the prescribing physician. It also provided accessibility and affordability as well as competition for biological drugs in the way that generics did for brand name drugs. She believed the legislation protected patients and benefitted the state of Alaska.

9:26:27 AM

Senator Olson asked if Ms. Monk was familiar with the situation in the health corporations in rural Alaska.

Ms. Monk replied that she had some knowledge of the situation.

Senator Olson asked whether she had visited those areas.

Ms. Monk relayed that she had been in Bethel two weeks previously.

Senator Olson asked Ms. Monk whether the organization had discussed the current legislation with rural health corporations and what their response had been.

Ms. Monk specified that ASHNHA had shared the information with their partners and there had been no response.

Senator Olson asked about adverse reactions.

Ms. Monk stated that there was no concern expressed about the language in the bill including the notification and process of using biologic drugs. She noted she was not a medical provider and could not speak to any risks, but no one had expressed concern to the organization about risks.

9:27:37 AM

MARK GUIMOND, THE ARTHRITIS FOUNDATION, WASHINGTON D.C. (via teleconference), spoke in support of the bill. He thought biologic products changed lives in a positive way. He stated it made the difference between a child being in a wheelchair, or someone being on disability aid, and living an active life. He furthered that biosimilar products were composed of living cells and would be injected or intravenous. They were not products that would be readily available outside a pharmacy. In Alaska, retail pharmacies dispensed about 1,100 medical products a week, and these products would represent only 13 of that 1,100. Biosimilars offered a more affordable option. The foundation supported the communication stipulation within the bill. He underlined that it had been a part of every other similar piece of legislation that had passed, and Alaska would be aligned with other states in maintaining it. He relayed that the majority of arthritis patients also suffered from additional chronic conditions and knowing the specifics of the drug product was vital to ensuring that those other medications were not affected.

9:29:56 AM

ASHLYN ANTONELLI, SELF, ANCHORAGE (via teleconference), testified in support of the bill. She had suffered from a brain tumor and other chronic pain illnesses. Her course of therapy had included biologic products. If her doctor had not prevented the substitution and it was FDA approved, she wanted that option. She wanted the substitution recorded for her doctor. She agreed with the three-day notification rule. She did not want to wait for future legislation to enable her to benefit from the new products. She discussed her personal experience with high costs of the other biologics. She answered a query about anaphylactic shock previously posed to the sponsor by Senator Olson, stating

that it had taken six weeks to appear and that she did not think it would happen within three days.

Senator Olson asked about her experience with adverse reactions and asked for verification that it had manifested in a rash.

Ms. Antonelli recounted having an allergic reaction to a drug and seeing a specialist to find another drug to counteract the reaction. She detailed that it had taken about six weeks for the rash to appear. She felt that in the three-day notification period, her doctor would be fully informed of which medication she was taking.

Senator Olson asked if Ms. Antonelli knew about HLA-B27. He wondered how she knew that the biologic was the cause of the allergic reaction.

Ms. Antonelli replied that her doctor had staggered administration of the drug. She discussed the timing of prescription aimed at determining which product had caused any reactions.

9:34:29 AM

ROBERT THOMS, SELF, MAT-SU (via teleconference), spoke in support of the bill. He discussed his decorated military experience. He informed that he suffered from chronic pain for the last 45 years. He had been on a non-biologic medication and had suffered adverse effects. He had switched to a biologic product that had benefitted him tremendously. He was concerned that his medication may cease working. He had taken an allergy medicine that had stopped working, and he had subsequently used a substitute which had begun working immediately. He discussed a previous bill hearing at which an individual had questioned the need for haste in passing the bill. He responded that the bill was needed in advance of those products coming onto the market so that patients could make immediate use of them.

9:37:18 AM

CINDY CASERTA, US PAIN FOUNDATION, MAT-SU (via teleconference), testified in support of the bill. She stated that the bill would help all patients who needed

immediate access to the products in question. She discussed her personal experience caring for her husband.

Senator Olson thanked Mr. Thoms for his service.

Co-Chair MacKinnon thanked Mr. Thoms on behalf of the entire committee.

9:38:55 AM

KERRY MCCLELLAND, COLON CANCER ALLIANCE, ANCHORAGE (via teleconference), testified in support of the bill. He was a cancer survivor and hoped the legislation could make the products available as soon as possible. He stated that if his cancer were to return, he wanted to access the drugs in question in-state rather than having to travel to the Lower 48.

9:40:20 AM

Co-Chair MacKinnon CLOSED public testimony.

Vice-Chair Bishop read FN1 from the Department of Commerce, Community and Economic Development.

> If the bill passes the division will require $4,500 for legal costs to amend regulations, printing, and postage in the first year.
> Professional licensing programs within the Division of Corporations, Business and Professional Licensing are funded by Receipt Supported Services, fund source 1156 Rcpt Svcs (DGF). Licensing fees for each occupation are set per AS 08.01.065 so the total amount of revenue collected approximately equals the occupation's actual regulatory costs.

9:41:51 AM

Senator Dunleavy suggested that the money be taken from the Board of Pharmacy budget which showed a carry-over of $544,000, as opposed to General Fund money.

Co-Chair MacKinnon relayed that there was no General Fund money in the item, that it was coming from designated fund receipts, but that it could be more closely examined.

Co-Chair MacKinnon informed committee members that proposed amendments were due the following Friday at 5:00 p.m.

Co-Chair MacKinnon discussed the schedule for the following meeting.

#
ADJOURNMENT
9:43:15 AM

The meeting was adjourned at 9:43 a.m.