

**ALASKA STATE LEGISLATURE
SENATE HEALTH, EDUCATION AND SOCIAL SERVICES
STANDING COMMITTEE**

April 16, 2003
1:35 p.m.

MEMBERS PRESENT

Senator Fred Dyson, Chair
Senator Gary Wilken
Senator Bettye Davis

MEMBERS ABSENT

Senator Lyda Green, Vice Chair
Senator Gretchen Guess

COMMITTEE CALENDAR

Confirmation Hearings:

Board of Professional Counselors
Anne Henry
Stephanie Friese

Board of Nursing
James Jurrens
Cathy Giessel

CONFIRMATIONS ADVANCED

SENATE BILL NO. 179

"An Act allowing teacher certification for certain persons based on a criminal history background check without fingerprints."

MOVED CSSB 179(HES) OUT OF COMMITTEE

SENATE BILL NO. 138

"An Act annulling a regulation relating to use of collaborative practice authority by a pharmacist under written protocols approved by persons licensed to prescribe drugs; prohibiting the Board of Pharmacy from adopting a similar regulation in the future; and providing for an effective date."

HEARD AND HELD

PREVIOUS ACTION

SB 179 - No previous action to consider.

SB 138 - No previous action to consider.

WITNESS REGISTER

Mr. Zach Warwick
Staff to Senator Therriault
Alaska State Capitol
Juneau, AK 99801-1182

POSITION STATEMENT: Commented on SB 179 for the sponsor.

Ms. Melinda Prusak
PO Box 71827
Fairbanks AK 99707

POSITION STATEMENT: Commented on SB 179.

Ms. Annie Carpeneti
Criminal Division
Department of Law
PO Box 110300
Juneau, AK 99811-0300

POSITION STATEMENT: Supported SB 179.

Ms. Diane Schenker
Department of Public Safety
PO Box 111200
Juneau, AK 99811-1200

POSITION STATEMENT: Supported CSSB 179(HES).

Ms. Angie LeBoeuf, Past President
Pharmacy Association
Offnet

POSITION STATEMENT: Opposed SB 138.

Ms. Laraine Derr, President
Alaska Hospital and Nursing Home Association
426 Main Street
Juneau AK 99801

POSITION STATEMENT: Commented on SB 138.

Mr. Jim Jordan, Executive Director
Alaska State Medical Association
4107 Laurel Street
Anchorage AK 99508

POSITION STATEMENT: Commented on SB 138.

Dr. Paul Worrell
Alaska State Medical Association
4107 Laurel Street
Anchorage AK
POSITION STATEMENT: Commented on SB 138.

Dr. Michael Manuel, President
Anchorage Medical Society and
Alaskan Physicians and Surgeons
3340 Providence Dr.
Anchorage AK
POSITION STATEMENT: Supported SB 138.

Dr. Carolyn Brown
No address provided
POSITION STATEMENT: Opposed SB 138.

Dr. Colleen Murphy
Anchorage AK
POSITION STATEMENT: Opposed SB 138.

Ms. Cathy Giesel
Anchorage AK
POSITION STATEMENT: Supported SB 138.

Dr. Terry Bab
Doctor of Pharmacy
Valley Hospital
Palmer AK
POSITION STATEMENT: Opposed SB 138.

Dr. Elaine Reale
Clinic Manager
Providence Alaska Medical Center Pharmacy
Anchorage AK
POSITION STATEMENT: Opposed SB 138.

Mr. Bill Altland
Craig AK 99921
POSITION STATEMENT: Commented on SB 138.

Mr. Jerry Brown, President
Alaska Pharmacist's Association
4107 Laurel St. #101
Anchorage AK 99508
POSITION STATEMENT: Commented on SB 138.

ACTION NARRATIVE

TAPE 03-22, SIDE A

CHAIR FRED DYSON called the Senate Health, Education and Social Services Standing Committee meeting to order at 1:35 p.m. Present were SENATORS WILKEN, DAVIS and CHAIR DYSON. He asked Ms. Anne Henry, nominee for the Board of Professional Counselors, why she wanted to continue to serve on the board.

MS. ANNE HENRY, Board of Professional Counselors, said she had been chairing the board since its inception and the board still has a great deal to do regarding licensing people. She also believes more regulations are needed.

CHAIR DYSON asked if the legislature had done wrong by requiring the [board] to pay for litigation out of licensing fees.

MS. HENRY explained that it is a different way of doing things.

CHAIR DYSON thanked her for her willingness to serve and asked Mr. Jurrens to comment on his nomination.

MR. JAMES JURRENS, Board of Nursing nominee, said he hopes to have a positive influence on the nursing profession in Alaska.

SENATOR GARY WILKEN asked if he has participated in the program that began at the University four years ago to bring more nurses to the state and would he support and be involved in that program if he were on the Board of Nursing.

MR. JURRENS replied that he didn't have intimate knowledge of that program, but he is in favor of any program that would enhance nursing, both as a professional practice and as a career field for young people.

MS. CATHY GIESSEL, Board of Nursing, told members she knew there was an opening on the board and wants to serve.

CHAIR DYSON asked if she is aware of anything that needs to be changed or problems that need to be solved.

MS. GIESSEL said the board has already discussed the nursing shortage and she has been active in promoting SB 154, which addresses the nursing shortage. She served on the governor's transition advisory council last fall that promoted the nursing shortage as a priority.

SENATOR WILKEN asked if she would be a supporter of the university program.

MS. GIESSEL replied yes, definitely.

MS. STEPHANIE FRIESE, Board of Professional Counselors, said she is interested in protecting the public from incompetent or unethical counselors.

SENATOR WILKEN moved to forward all the names of the nominees to the full body for consideration. There were no objections and it was so ordered.

SB 179-TEACHER CERTIFICATION: FINGERPRINTS

CHAIR FRED DYSON announced SB 179 to be up for consideration.

MR. ZACH WARWICK, staff to Senator Therriault, said a constituent who is a teacher brought the idea behind SB 179 to Senator Therriault's attention. This teacher left Alaska for many years and came back and had to renew her license. She was required to submit fingerprints as part of the process. Teaching and nursing are two of the leading professions for which fingerprints get worn out to the point of being unreadable. As a result, this teacher, who is currently teaching, has been resubmitting her fingerprints for the past couple of years. The state has to keep reprocessing the prints and give her conditional certificates every three months.

The Department of Education and Early Development (DEED) did some research and found that 42 people have had to resubmit three sets of fingerprints in nine months. This bill adds language that says if a person cannot submit legible fingerprint cards due to a permanent disability that precludes the person's ability to submit fingerprints. A number of people in the state without fingers or hands are attempting to teach.

MR. WARWICK said that the DEED feels that the language on lines 5 to 7, starting with "whenever" and ending with "teacher" should be deleted, because that paragraph does not refer to fingerprints in reference to a teaching certificate. Another concern expressed by the person who does the hiring in the Palmer school district said that the district never gets fingerprint checks back within three months and suggested changing to a five-month period.

The Governor's Office also said that it has some issues with fingerprints. Supposedly, the state is not in compliance with federal law regarding fingerprint background checks. He said the Governor's Office did not have time to prepare a committee substitute before the meeting today.

CHAIR DYSON asked Mr. Warwick if Senator Therriault would agree to conceptual amendments and if it is important to get this legislation enacted this session.

MR. WARWICK indicated the conceptual amendments would be up to the chairman, but if this legislation passes this year, the teachers would not have to go through the application process again. The Department of Administration (DOA) has asked for an extension until July 2004 to bring the fingerprint background checks into compliance, but if that request is turned down, DOA might not get federal help to do the background checks.

SENATOR GARY WILKEN said he had two and a half pages of conceptual amendments for the committee to look at.

MS. MELINDA PRUSAK said she tried to renew her teaching credential in December 2002 and her fingerprints were rejected. She reprinted two more times in Fairbanks and then had a public safety officer in Anchorage do the printing. She then tried going to the FBI and others, but her fingerprints are unreadable.

MS. ANNIE CARPENETI, Criminal Division, Department of Law, said that several areas of state law require a background check for a person to get a license, generally people who work with children and vulnerable adults. The FBI requires states to have certain statutory provisions to participate in its national repository. A review of the statute in 2001 identified a number of inadequacies, but without an extension of the July 1 deadline, the state will be unable to get national background checks for people like teachers. She noted that Senator Wilken's amendment took care of her concerns and had been approved by the FBI.

SENATOR WILKEN moved to adopt Amendment 1. There were no objections and it was so ordered.

SENATOR WILKEN moved to adopt conceptual Amendment 2, which would change three months to five months. There were no objections and it was so ordered.

SENATOR WILKEN moved to delete language on page 1, line 5, to the word "teacher" in line 7. There were no objections and it was so ordered.

SENATOR WILKEN moved to pass CSSB 179(HES) from committee with individual recommendations. There were no objections and it was so ordered.

MR. KEVIN SWEENEY, Department of Education and Early Development, said the department had some problems with the bill, but it would work them out with the sponsor.

MS. DIANE SCHENKER, Department of Public Safety, supported the CS.

SB 138-PHARMACIST/DOCTOR COLLABORATIVE PROTOCOLS

CHAIR FRED DYSON, sponsor of SB 138, explained that most states allow for some collaborative practices that give someone with authority to prescribe medicines without a doctor being present. A couple of years ago Alaska had no law allowing the delegation of prescriptive authority. The Board of Pharmacy issued regulations that have been in effect for about one year, but the Alaska State Medical Association and the State Medical Board took exception to those regulations and encouraged some changes. An unintended consequence of the regulations allows prescriptions to be delivered to a patient with no relationship at all to any doctor, although Chair Dyson said hadn't heard of anyone being harmed.

MS. ANGIE LEBOEUF, past President, Pharmacy Association, said collaborative practice is not a new concept. It has been occurring for 20 to 30 years, mostly in hospitals, and was previously referred to as pharmaceutical care. Forty states currently have collaborative care regulations with oversight by their Boards of Pharmacy and are designed as an agreement between a pharmacist and a physician. If a patient meets the criteria, the protocol is initiated or adjusted to meet that patient's needs. Pharmacists are normally qualified to do such an analysis.

She informed the committee that the U.S. Center for Disease Control (CDC) requested that pharmacists learn to give immunizations and since September 11, 2001, the National Preparedness Resource Group is assimilating 10 groups of 200 pharmacists across America to be available to administer immunizations in the event of a biological warfare attack.

Collaborative practice is also used with asthma management, diabetes and hypertension treatments.

MS. LEBOEUF explained that pharmacists spend six years in a professional school of pharmacy and it is a huge waste if they are not used to their full potential. Her personal research on the Internet revealed 98,000 matches for collaborative practice, but she couldn't find anyone who was harmed by participating as a member of a health care team in this way. She concluded, "So, therefore, I would respectfully request that this not be pursued through statute and be brought before the Board of Pharmacy instead."

CHAIR DYSON clarified that it was not his intention to preclude collaborative agreements and asked if her association supports collaborative agreements on prescription drugs when there is no contact between the patient and a doctor.

MS. LEBOEUF replied that usually the protocol is set between a physician and a pharmacist, but the patient doesn't necessarily see a doctor first. To her knowledge, no one has participated on any medications other than immunizations and emergency contraceptives.

MS. LARAINÉ DERR, President of the Alaska Hospital and Nursing Home Association (ASHNA), said that protocols are constantly in use and allow more efficiency within hospitals and nursing homes as physicians and pharmacists alike know what is expected of them. The language in SB 138 would annul those activities.

CHAIR DYSON asked her if hospitals and nursing homes were operating efficiently before the regulations came out 18 months ago. Ms. Derr indicated they were.

CHAIR DYSON said that annulling those regulations wouldn't do any harm then.

MS. DERR understood his point but added that five states have passed laws on collaborative practice.

MR. JIM JORDAN, Executive Director, Alaska State Medical Association (ASMA), said the ASMA felt the Pharmacy Board did not have the statutory authority to adopt the regulation that was adopted a little over one year ago. The ASMA is concerned about collaborative relationships in cases where there is no physician/patient relationship. He maintained, "We feel that the

cornerstone to good medical care is that patient/physician relationship."

MR. JORDAN said that collaborative relationships have been used in the hospital setting for years. The protocols and guidelines are established through the operations of committees called pharmaceutical and therapeutics committees.

DR. PAUL WORRELL set out a sample of bottles he had from an old medicine collection from Nome in the late 1800s. He related that one of the bottles had contained a cure for consumption, which is tuberculosis, for which there was no cure back then. In the 1900s, many medicines were put in bottles with claims that they cured all sorts of diseases, but those claims were mostly nonsense. In 1903, the Federal Drug Administration (FDA) was formed to try to create some sense out of the medical system. One of the first things it did was go to Coca-Cola and ask if it wanted to be a beverage company or a drug company because the FDA was going to start regulating drug companies. If Coca-Cola wanted to be a beverage company, it had to take the cocaine out of Coca-Cola.

From those days on, the FDA tried to find medicines that really were effective in treating the human race's problems. Now, a century later, the FDA is part of the whole team - the medical school research industry and the pharmaceutical research industry. He thought the research industries would not have made as much progress if the FDA hadn't kept the hucksters and hustlers out of the mix. That is pertinent because the pharmacy protocols that were passed last year appeared to be designed to get around the FDA rules, which prohibited medicines from being given out over the counter (OTC). He informed the committee that the FDA would request 10 to 30 professors out of the 100 medical schools to advise them on any particular drug. He does not think it is wise to have the state make decisions about research and pharmacology.

TAPE 03-22, SIDE B

DR. WORRELL said the protocols that were passed last year were totally different than those that exist for in-patient use in a hospital or nursing home where the doctor must visit the patient every day. They allow for outpatient use of medicines.

He noted that if hospital protocols went away tomorrow, the hospitals would not stop functioning. A doctor could just tell a nurse to do most of those things. To practice medicine in the

state of Alaska a doctor has to go to school for 10 years; most go for 12 years. If just a simple checklist was needed, it wouldn't make sense to have to go to school for that long. He accused the protocols of being "phenomenally vague." The recent regulations change what most people normally think of as a prescription to almost anything a pharmacy board says it is.

CHAIR DYSON asked how children get vaccinated in school without a specific prescription from a doctor.

DR. WORRELL replied that some are given via public health doctors' signatures to schools. A private doctor authorized some of the immunizations given at Carrs, but some people who were giving them had no authority whatsoever.

CHAIR DYSON said one collaborative agreement that concerns him is the dispensing of emergency contraception without the patient having a specific doctor prescribe it. He asked Dr. Worrell to describe the potential dangers to someone who receives emergency contraception without seeing a physician.

DR. WORRELL said the FDA felt those medicines were not safe without a doctor's prescription. The recent pharmacy regulations allow any doctor in the state to sign a protocol so that the pharmacist can dispense a prescription OTC by asking the patient eight questions. A doctor has never taken the patient's history and might even live in another city. Drug reactions and side effects can't be monitored. Morning-after pills have associated increased risk of ectopic pregnancies, which could be a problem in Bush communities because they require surgical intervention, sometimes quite quickly. Estrogen use has many side effects with the biggest being blood clots. Patients can have different syndromes and don't know they have them; it is considered unsafe to put them on any estrogen-type medications.

CHAIR DYSON asked him if that family of drugs is not recommended for people with high blood pressure and who are heavy smokers.

DR. WORRELL replied that people over 35 who are heavy smokers, as well as some people who are overweight, are in that category. He explained whenever a physician suggests a course of treatment to a patient, he becomes involved in the process of gaining that patient's consent for doing the treatment. Outside the hospital, there is a question in the association's mind as to how that informed consent takes place if the physician is not involved with prescribing the drug. He said a recent Supreme Court case increased the complexity of the question.

CHAIR DYSON said he understands in some collaborative agreements the only relationship between a specific physician and a patient is the informed consent form that is sent to the physician every 90 days. He asked Dr. Worrell if he thought that is good medical practice.

DR. WORRELL replied that is not a true informed consent form, but basically a checklist that the pharmacist asks the patient when the patient requests the medicine. If the patient has enough yes answers, he or she is given the medicine. That's the form that needs to be mailed back to the doctor within 90 days so the doctor knows how many prescriptions went out on his signature. In reality, that doesn't tell the physician how the medicine is working or how many complications occurred. It's not a real follow-up.

MR. JORDAN said with informed consent, a patient asks more questions about a particular course of treatment and the standard of the understanding and explanation that a physician must go through is higher. He noted, "Any question raises the bar."

CHAIR DYSON stated it was not the committee's intention to preclude collaborative agreements. However, he wants to eliminate any bad medical practices and make sure patients are protected.

DR. MICHAEL MANUEL, President of the Anchorage Medical Society, said he is also representing the Alaskan Physicians and Surgeons. Both groups are strongly supportive of SB 138. He said the way the regulations are set up, there is potential for unbridled coverage of patients without any physician oversight. That is outside of the intent for which the regulation was originally imposed.

DR. CAROLYN BROWN said she understands the chairman's intention, but the bill's current language gets rid of collaborative practice. She thought it is an attempt to stop collaborative practice between Alaska's pharmacists and physicians, specifically for the prevention of emergency contraception. Over 40 states already use collaborative agreements for a lot of purposes. Thousands of documents reveal no adverse affects from the use of emergency contraception. She took issue with Dr. Worrell's statements about the damages of emergency contraception and said long-term oral contraception has nothing

to do with emergency contraception and the literature is replete with documentation of that.

Second, she said there is no collaborative agreement unless a physician decides to participate and, if a physician does decide to participate, it would be in the best interest of the patient.

CHAIR DYSON asked if she believes the FDA should make emergency contraception available OTC.

DR. BROWN replied absolutely and said there is quite a bit of literature to support that position.

CHAIR DYSON asked if she had any idea if and when the FDA might rule on that.

DR. BROWN replied that she didn't know, but it takes the FDA a long time to do anything.

CHAIR DYSON asked her if it is her view that there is no danger in authorizing a pharmacist to dispense emergency contraception.

DR. BROWN replied that is her view and also that of Dr. David Grimes who is one of the leading proponents of it in the country. He has clearly stated in a number of articles and studies that it's safer than giving Bayer aspirin to women. She pointed out that no lawsuits have been adjudicated against physicians who provide emergency contraception, nor is there any substantial literature to support that it is damaging to a person who takes it.

DR. COLLEEN MURPHY, OB-GYN, urged the committee to support the on-going practice of collaborative drug therapy protocols. The regulations that were passed in 2001 have allowed the practice of medicine to catch up with what has been done for many years. Health care now requires a team and the pharmacist is a key member. She said using protocols makes therapy much safer.

As a medical doctor, she has heard the physician community's concern about the regulation and the possibility of medical doctors potentially abusing the pharmacy practice, but she did not think they should be regulating physician behavior by striking down the regulation. If the Medical Association has concerns about use of ambulatory collaborative drug therapy protocols, it should address those concerns in its own medical statutes and regulations. She repeated that using the drug

protocol has helped her improve care in both inpatient and outpatient settings.

CHAIR DYSON asked her if she thought emergency contraception was dangerous and if it should be OTC.

DR. MURPHY replied that the OTC application was made on February 14, 2001 and over 16 other countries have that status. Emergency contraception medication meets all the criteria the FDA requires for OTC status. It's a condition that is easily diagnosed, the medication is safe and the patient can follow the instructions easily. She added, "Frankly, this is a huge public health issue that does not require direct intervention by a medical provider."

MS. CATHY GIESEL supported Dr. Worrell's comments and passage of SB 138.

MR. TERRY BAB concurred with Dr. Brown and Dr. Murhpy's comments. He is concerned that this bill will eliminate all collaborative practice agreements including those performed in a hospital setting. It will decrease safety and efficiency and ultimately increase the cost of health care. They would not be able to provide time-sensitive medications or to act on immunizations. She offered:

I would share that the American Public Health Association, the American Medical Association and the American College of Obstetrics and Gynecology support the provision of EC [emergency contraceptives] to an OTC status, specifically citing the safety and efficacy. In due respect to Dr. Worrell of ectopic pregnancy, I am unsure about how a particular physician may screen a woman for ectopic pregnancy. It occurs with or without birth control pills. I am concerned with the limited access should a woman request emergency contraception. It's a time-sensitive medication meaning that delays in treatment may lead to more unintended pregnancies with associated risks and costs. There are many physicians' offices that exclude seeing new patients on the basis of just seeing their established patients. There is no or limited access on evenings and on weekends and my concern is that by eliminating this ability to practice collaboratively, our risk for unintended pregnancies will rise.

In 1994, 50 percent of all pregnancies were unintended. Of these, 50 percent ended in induced abortion, specifically, 1.4 million. This ability to practice collaboratively issues an opportunity to reduce the public health burden of these unintended pregnancies.

CHAIR DYSON asked him if he is a professional.

DR. BAB replied that he is a Doctor of Pharmacy and is at Valley Hospital in Palmer.

CHAIR DYSON asked if he thought regulations should be tightened so that not every prescriptive drug could be subject to a collaborative agreement.

DR. BAB replied that he didn't think that was necessary, since it is a voluntary agreement that a medical practitioner would institute.

DR. ELAINE REALE, Clinical Manager, Providence Alaska Medical Center Pharmacy, opposed SB 138 and said that Providence legal counsel advised her Providence would have to stop its collaborative practice, which would have a negative effect on patient care. It would cause delays and changes to drug therapy that physicians have requested and would result in more phone calls, decreasing efficiencies for both. It would also increase the costs of some medications to patients. She clarified that Heperin and alcohol withdrawal protocols are not pharmacist-managed protocols at Providence. Passage of SB 138 would also stop the worfren (ph) clinic at the Family Practice Center. Worfren is an anti-coagulant that can cause bleeding if not dosed properly.

Physicians refer their patients to her after making a diagnosis with the patient's full consent. The pharmacist is able to focus on dosage monitoring and can intensively track patients while they are on the medication. There have been no adverse events in the one-year of the clinic's operation.

MS. REALE also pointed out that passage of this bill is a statement that the Board of Pharmacy doesn't have the right to regulate its own profession, a really bad precedent. She said a meeting has been scheduled with the Medical Board to discuss these issues.

CHAIR DYSON asked if she was also speaking on behalf of Providence Hospital.

MS. REALE said she was not; she was speaking on her own behalf as the director of Pharmacy.

CHAIR DYSON asked when that meeting was going to take place.

MS. REALE thought it would happen in two weeks.

CHAIR DYSON asked if she currently has some collaborative agreements with physicians.

TAPE 03-23, SIDE A

MS. REALE said it has been going on for 30 to 40 years and now a regulation supports it. If that regulation is repealed, the support will not be there.

CHAIR DYSON asked if her position is that they wouldn't be able to continue the kinds of cooperative relationships they have had for the last 30 years if the regulations are repealed while new ones are being promulgated.

MS. REALE replied that is correct.

MR. BILL ALTLAND, a resident of Craig, said he and his wife run a pharmacy business in a rural area. His main concern is the safety of the patient and he believes that collaborative practice, whether it's regulated or not, is something that is happening a lot in the rural areas. Many smaller places will never have an M.D. and there are many arrangements where a physician will never see the patient. He believes SB 138 is way too broad because it does away with Pharmacy Board regulations, which are a step in the right direction toward at least one part of what is already happening.

MR. JERRY BROWN, President, Alaska Pharmacists Association, said the regulation has recognized collaborative agreements as a viable way to conduct health care in Alaska and this bill now says that is not the correct way. He stated that pharmacists have six years of extensive education, including two and half years of pharmacology, extensive clinical training and a year and a half of disease management. They are involved in drug disease management processes, which is what collaborative care is addressing. Pharmacists should be allowed to do collaborative

care and, if this bill passes, current collaborative care will be at risk of failure.

CHAIR DYSON interrupted to say that no one wants to do away with collaborative practices and he asked if Mr. Brown thought the Pharmacy Board regulations are exactly what they should be.

MR. BROWN replied that he believes they are. He thought concerns about the physician patient relationship had already been addressed.

CHAIR DYSON asked him to clarify whether he said things are just fine the way they are - that doctors may have no relationship with their patients and only know about them by name 90 days afterwards.

MR. BROWN said that is what he is saying. Currently, the physician and pharmacist in a collaborative care agreement know the patient. The reports are required in 90 days, which is no different than what physician assistants are doing right now in places like Healy or Cordova. In those instances, the physician never sees the patient. A physician assistant has far less educational background than a pharmacist does in drug therapy.

CHAIR DYSON thanked all participants for their testimony and said he would hold the bill. He adjourned the meeting at 3:25 p.m.